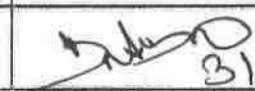
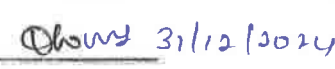
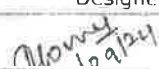
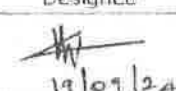


	Safetab Life Science				
	BATCH MANUFACTURING RECORD		Page No.:	1 of 116	
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	2,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

BATCH MANUFACTURING RECORD COVER SHEET:

PRODUCT NAME	LITACOLD FLU TABLETS		
LABEL CLAIM	Each Uncoated tablet contains: Chlorphenamine Maleate BP 2mg Phenylephrine Hydrochloride BP 5mg Caffeine Anhydrous BP 30mg Paracetamol BP 500mg		
PACK SIZE	TP: 1X4's strip pack		
STORAGE CONDITION	Store in cool and dry place Protect from light and moisture.		
SHELF LIFE	36 MONTHS		
CUSTOMER NAME	GENERIC HEALTHCARE PVT.LTD.		
EFFECTIVE BATCH NUMBER	G17241004	DATE:	01/10/2024
MANUFACTURING LICENCE No.	21 14 4378		
MFG. DATE:	01/2025	BMR. No	STBMR:427/02
EXP. DATE:	12/2027	Supersedes BMR.No	STBMR:427/01
BMR ISSUED BY/DATE (QA)	dhows 31/12/2024		
BMR CHECKED & RECEIVED BY/DATE (PRODUCTION)	 31/12/24		
Allotted By: QA Executive Sign/Date:  31/12/2024			
DATE OF COMMENCEMENT: 31/12/2024		DATE OF COMPLETION: 11/02/25	
This BMR contains 116 Pages + <u>APPROX-2</u> Additional Pages			
Checked by Competent Staff Sign/Date:  11/02/25			

Title	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
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Signature	 12/02/24	 19/02/24	 19/02/24	
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BATCH MANUFACTURING RECORD

Page No.:

2 of 116

Brand Name

LITACOLD FLU TABLETS

Product ID
No.:

978

Batch Size

12,50,000 Tablets

Generic Name:

Paracetamol, Phenylephrine
Hydrochloride, Chlorphenamine Maleate
and Caffeine Anhydrous Tablets

MFC NO:

ST/MFC/119/R6

Supersedes
MFC No:

ST/MFC/119/R5

Batch No.:

G17250103

Mfg.Date:

01/2025

Exp.Date:

12/2027

1.0 LIST OF EQUIPMENTS:

S.No	Name of Equipment	Equipment ID No. to be used
1	Dispensing Booth	ST/SRDB/001
2	Balance -30 Kg Capacity	ST/SRWB/001
3	Balance -620 g Capacity	ST/SRWB/002
4	Balance -150 Kg Capacity	ST/WB/189, ST/PRWB/009, ST/PRWB/010, ST/PRWB/011, ST/PRWB/012, ST/PRWB/013
5	Balance -100 Kg Capacity	ST/PRWB/002
6	Balance - 220g Capacity	ST/WB/202, ST/PRWB/029, ST/PRWB/030, ST/PRWB/031, ST/PRWB/033
7	Vibro Sifter	ST/PRVS/001 or ST/PRVS/002 or ST/PRVS/003 or ST/PRVS/004
8	Rapid Mixer Granulator 600LTS	ST/PRRG/005
9	Fluid bed drier 250Kgs	ST/PRFD/003
10	Multimill	ST/PRML/001 or ST/PRML/002
11	Octagonal blender (2200L)	ST/PROB/001
12	Compression Machine	ST/PRCM/004 or ST/PRCM/005
13	Disintegration Tester	ST/QADT/002 or ST/QADT/003
14	Friability Test Apparatus	ST/QAFR/002 or ST/QAFR/003
15	Hardness Tester	ST/QAHT/001 or ST/QAHT/002
16	Vernier Caliper	ST/QAVC/003
17	IR moisture Balance	ST/IPMB/001

Title	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
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Signature	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	
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BATCH MANUFACTURING RECORD

Page No.:

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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

2.0 DISPENSING

2.1 LINE CLEARANCE CHECKS:

S.No	CHECKS	Observation	
		store	IPQA
1	Ensure that all empty containers, labels, used Polybags, hand gloves of previous dispensed Product/ batch are removed from the area.	✓	✓
2	Ensure that all dispensed material of previous product / batch removed from the area.	✓	✓
3	Ensure that the previous batch BMR / documents are removed from the area.	✓	✓
4	Check the housekeeping general cleanliness of the floor, walls, ceiling, pass box, doors and door view panels of man and material entry of dispensing area is clean.	✓	✓
5	Check the cleanliness of the working table, cupboard, washing area and waste bin.	✓	✓
6	Check the cleanliness of the drain points.	✓	✓
7	Ensure that the dispensing booth is cleaned and it's status.	✓	✓
8	Check the cleanliness of the supply and return grill.	✓	✓
9	Check the cleanliness of side wall of the dispensing booth.	✓	✓
10	Check the differential pressure of pre filter, intermediate filter and HEPA filter are within the limit	✓	✓
11	Check the cleanliness of the utility line (compressed air, First RO water and purified water).	✓	✓
12	Check the cleanliness of the SS side panel and SS Stool.	✓	✓
13	Ensure that the balances are cleaned and it's calibration status.	✓	✓
14	Check the status board of the area is updated.	✓	✓
15	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.	✓	✓
16	Check the differential pressure of the area should be within the limit.	✓	✓
17	Ensure that dispensing tools or accessories like scoops, spoons are cleaned and labeled with "Clean" label.	✓	✓
18	Check proper gowning procedure followed as per the SOP	✓	✓
19	Ensure the concurrent entries of log book.	✓	✓
20	Ensure that the Laminar of dispensing booth run Not less than 15 minutes after switch on.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (store) sign/date: [Signature] 02/01/25

Verified by (IPQA) sign/date: [Signature] 02/01/25

Equipment	Dispensing Booth	Weighing Balance				AREA
Equipment. ID No.	ST/SEDG1002	ST/SEDG1001	ST/SEDG1003	ST/SEDG1004	ST/SEDG1005	
Previous Product & Batch No.	ANLO-VH10/25/160 - G1724/271					
Cleaned By	SANKAR	SANKAR	SANKAR	SANKAR	SANKAR	
Checked by Stores Sign/Date	[Signature] 02/01/25	[Signature] 02/01/25	[Signature] 02/01/25	[Signature] 02/01/25	[Signature] 02/01/25	
Counter checked by IPQA/Sign/Date	[Signature] 02/01/25	[Signature] 02/01/25	[Signature] 02/01/25	[Signature] 02/01/25	[Signature] 02/01/25	

2.2 ENVIRONMENTAL CONDITIONS:

Area: Dispensing		Observation	Stores Sign
Differential pressure for dispensing Booth	Temperature: 23°C to 27°C	25.0°C	[Signature]
	Relative Humidity: 45% to 55%	50%	[Signature]
	Differential pressure NLT 0.5mm of water	0.6	[Signature]
	Pre Filter 1-5mm of water	4	[Signature]
	Fine Filter 4-10mm of water	8	[Signature]
	HEAP Filter 8-20mm of water	10	[Signature]

2.3 APPROVAL FOR DISPENSING BY IPQA: Sign: [Signature]

Date: 02/01/25

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature	[Signature] 19/09/24	[Signature] 19/09/24	[Signature] 19/09/24

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BATCH MANUFACTURING RECORD					
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Page No.:	4 of 116
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Batch Size	12.50 000 Tablets
Batch No.:	G17250103	Mfg.Date:	01/2025	Supersedes MFC No:	ST/MFC/119/R5
			Exp.Date:	12/2027	

3.0 INDENT OF RAW MATERIALS:

DRY MIXING											
S. No	Name of the Ingredients	Material Code	Label claim per tablet in mg	Spec	Std Qty for 12.50L(Kg)						Vendor
					Total Qty (Kg)	For LOT I	For LOT II	For LOT III	For LOT IV	For LOT V	
1	Chlorphenamine Maleate *	RMAC0064	2.000	BP	2.500	0.500	0.500	0.500	0.500	0.500	Supriya Life Science/Auro Labs
2	Phenylephrine Hydrochloride*	RMAP0031	5.000	BP	6.250	1.250	1.250	1.250	1.250	1.250	Aarti Pharma lab/Divis lab
3	Caffeine Anhydrous *	RMAC0065	30.000	BP	37.500	7.500	7.500	7.500	7.500	7.500	AartiIndustries/ Balaji healthcare/ Aarti pharma
4	Paracetamol *	RMAP0030	500.000	BP	625.000	125.00	125.00	125.00	125.00	125.00	Farmson Analgesics/ Valiant Lab/Sri Krishna
5	Pregelatinized Starch	RMEP0046	15.000	BP	18.750	3.750	3.750	3.750	3.750	3.750	Colorcon
6	Microcrystalline Cellulose PH 101#	RMEM001	24.735	BP	30.920	6.184	6.184	6.184	6.184	6.184	Sigachi
BINDER PREPARATION											
7	Povidone K90	RMEP0045	12.500	BP	15.625	3.125	3.125	3.125	3.125	3.125	HaungshanBonsunPharma
8	Purified Water@	RMEP0033	100.000	BP	125.000	25.000	25.000	25.000	25.000	25.000	Inhouse
9	Tartrazine Supra INH	RMET0011	0.135	INH	0.170	0.034	0.034	0.034	0.034	0.034	Standardcon
10	Methyl Paraben sodium	RMEM002	0.500	BP	0.625	0.125	0.125	0.125	0.125	0.125	Alta Laboratory
Lubrication											
11	Pregelatinized Starch	RMEP0046	10.000	BP						12.500	Colorcon
12	Sodium Starch Glycolate	RMES0029	17.000	BP						21.250	Roquette
13	Purified Talc	RMET0012	7.000	BP						8.750	Neelkanth/ Imerys
14	Colloidal silicon Dioxide	RMEC0017	5.000	BP						6.250	Wacker
15	Tartrazine Lake INH	RMET0013	0.130	INH						0.163	Standardcon
16	Magnesium Stearate	RMEM003	6.000	BP						7.500	Nitika

@ Does not appear in final product evaporates during processing.

*,# -Refer Potency

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BATCH MANUFACTURING RECORD

Page No.:

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Brand Name LITACOLD FLU TABLETS

Product ID No.:

978

Batch Size

12,50,000 Tablets

Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets

MFC NO:

ST/MFC/119/R6

Supersedes MFC No:

ST/MFC/119/R5

Batch No.: G17250103

Mfg.Date:

01/2025

Exp.Date:

12/2027

3.1 DISPENSING OF RAW MATERIALS AGAINST RAW MATERIAL INDENT:

Dispensing Started at Date 02/10/25 Time

S.No	Name of the Ingredients	LOT	Actual Qty. per batch(Kg)	A.R No:	Gross Weight (Kg)	Tare Weight(Kg)	Net Weight(Kg)	Weighed By Stores	Checked by stores	Verified by IPQA	Vendor
1	Chlorphenamine Maleate BP	I	*	AC2241903	0.529	0.028	0.501	SANKAR	AT	AT	Supra
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	
		II	*	AC2241903	0.529	0.028	0.501	SANKAR	AT	AT	
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	
		III	*	AC2241903	0.529	0.028	0.501	SANKAR	AT	AT	
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	
		IV	*	AC2241903	0.529	0.028	0.501	SANKAR	AT	AT	
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	
		V	*	AC2241903	0.529	0.028	0.501	SANKAR	AT	AT	
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	
2	Phenylephrine Hydrochloride BP	I	*	AC2241906	1.291	0.038	1.253	SANKAR	AT	AT	D2025
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	
		II	*	AC2241906	1.291	0.038	1.253	SANKAR	AT	AT	
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	
		III	*	AC2241906	1.291	0.038	1.253	SANKAR	AT	AT	
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	
		IV	*	AC2241906	1.291	0.038	1.253	SANKAR	AT	AT	
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	
		V	*	AC2241906	1.291	0.038	1.253	SANKAR	AT	AT	
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	

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BATCH MANUFACTURING RECORD

Page No.:

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Brand Name

LITACOLD FLU TABLETS

Product ID No.:

978

Batch Size

12,50,000 Tablets

Generic Name:

Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets

MFC NO:

ST/MFC/119/R6

Supersedes MFC No:

ST/MFC/119/R5

Batch No.:

G17250103

Mfg.Date:

01/2025

Exp.Date:

12/2027

S.No	Name of the Ingredients	LOT	Actual Qty. per batch(Kg)	A.R No	Gross Weight (Kg)	Tare Weight (Kg)	Net Weight (Kg)	Weighted By Stores	Checked by stores	Verified by IQA	Vendor
3	Caffeine Anhydrous BP	I	*	QCR241955	7.695	0.160	7.535	SANKAR	SL	(P)	ABRNT
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	
		II	*	QCR241955	7.695	0.160	7.535	SANKAR	SL	(P)	
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	
		III	*	QCR241955	7.695	0.160	7.535	SANKAR	SL	(P)	
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	
		IV	*	QCR241955	7.695	0.160	7.535	SANKAR	SL	(P)	
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	
		V	*	QCR241955	7.695	0.160	7.535	SANKAR	SL	(P)	
				-	-	-	-	-	-	-	
				-	-	-	-	-	-	-	
4	Paracetamol BP	I	*	QCR241933	25.250	0.250	25.000	SANKAR	SL	(P)	VALBNT
				QCR241933	25.250	0.250	25.000	SANKAR	SL	(P)	
				QCR241933	25.250	0.250	25.000	SANKAR	SL	(P)	
				QCR241933	25.250	0.250	25.000	SANKAR	SL	(P)	
				QCR241933	25.250	0.250	25.000	SANKAR	SL	(P)	
				QCR241933	1.078	0.038	1.040	SANKAR	SL	(P)	
		II	*	QCR241933	25.250	0.250	25.000	SANKAR	SL	(P)	
				QCR241933	14.632	0.160	14.472	SANKAR	SL	(P)	
				QCR241934	25.250	0.250	25.000	SANKAR	SL	(P)	
				QCR241934	25.250	0.250	25.000	SANKAR	SL	(P)	
				QCR241934	25.250	0.250	25.000	SANKAR	SL	(P)	
				QCR241934	25.250	0.250	25.000	SANKAR	SL	(P)	
				QCR241934	11.728	0.160	11.568	SANKAR	SL	(P)	
				-	-	-	-	-	-	-	

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Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
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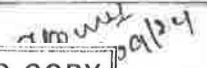
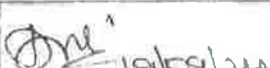
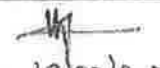
BATCH MANUFACTURING RECORD

Page No.:

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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

S.No	Name of the Ingredients	LOT	Actual Qty. per batch(Kg)	A.R No:	Gross Weight (Kg)	Tare Weight(Kg)	Net Weight(Kg)	Weighed by store	Checked by stores	Verified by IPQA	Vendor
	Paracetamol BP	III	*	QCR241934	25.250	0.250	25.000	SANKAR	df	(12)	✓
				QCR241934	25.250	0.250	25.000	SANKAR	df	(12)	✓
				QCR241934	25.250	0.250	25.000	SANKAR	df	(12)	A
				QCR241934	25.250	0.250	25.000	SANKAR	df	(12)	✓
				QCR241934	25.250	0.250	25.000	SANKAR	df	(12)	S
				QCR241934	1.078	0.038	1.040	SANKAR	df	(12)	A
		IV	*	QCR241934	25.250	0.250	25.000	SANKAR	df	(12)	N
				QCR241934	25.250	0.250	25.000	SANKAR	df	(12)	T
				QCR241934	25.250	0.250	25.000	SANKAR	df	(12)	✓
				QCR241934	25.250	0.250	25.000	SANKAR	df	(12)	✓
				QCR241934	25.250	0.250	25.000	SANKAR	df	(12)	✓
				QCR241934	1.078	0.038	1.040	SANKAR	df	(12)	✓
		V	*	QCR241934	25.250	0.250	25.000	SANKAR	df	(12)	✓
				QCR241934	25.250	0.250	25.000	SANKAR	df	(12)	✓
				QCR241934	25.250	0.250	25.000	SANKAR	df	(12)	✓
				QCR241934	25.250	0.250	25.000	SANKAR	df	(12)	✓
				QCR241934	25.250	0.250	25.000	SANKAR	df	(12)	✓
				QCR241934	25.250	0.250	25.000	SANKAR	df	(12)	✓
				QCR241934	25.250	0.250	25.000	SANKAR	df	(12)	✓
				QCR241934	25.250	0.250	25.000	SANKAR	df	(12)	✓
				QCR241934	25.250	0.250	25.000	SANKAR	df	(12)	✓
				QCR241934	1.078	0.038	1.040	SANKAR	df	(12)	✓
					-	-	-	-	-	-	-
					-	-	-	-	-	-	-
					-	-	-	-	-	-	-

Title	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature				
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BATCH MANUFACTURING RECORD

Page No.:

8 of 116

Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg. Date:	01/2025	Exp. Date:	12/2027

S.No	Name of the Ingredients	LOT	Actual Qty. per batch(Kg)	A.R No:	Gross Weight (Kg)	Tare weight(Kg)	Net Weight (Kg)	Weighted	Checked by stores	Verified by IPQA	Vendor
5	Pregelatinized Starch BP	I	3.750	ACR241904	3.830	0.080	3.750	Sankar	AS	(R)	Colapoo
		II	3.750	ACR241904	3.830	0.080	3.750	Sankar	AS	(R)	
		III	3.750	ACR241904	3.830	0.080	3.750	Sankar	AS	(R)	
		IV	3.750	ACR241904	3.830	0.080	3.750	Sankar	AS	(R)	
		V	3.750	ACR241904	3.830	0.080	3.750	Sankar	AS	(R)	
6	Microcrystalline Cellulose PH 101 BP	I	***	ACR241887	5.186	0.080	5.106	Sankar	AS	(R)	Sankar
		II	***	ACR241887	5.186	0.080	5.106	Sankar	AS	(R)	
		III	***	ACR241887	5.186	0.080	5.106	Sankar	AS	(R)	
		IV	***	ACR241887	5.186	0.080	5.106	Sankar	AS	(R)	
		V	***	ACR241887	5.186	0.080	5.106	Sankar	AS	(R)	
7	Povidone K90 BP	I	3.125	ACR241854	3.205	0.080	3.125	Sankar	AS	(R)	Hansel AN
		II	3.125	ACR241854	3.205	0.080	3.125	Sankar	AS	(R)	
		III	3.125	ACR241854	3.205	0.080	3.125	Sankar	AS	(R)	
		IV	3.125	ACR241854	3.205	0.080	3.125	Sankar	AS	(R)	
		V	3.125	ACR241854	3.205	0.080	3.125	Sankar	AS	(R)	

Title	Prepared by:	Checked by:	Approved by:
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BATCH MANUFACTURING RECORD

Page No.:

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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

S.No	Name of the Ingredients	LOT	Actual Qty. per batch(Kg)	A.R No:	Gross Weight (Kg)	Tare Weight(Kg)	Net Weight (Kg)	Weighted	Checked by stores	Verified by IPQA	Vendor
8	Tartrazine supra INH	I	0.034	ACP241925	0.038	0.004	0.034	Sample	SI	(P)	STANDARD CON
		II	0.034	ACP241925	0.038	0.004	0.034	Sample	SI	(P)	
		III	0.034	ACP241925	0.038	0.004	0.034	Sample	SI	(P)	
		IV	0.034	ACP241925	0.038	0.004	0.034	Sample	SI	(P)	
		V	0.034	ACP241925	0.038	0.004	0.034	Sample	SI	(P)	
9	Methyl Paraben Sodium BP	I	0.125	ACP241875	0.129	0.004	0.125	Sample	SI	(P)	ALTA
		II	0.125	ACP241875	0.129	0.004	0.125	Sample	SI	(P)	
		III	0.125	ACP241875	0.129	0.004	0.125	Sample	SI	(P)	
		IV	0.125	ACP241875	0.129	0.004	0.125	Sample	SI	(P)	
		V	0.125	ACP241875	0.129	0.004	0.125	Sample	SI	(P)	
10	Pregelatinized Starch BP		12,500	ACP241904	12.660	0.160	12.500	Sample	SI	(P)	Colorcon
11	Sodium Starch Glycolate BP		21.250	ACP241867	21.410	0.160	21.250	Sample	SI	(P)	Amesha
12	Purified Talc BP		8.750	ACP241844	8.830	0.080	8.750	Sample	SI	(P)	NEELKANTH
13	Colloidal Silicon dioxide BP		6.250	ACP241882	2.080	0.080	2.000	Sample	SI	(P)	CABOT
				ACP241882	2.080	0.080	2.000	Sample	SI	(P)	
14	Tartrazine Lake INH		0.163	ACP241926	0.167	0.004	0.163	Sample	SI	(P)	STANDARD CON
15	Magnesium Stearate BP		7.500	ACP241969	7.580	0.080	7.500	Sample	SI	(P)	ALTA

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BATCH MANUFACTURING RECORD

Page No.: 10 of 116
Batch Size: 12,50,000 Tablets
Supersedes MFC No: ST/MFC/119/R5
Exp.Date: 12/2027

Brand Name: LITACOLD FLU TABLETS
Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets
Batch No.: G17250103

Product ID No.: 978
MFC NO: ST/MFC/119/R6
Mfg.Date: 01/2025

4.0 CALCULATION:

4.1 Potency calculation for Paracetamol :

Q.C AR.No. for Paracetamol	Mfg. Date	Expiry Date	Assay of Paracetamol on dried basis	LOD %
abr 241933	01/24	SEP/29	100.4	0.2
abr 241934	01/24	SEP/29	99.43	0.48
—	—	—	—	—

*The given quantity is based on 100% Assay on dried basis and without Loss on drying.
Actual quantity to be added is calculated as:

Actual quantity, of Paracetamol = $500 \times 100 \times 100$ mg/tablet

$$1) = \frac{5000000}{9980} = 501.002 \text{ mg/tablet}, \quad 2) = \frac{5000000}{9895.2736} = 505.292 \text{ mg/tablet}$$
$$= 165.512 \text{ kg} \quad = 464.686 \text{ kg}$$
$$(330361 \text{ kg}) + (919639 \text{ kg})$$

*Qty of Paracetamol to be added per batch = 630.198 Kg's
Lot I = 126.040 Kg's
Lot II = 126.040 Kg's
Lot III = 126.040 Kg's
Lot IV = 126.040 Kg's
Lot V = 126.040 Kg's

Note: If the assay of Paracetamol is more than 100 %, calculation has to be done only for 100%

Calculation done by(store)/date: 02/01/25

checked by(production)/date: 02/01/25

Verified by(QA)/date: 02/01/25

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BATCH MANUFACTURING RECORD

Page No.: 11 of 116

Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

4.2 Potency calculation for Phenylephrine Hydrochloride :

Q.C AR.No. for Phenylephrine Hydrochloride	Mfg. Date	Expiry Date	Assay of Phenylephrine Hydrochloride on dried basis	LOD %
241906	06/24	SEP/29	100	0.2

*The given quantity is based on 100% Assay on dried basis and without Loss on drying.
Actual quantity to be added is calculated as:

Actual quantity, of Phenylephrine Hydrochloride = $\frac{5 \times 100 \times 100}{\% \text{ Assay on dried basis} \times (100 - \text{LOD} \%)} \text{ mg/tablet}$

$$= \frac{50000}{9980} = 5.010 \text{ mg/tablet}$$

*Qty of Phenylephrine Hydrochloride to be added per batch = 6.263 Kg's

Lot I = 1.253 Kg's
Lot II = 1.253 Kg's
Lot III = 1.253 Kg's
Lot IV = 1.253 Kg's
Lot V = 1.253 Kg's

Note: If the assay of Phenylephrine Hydrochloride is more than 100 %, calculation has to be done only for 100%

Calculation done by(store)/date: [Signature] 02/01/25 checked by(production)/date: [Signature] 02/01/25 Verified by(QA)/date: [Signature] 02/01/25

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BATCH MANUFACTURING RECORD

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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorpheniramine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

4.3 Potency calculation for Chlorpheniramine Maleate :

Q.C AR.No. for Chlorpheniramine Maleate	Mfg. Date	Expiry Date	Assay of Chlorpheniramine Maleate on dried basis	LOD %
062-241903	01/24	SEP/29	100.24	0.16
-	-	-	-	-

*The given quantity is based on 100% Assay on dried basis and without Loss on drying.
Actual quantity to be added is calculated as:

 $2 \times 100 \times 100$

Actual quantity, of Chlorpheniramine Maleate =mg/tablet

 $\% \text{ Assay on dried basis} \times (100 - \text{LOD} \%)$

$$= \frac{20000}{9984} = 2.003 \text{ mg/tablet}$$

*Qty of Chlorpheniramine Maleate to be added per batch = 2.504 Kg's

Lot I = 0.501 Kg's

Lot II = 0.501 Kg's

Lot III = 0.501 Kg's

Lot IV = 0.501 Kg's

Lot V = 0.501 Kg's

Note: If the assay of Chlorpheniramine Maleate is more than 100 %, calculation has to be done only for 100%

Calculation done by(store)/date: P.V. 02/01/25 checked by(production)/date: P. 02/01/25 Verified by(QA)/date: P. 02/01/25

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BATCH MANUFACTURING RECORD				Page No.:	13 of 116
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorpheniramine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg. Date:	01/2025	Exp. Date:	12/2027

4.4 Potency calculation for Caffeine Anhydrous :

Q.C AR.No. for Caffeine Anhydrous	Mfg. Date	Expiry Date	Assay of Caffeine Anhydrous on dried basis	LOD %
02/24/1955	01/24	SEP/29	101.21	0.46.

*The given quantity is based on 100% Assay on dried basis and without Loss on drying.
Actual quantity to be added is calculated as:

Actual quantity. of Caffeine Anhydrous = $\frac{30 \times 100 \times 100}{\text{Assay}} \text{ mg/tablet}$

% Assay on dried basis X (100 - LOD %)

$$= \frac{300000}{9954} = 30.134 \text{ mg/tablet}$$

*Qty of Caffeine Anhydrous to be added per batch = 37.674 Kg's

Lot I = 7.525 Kg's

Lot II = 7.535 Kg's

Lot III = 7.535 Kg's

Lot IV = 7.535 Kg's

Lot V = 7.535 Kg's ✓

Quantity of Microcrystalline cellulose PH 101 varies based on assay content of Paracetamol, Phenylephrine Hydrochloride, Chlorpheniramine Maleate, Caffeine Anhydrous for keeping the core tablet weight constant

Note: If the assay of Caffeine Anhydrous is more than 100 %, calculation has to be done only for 100%.

4.4.1 Calculation for Quantity of Microcrystalline cellulose PH 101 to be dispensed

**Actual quantity of Microcrystalline cellulose PH 101 to be dispensed

= [Std. qty. of Caffeine Anhydrous + Std. qty. of Chlorpheniramine Maleate + Std. qty. of Phenylephrine Hydrochloride + Std. qty. of Paracetamol + Std. qty. of Microcrystalline cellulose PH 101] - [Actual qty. of Caffeine Anhydrous + Actual qty. of Chlorpheniramine Maleate + Actual qty. of Phenylephrine Hydrochloride + Actual qty. of Paracetamol]

$$= [37.500 + 2.500 + 6.250 + 625.000 + 30.920] - [37.674 + 2.500 + 6.262 + 630.198]$$

$$= 25.531 \text{ Kg}$$

*Qty of Microcrystalline cellulose PH 101 to be added per batch = 25.531 Kg's

Lot I = 5.106 Kg's

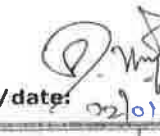
Lot II = 5.106 Kg's

Lot III = 5.106 Kg's

Lot IV = 5.106 Kg's

Lot V = 5.106 Kg's

Calculation done by (store)/date: 02/01/25 checked by (production)/date: 02/01/25 Verified by (QA)/date: 02/01/25

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BATCH MANUFACTURING RECORD

Page No.:	14 of 116
Batch Size	12,50,000 Tablets
Supersedes MFC No:	ST/MFC/119/R5
Exp.Date:	12/2027

Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6
Batch No.:	G17250103	Mfg.Date:	01/2025

5.0 VERIFICATION OF DISPENSED MATERIALS:

S.No	Name of the Ingredients	Lot	Gross weight in Kg	A.R.No.	Checked by Production Sign/Date	Verified by IPQA Sign/Date
1	Chlorphenamine Maleate BP	I	0.52	QCR241903	P 20/01/25	V.P.H. 20/01/25
		II	0.52	QCR241903	P 20/01/25	V.P.H. 20/01/25
		III	0.52	QCR241903	P 20/01/25	V.P.H. 20/01/25
		IV	0.52	QCR241903	P 20/01/25	V.P.H. 20/01/25
		V	0.52	QCR241903	P 20/01/25	V.P.H. 20/01/25
2	Phenylephrine Hydrochloride BP	I	1.29	QCR241906	P 20/01/25	V.P.H. 20/01/25
		II	1.29	QCR241906	P 20/01/25	V.P.H. 20/01/25
		III	1.29	QCR241906	P 20/01/25	V.P.H. 20/01/25
		IV	1.29	QCR241906	P 20/01/25	V.P.H. 20/01/25
		V	1.29	QCR241906	P 20/01/25	V.P.H. 20/01/25
3	Caffeine Anhydrous BP	I	7.69	QCR241955	P 20/01/25	V.P.H. 20/01/25
		II	7.69	QCR241955	P 20/01/25	V.P.H. 20/01/25
		III	7.69	QCR241955	P 20/01/25	V.P.H. 20/01/25
		IV	7.69	QCR241955	P 20/01/25	V.P.H. 20/01/25
		V	7.69	QCR241955	P 20/01/25	V.P.H. 20/01/25
4	Paracetamol BP	I	25.25	QCR241933	P 20/01/25	V.P.H. 20/01/25
			25.25	QCR241933	P 20/01/25	V.P.H. 20/01/25
			25.25	QCR241933	P 20/01/25	V.P.H. 20/01/25
			25.25	QCR241933	P 20/01/25	V.P.H. 20/01/25
			25.25	QCR241933	P 20/01/25	V.P.H. 20/01/25
			1.088	QCR241933	P 20/01/25	V.P.H. 20/01/25

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BATCH MANUFACTURING RECORD

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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

S.No	Name of the Ingredients	Lot	Gross weight in Kg	A.R.No.	Checked by Production Sign/Date	Verified by IPQA Sign/Date
	Paracetamol BP	II	25.25	QCR241933	P20101/25	V.P.R20101/25
			25.65	QCR241933	P20101/25	V.P.R20101/25
			25.25	QCR241934	P20101/25	V.P.R20101/25
			25.25	QCR241934	P20101/25	V.P.R20101/25
			25.25	QCR241934	P20101/25	V.P.R20101/25
			11.72	QCR241934	P20101/25	V.P.R20101/25
		III	25.25	QCR241934	P20101/25	V.P.R20101/25
			25.25	QCR241934	P20101/25	V.P.R20101/25
			25.25	QCR241934	P20101/25	V.P.R20101/25
			25.25	QCR241934	P20101/25	V.P.R20101/25
			25.25	QCR241934	P20101/25	V.P.R20101/25
			1.78	QCR241934	P20101/25	V.P.R20101/25
		IV	25.25	QCR241934	P20101/25	V.P.R20101/25
			25.25	QCR241934	P20101/25	V.P.R20101/25
			25.25	QCR241934	P20101/25	V.P.R20101/25
			25.25	QCR241934	P20101/25	V.P.R20101/25
			25.25	QCR241934	P20101/25	V.P.R20101/25
			1.08	QCR241934	P20101/25	V.P.R20101/25
		V	25.25	QCR241934	P20101/25	V.P.R20101/25
			25.25	QCR241934	P20101/25	V.P.R20101/25
			25.25	QCR241934	P20101/25	V.P.R20101/25
			25.25	QCR241934	P20101/25	V.P.R20101/25
			25.25	QCR241934	P20101/25	V.P.R20101/25
			1.08	QCR241934	P20101/25	V.P.R20101/25
5	Pregelatinized Starch BP	I	3.83	QCR241904	P20101/25	V.P.R20101/25
		II	3.83	QCR241904	P20101/25	V.P.R20101/25
		III	3.83	QCR241904	P20101/25	V.P.R20101/25
		IV	3.83	QCR241904	P20101/25	V.P.R20101/25
		V	3.83	QCR241904	P20101/25	V.P.R20101/25

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BATCH MANUFACTURING RECORD

Page No.: 16 of 116
Batch Size: 12,50,000 Tablets
Supersedes MFC No: SI/MFC/119/R5
Exp.Date: 12/2027

Brand Name: LITACOLD FLU TABLETS
Product ID No.: 978
Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets
MFC NO: ST/MFC/119/R6
Batch No.: G17250103
Mfg.Date: 01/2025

S.No	Name of the Ingredients	Lot	Gross weight in Kg	A.R.No.	Checked by Production Sign/Date	Verified by IPQA Sign/Date
6	Microcrystalline Cellulose PH 101 BP	I	5.18	QCR241887	P20/01/25	V.P.H. 20/01/25
		II	5.18	QCR241887	P20/01/25	V.P.H. 20/01/25
		III	5.18	QCR241887	P20/01/25	V.P.H. 20/01/25
		IV	5.18	QCR241887	P20/01/25	V.P.H. 20/01/25
		V	5.18	QCR241887	P20/01/25	V.P.H. 20/01/25
7	Povidone K90 P	I	3.20	QCR241854	P20/01/25	V.P.H. 20/01/25
		II	3.20	QCR241854	P20/01/25	V.P.H. 20/01/25
		III	3.20	QCR241854	P20/01/25	V.P.H. 20/01/25
		IV	3.20	QCR241854	P20/01/25	V.P.H. 20/01/25
		V	3.20	QCR241854	P20/01/25	V.P.H. 20/01/25
8	Tartrazine Supra INH	I	0.03	QCR241925	P20/01/25	V.P.H. 20/01/25
		II	0.03	QCR241925	P20/01/25	V.P.H. 20/01/25
		III	0.03	QCR241925	P20/01/25	V.P.H. 20/01/25
		IV	0.03	QCR241925	P20/01/25	V.P.H. 20/01/25
		V	0.03	QCR241925	P20/01/25	V.P.H. 20/01/25
9	Methyl Paraben Sodium BP	I	0.12	QCR241875	P20/01/25	V.P.H. 20/01/25
		II	0.12	QCR241875	P20/01/25	V.P.H. 20/01/25
		III	0.12	QCR241875	P20/01/25	V.P.H. 20/01/25
		IV	0.12	QCR241875	P20/01/25	V.P.H. 20/01/25
		V	0.12	QCR241875	P20/01/25	V.P.H. 20/01/25

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BATCH MANUFACTURING RECORD

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Brand Name

LITACOLD FLU TABLETS

Product ID No.:

978

Batch Size

12,50,000 Tablets

Generic Name:

Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets

MFC NO:

ST/MFC/119/R6

Supersedes MFC No:

ST/MFC/119/R5

Batch No.:

G17250103

Mfg.Date:

01/2025

Exp.Date:

12/2027

S.No	Name of the Ingredients	Gross weight in Kg	A.R.No.	Checked by Production Sign/Date	Verified by IPQA Sign/Date
10	Pregeiatinized starch BP	12.560	QCR241904	21/01/24	21/01/24
11	Sodium Starch Glycolate BP	21.410	QCR241867	21/01/24	21/01/24
12	Purified Talc BP	8.830	QCR241844	21/01/24	21/01/24
13	Colloidal Silicon Dioxide BP	2.080 2.080 2.080 0.330	QCR241882 QCR241882 QCR241882	21/01/24 21/01/24 21/01/24	21/01/24 21/01/24 21/01/25
14	Tartrazine Lake INH	0.167	QCR241926	21/01/24	21/01/24
15	Magnesium stearate BP	7.580	QCR241969	21/01/24	21/01/25
16	Purified water				

Note: Check the weight of the dispensed material, if found satisfactory, then proceeds to next stage, if any discrepancy inform to QA head for further instruction

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		Safetab Life Science			
BATCH MANUFACTURING RECORD				Page No.:	18 of 116
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,500 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

6.0 AFFIX DISPENSING CARD:

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241933 | Retest Date: 26/11/25

Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 1 | Pack 6 of 1 | Bal. Id.: ST/WB/189
Req. Qty.: 625.0 Kg | Issd. Qty.: 126.04 Kg | Conv. Fa.: 1
Gr. Wt.: 1.078 Kg | Tr. Wt.: 0.038 Kg | NI. Wt.: 1.04 Kg

Dispensed By
(Store)
LBST-001 Revision No: R1

Checked By
(QA)
ID: DE-REC-2025-0019 - 01

Verified By
(Prod.)
Thu Jan 02 25 07:31:58

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMET0011 | Category: NA

Item Name: TARTRAZINE SUPRA INH

Operation: Granulation

AR No.: QCR241925 | Retest Date: 05/12/26

Mfr: STANDARDCON PVT. LTD. (V0227)

Lot No.: 1 | Pack 1 of 1 | Bal. Id.: ST/SRWB/002
Req. Qty.: 0.17 Kg | Issd. Qty.: 0.034 Kg | Conv. Fa.: 1
Gr. Wt.: 0.038 Kg | Tr. Wt.: 0.004 Kg | NI. Wt.: 0.034 Kg

Dispensed By
(Store)
LBST-001 Revision No: R1

Checked By
(QA)
ID: DE-REC-2025-0016 - 37

Verified By
(Prod.)
Thu Jan 02 25 07:08:05

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMAP0031 | Category: NA

Item Name: PHENYLEPHRINE HYDROCHLORIDE BP

Operation: Granulation

AR No.: QCR241906 | Retest Date: 19/11/25

Mfr: DIVI OCS LABORATORIES LTD. (V0014)

Lot No.: 1 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 6.25 Kg | Issd. Qty.: 1.253 Kg | Conv. Fa.: 1
Gr. Wt.: 1.291 Kg | Tr. Wt.: 0.038 Kg | NI. Wt.: 1.253 Kg

Dispensed By
(Store)
LBST-001 Revision No: R1

Checked By
(QA)
ID: DE-REC-2025-0018 - 6

Verified By
(Prod.)
Thu Jan 02 25 07:17:38

Dispensed materials label pasted by (production sign/date):

20/01/25

verified by (IPQA) sign/date:

20/01/25

Title	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature				
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Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.: 19 of 116
Batch Size: 12,50,000 Tablets
Supersedes MFC No: ST/MFC/119/R5
Exp.Date: 12/2027

Brand Name: LITACOLD FLU TABLETS
Product ID No.: 978
Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets
MFC NO: ST/MFC/119/R6
Batch No.: G17250103
Mfg.Date: 01/2025

6.0A AFFIX DISPENSING CARD:

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets



Item Code: RMEP0046 | Category: NA

Item Name: PREGELATINIZED STARCH BP STARCH 1500

Operation: Granulation

AR No.: QCR241904 | Retest Date: 21/11/25

Mfr: COLORCON ASIA PRIVATE LIMITED. (V0163)

Lot No.: 1 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 18.75 Kg | Issd. Qty.: 3.125 Kg | Conv. Fa.: 1
Gr. Wt.: 3.205 Kg | Tr. Wt.: 0.08 Kg | Nt. Wt. 3.125 Kg

Dispensed By
(Store)

LBST:001 Revision No: R1

Checked By
(QA)

ID: DE-REC-2025-0019 - 22

Verified By
(Prod.)

Thu Jan 02 25 08:44:04

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets



Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241933 | Retest Date: 26/11/25

Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 1 | Pack 1 of 1 | Bal. Id.: ST/WB/189
Req. Qty.: 625.0 Kg | Issd. Qty.: 25.0 Kg | Conv. Fa.: 1
Gr. Wt.: 25.25 Kg | Tr. Wt.: 0.25 Kg | Nt. Wt. 25.0 Kg

Dispensed By
(Store)

LBST:001 Revision No: R1

Checked By
(QA)

ID: DE-REC-2025-0019 - 16

Verified By
(Prod.)

Thu Jan 02 25 07:29:08



DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241933 | Retest Date: 26/11/25

Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 1 | Pack 2 of 1 | Bal. Id.: ST/WB/189
Req. Qty.: 625.0 Kg | Issd. Qty.: 50.0 Kg | Conv. Fa.: 1
Gr. Wt.: 25.25 Kg | Tr. Wt.: 0.25 Kg | Nt. Wt. 25.0 Kg

Dispensed By
(Store)

LBST:001 Revision No: R1

Checked By
(QA)

ID: DE-REC-2025-0019 - 57

Verified By
(Prod.)

Thu Jan 02 25 07:29:36

Dispensed materials label pasted by (production sign/date):

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Title	Prepared by:	Checked by:	Approved by:
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Signature			

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Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.: 20 of 116
Batch Size: 12,50,000 Tablets
Supersedes MFC No: ST/MFC/119/R5
Exp.Date: 12/2027

Brand Name: LITACOLD FLU TABLETS
Product ID No.: 978
Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets
MFC NO: ST/MFC/119/R6
Batch No.: G17250103
Mfg.Date: 01/2025

6.0B AFFIX DISPENSING CARD:

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMET0011 | Category: NA

Item Name: TARTRAZINE SUPRA INH

Operation: Granulation

AR No.: QCR241925 | Retest Date: 05/12/26

Mfr: STANDARDCON PVT. LTD. (V0227)

Lot No.: 2 | Pack 1 of 1 | Bal. Id.: ST/SRWB/002
Req. Qty.: 0.17 Kg | Issd. Qty.: 0.068 Kg | Conv. Fa.: 1
Gr. Wt.: 0.038 Kg | Tr. Wt.: 0.004 Kg | Nt. Wt.: 0.034 Kg

Dispensed By
(Store)

LBST-001 Revision No: R1

Checked By
(QA)

ID: DE-REC-2025-0019 - 38

Verified By
(Prod.)

Thu Jan 02 25 07:08:38

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMAP0031 | Category: NA

Item Name: PHENYLEPHRINE HYDROCHLORIDE BP

Operation: Granulation

AR No.: QCR241906 | Retest Date: 19/11/26

Mfr: DIVIÔÇOS LABORATORIES LTD. (V0014)

Lot No.: 2 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 6.25 Kg | Issd. Qty.: 2.506 Kg | Conv. Fa.: 1
Gr. Wt.: 1.291 Kg | Tr. Wt.: 0.038 Kg | Nt. Wt.: 1.253 Kg

Dispensed By
(Store)

LBST-001 Revision No: R1

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(QA)

ID: DE-REC-2025-0019 - 7

Verified By
(Prod.)

Thu Jan 02 25 07:17:51

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMAC0065 | Category: NA

Item Name: CAFFEINE ANHYDROUS BP

Operation: Granulation

AR No.: QCR241955 | Retest Date: 26/11/26

Mfr: AARTI PHARMALABS (V0443)

Lot No.: 2 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 37.5 Kg | Issd. Qty.: 15.07 Kg | Conv. Fa.: 1
Gr. Wt.: 7.695 Kg | Tr. Wt.: 0.16 Kg | Nt. Wt.: 7.535 Kg

Dispensed By
(Store)

LBST-001 Revision No: R1

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(QA)

ID: DE-REC-2025-0019 - 12

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(Prod.)

Thu Jan 02 25 07:24:10

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Title	Prepared by:	Checked by:	Approved by:
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Signature			
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		Safetab Life Science		Page No.: 21 of 116	
BATCH MANUFACTURING RECORD					
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

6.0C AFFIX DISPENSING CARD:

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241933 | Retest Date: 26/11/25

Mfr: VALIANT LABORATORIES LIMITED (V0345)

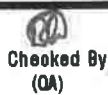
Lot No.: 2 | Pack 1 of 1 | Bal. Id.: ST/WB/189

Req. Qty.: 625.0 Kg | Issd. Qty.: 151.04 Kg | Conv. Fa.: 1

Gr. Wt.: 25.25 Kg | Tr. Wt.: 0.25 Kg | NI. Wt.: 25.0 Kg


Dispensed By
(Store)

LBST-001 Revision No: R1


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(QA)

ID: DE-REC-2025-0019 - 17


Verified By
(Prod.)

Thu Jan 02 25 07:32:25

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241934 | Retest Date: 09/12/25

Mfr: VALIANT LABORATORIES LIMITED (V0345)

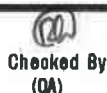
Lot No.: 2 | Pack 1 of 1 | Bal. Id.: ST/WB/189

Req. Qty.: 625.0 Kg | Issd. Qty.: 190.512 Kg | Conv. Fa.: 1

Gr. Wt.: 25.25 Kg | Tr. Wt.: 0.25 Kg | NI. Wt.: 25.0 Kg


Dispensed By
(Store)

LBST-001 Revision No: R1


Checked By
(QA)

ID: DE-REC-2025-0019 - 18


Verified By
(Prod.)

Thu Jan 02 25 07:33:55

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241934 | Retest Date: 09/12/25

Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 2 | Pack 2 of 1 | Bal. Id.: ST/WB/189

Req. Qty.: 625.0 Kg | Issd. Qty.: 215.512 Kg | Conv. Fa.: 1

Gr. Wt.: 25.25 Kg | Tr. Wt.: 0.25 Kg | NI. Wt.: 25.0 Kg


Dispensed By
(Store)

LBST-001 Revision No: R1

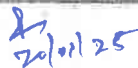

Checked By
(QA)

ID: DE-REC-2025-0019 - 03


Verified By
(Prod.)

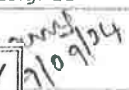
Thu Jan 02 25 07:34:17

Dispensed materials label pasted by (production sign/date):


20/01/25

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20/01/25

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			

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 Safetab Life Science		BATCH MANUFACTURING RECORD		Page No.:	22 of 116
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

6.0D AFFIX DISPENSING CARD:

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMAC0064 | Category: NA
Item Name: CHLORPHENIRAMINE MALEATE BP
Operation: Granulation

AR No.: QCR241903 | Retest Date: 18/11/25
Mfr: SUPRIYA LIFE SCIENCE LIMITED. (V0067)

Lot No.: 3 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 2.5 Kg | Issd. Qty.: 1.503 Kg | Conv. Fa.: 1
Gr. Wt.: 0.529 Kg | Tr. Wt.: 0.028 Kg | Nt. Wt.: 0.501 Kg

Dispensed By
(Store)

LBST-001 Revision No: R1

Checked By
(QA)

ID: DE-REC-2025-0019 - 3

Verified By
(Prod.)

Thu Jan 02 25 07:14:49

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMEP0045 | Category: NA
Item Name: POVIDONE K 90 BP
Operation: Granulation

AR No.: QCR241864 | Retest Date: 22/08/26
Mfr: HUANGSHAN BONSUN PHARMACEUTICALS (V01:9)

Lot No.: 3 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 15.625 Kg | Issd. Qty.: 9.375 Kg | Conv. Fa.: 1
Gr. Wt.: 3.205 Kg | Tr. Wt.: 0.08 Kg | Nt. Wt.: 3.125 Kg

Dispensed By
(Store)

LBST-001 Revision No: R1

Checked By
(QA)

ID: DE-REC-2025-0019 - 34

Verified By
(Prod.)

Thu Jan 02 25 00:41:51

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMEM0032 | Category: NA
Item Name: METHYL PARABEN SODIUM BP
Operation: Granulation

AR No.: QCR241875 | Retest Date: 02/12/26
Mfr: ALTA LABORATORIES LTD. (V0013)

Lot No.: 3 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 0.625 Kg | Issd. Qty.: 0.375 Kg | Conv. Fa.: 1
Gr. Wt.: 0.129 Kg | Tr. Wt.: 0.004 Kg | Nt. Wt.: 0.125 Kg

Dispensed By
(Store)

LBST-001 Revision No: R1

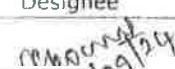
Checked By
(QA)

ID: DE-REC-2025-0019 - 44

Verified By
(Prod.)

Thu Jan 02 25 07:02:25

Dispensed materials label pasted by (production sign/date): 20/01/25 verified by (IPQA) sign/date: 20/01/25

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Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
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Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.:	23 of 116
Batch Size	12,50,000 Tablets
Supersedes MFC No:	ST/MFC/119/R5
Exp.Date:	12/2027

Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6
Batch No.:	G17250103	Mfg.Date:	01/2025

6.0E AFFIX DISPENSING CARD:

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets



Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241934 | Retest Date: 09/12/25

Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 3 | Pack 4 of 1 | Bal. Id.: ST/WB/189
Req. Qty.: 625.0 Kg | Issd. Qty.: 352.08 Kg | Conv. Fa.: 1
Gr. Wt.: 25.25 Kg | Tr. Wt.: 0.25 Kg | NI. Wt.: 25.0 Kg



Dispensed By
(Store)

LBST:001 Revision No: R1

Checked By
(QA)

ID: DE-REC-2025-0019 - 08

Verified By
(Prod.)

Thu Jan 02 25 07:38:28

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets



Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241934 | Retest Date: 09/12/25

Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 3 | Pack 5 of 1 | Bal. Id.: ST/WB/189
Req. Qty.: 625.0 Kg | Issd. Qty.: 377.08 Kg | Conv. Fa.: 1
Gr. Wt.: 25.25 Kg | Tr. Wt.: 0.25 Kg | NI. Wt.: 25.0 Kg



Dispensed By
(Store)

LBST:001 Revision No: R1

Checked By
(QA)

ID: DE-REC-2025-0019 - 08

Verified By
(Prod.)

Thu Jan 02 25 07:37:02

Dispensed materials label pasted by (production sign/date):

20/01/25

verified by (IPQA) sign/date:

20/01/25

Title	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature	 11/09/24	 11/09/24	 17/09/24	
UNCONTROLLED COPY				



Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.: 24 of 116
Batch Size: 12,50,000 Tablets
Supersedes MFC No: ST/MFC/119/R5
Exp.Date: 12/2027

Brand Name: LITACOLD FLU TABLETS
Product ID No.: 978
MFC NO: ST/MFC/119/R6
Mfg.Date: 01/2025

Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets

Batch No.: G17250103

6.0F AFFIX DISPENSING CARD:

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)
Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241934 | Retest Date: 09/12/25
Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 4 | Pack 5 of 1 | Bal. Id.: ST/WB/189
Req. Qty.: 625.0 Kg | Issd. Qty.: 503.12 Kg | Conv. Fa.: 1
Gr. Wt.: 25.25 Kg | Tr. Wt.: 0.25 Kg | Nt. Wt.: 25.0 Kg

Dispensed By
(Store)
LBST-001 Revision No: R1

Checked By
(QA)
ID: DE-REC-2025-0019 - 74

Verified By
(Prod.)
Thu Jan 02 25 07:40:27

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)
Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241934 | Retest Date: 09/12/25
Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 4 | Pack 4 of 1 | Bal. Id.: ST/WB/189
Req. Qty.: 625.0 Kg | Issd. Qty.: 478.12 Kg | Conv. Fa.: 1
Gr. Wt.: 25.25 Kg | Tr. Wt.: 0.25 Kg | Nt. Wt.: 25.0 Kg

Dispensed By
(Store)
LBST-001 Revision No: R1

Checked By
(QA)
ID: DE-REC-2025-0019 - 73

Verified By
(Prod.)
Thu Jan 02 25 07:04:04

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)
Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241934 | Retest Date: 09/12/25
Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 4 | Pack 3 of 1 | Bal. Id.: ST/WB/189
Req. Qty.: 625.0 Kg | Issd. Qty.: 453.12 Kg | Conv. Fa.: 1
Gr. Wt.: 25.25 Kg | Tr. Wt.: 0.25 Kg | Nt. Wt.: 25.0 Kg

Dispensed By
(Store)

Checked By
(QA)

Verified By
(Prod.)

LBST-001 Revision No: R1

ID: DE-REC-2025-0019 - 72

Thu Jan 02 25 07:30:27

Dispensed materials label pasted by (production sign/date)

verified by (IPQA) sign/date:

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
UNCONTROLLED COPY			

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Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.: 25 of 116
Batch Size: 12,50,000 Tablets
Supersedes MFC No: ST/MFC/119/R5
Exp.Date: 12/2027

Brand Name: LITACOLD FLU TABLETS
Product ID No.: 978
Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets
MFC NO: ST/MFC/119/R6
Batch No.: G17250103
Mfg.Date: 01/2025

6.0G AFFIX DISPENSING CARD:

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)
Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMAP0030 | Category: NA
Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241934 | Retest Date: 09/12/25
Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 4 | Pack 2 of 1 | Bal. Id.: ST/WB/189
Req. Qty.: 625.0 Kg | Issd. Qty.: 428.12 Kg | Conv. Fa.: 1
Gr. Wt.: 25.25 Kg | Tr. Wt.: 0.25 Kg | Nt. Wt.: 25.0 Kg

Dispensed By
(Store)
LBST-001 Revision No: R1

Checked By
(QA)
ID: DE-REC-2025-0019 - 71

Verified By
(Prod.)
Thu Jan 02 25 07:38:

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)
Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMAP0030 | Category: NA
Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241934 | Retest Date: 09/12/25
Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 4 | Pack 1 of 1 | Bal. Id.: ST/WB/189
Req. Qty.: 625.0 Kg | Issd. Qty.: 403.12 Kg | Conv. Fa.: 1
Gr. Wt.: 25.25 Kg | Tr. Wt.: 0.25 Kg | Nt. Wt.: 25.0 Kg

Dispensed By
(Store)
LBST-001 Revision No: R1

Checked By
(QA)
ID: DE-REC-2025-0019 - 20

Verified By
(Prod.)
Thu Jan 02 25 07:38:35

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)
Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMEP0046 | Category: NA

Item Name: PREGELATINIZED STARCH BP STARCH 1500

Operation: Granulation

AR No.: QCR241904 | Retest Date: 21/11/25

Mfr: COLORCON ASIA PRIVATE LIMITED. (V0163)

Lot No.: 4 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 18.75 Kg | Issd. Qty.: 15.0 Kg | Conv. Fa.: 1
Gr. Wt.: 3.83 Kg | Tr. Wt.: 0.08 Kg | Nt. Wt.: 3.75 Kg

Dispensed By
(Store)
LBST-001 Revision No: R1

Checked By
(QA)
ID: DE-REC-2025-0019 - 25

Verified By
(Prod.)
Thu Jan 02 25 08:45:35

Dispensed materials label pasted by(production sign/date):

verified by(IPQA) sign/date:

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
UNCONTROLLED COPY		CONTROLLED COPY	

		Safetab Life Science			
BATCH MANUFACTURING RECORD				Page No.:	26 of 116
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

6.0H AFFIX DISPENSING CARD:

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMEM0032 | Category: NA
Item Name: METHYL PARABEN SODIUM BP
Operation: Granulation

AR No.: QCR241875 | Retest Date: 02/12/26
Mfr: ALTA LABORATORIES LTD. (V0013)

Lot No.: 4 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 0.625 Kg | Issd. Qty.: 0.5 Kg | Conv. Fa.: 1
Gr. Wt.: 0.129 Kg | Tr. Wt.: 0.004 Kg | Nt. Wt.: 0.125 Kg


Dispensed By
(Store)
LBST-001 Revision No: R1


Checked By
(QA)
ID: DE-REC-2025-0019 - 4E


Verified By
(Prod.)
Thu Jan 02 25 07:02:39



DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMEP0045 | Category: NA

Item Name: POVIDONE K 90 BP

Operation: Granulation

AR No.: QCR241854 | Retest Date: 22/08/26

Mfr: HUANGSHAN BONSUN PHARMACEUTICALS (V011:9)

Lot No.: 4 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 15.625 Kg | Issd. Qty.: 12.5 Kg | Conv. Fa.: 1
Gr. Wt.: 3.205 Kg | Tr. Wt.: 0.08 Kg | Nt. Wt.: 3.125 Kg


Verified By
(Prod.)
Thu Jan 02 25 06:43:19


Checked By
(QA)
ID: DE-REC-2025-0019 - 3E


Dispensed By
(Store)
LBST-001 Revision No: R1

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMEM0031 | Category: NA
Item Name: MICROCRYSTALLINE CELLULOSE POWDER PH
Operation: Granulation

AR No.: QCR241887 | Retest Date: 21/11/25
Mfr: SIGACHI INDUSTRIES PVT LTD. (V0162)

Lot No.: 4 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 30.92 Kg | Issd. Qty.: 20.424 Kg | Conv. Fa.: 1
Gr. Wt.: 5.186 Kg | Tr. Wt.: 0.08 Kg | Nt. Wt.: 5.106 Kg

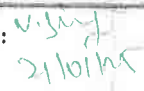

Dispensed By
(Store)
LBST-001 Revision No: R1

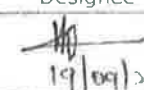

Checked By
(QA)
ID: DE-REC-2025-0019 - 3D


Verified By
(Prod.)
Thu Jan 02 25 06:55:40



Dispensed materials label pasted by (production sign/date)

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Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
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		Safetab Life Science			
BATCH MANUFACTURING RECORD				Page No.:	27 of 116
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorpheniramine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

6.0IAFFIX DISPENSING CARD:

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR - 978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets



Item Code: RMAC0064 | Category: NA
Item Name: CHLORPHENIRAMINE MALEATE BP
Operation: Granulation

AR No.: QCR241903 | Retest Date: 18/11/25
Mfr: SUPRIYA LIFE SCIENCE LIMITED. (V0067)

Lot No.: 4 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 2.5 Kg | Issd. Qty.: 2.004 Kg | Conv. Fa.: 1
Gr. Wt.: 0.529 Kg | Tr. Wt.: 0.028 Kg | Nt. Wt.: 0.501 Kg



Dispensed By
(Store)

LBST-001 Revision No: R1

Checked By
(QA)

ID: DE-REC-2025-0019 - 4

Verified By
(Prod.)

Thu Jan 02 25 07:15:09

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR - 978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets



Item Code: RMAC0065 | Category: NA
Item Name: CAFFEINE ANHYDROUS BP
Operation: Granulation

AR No.: QCR241955 | Retest Date: 26/11/25
Mfr: AARTI PHARMALABS (V0443)

Lot No.: 4 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 37.5 Kg | Issd. Qty.: 30.14 Kg | Conv. Fa.: 1
Gr. Wt.: 7.695 Kg | Tr. Wt.: 0.16 Kg | Nt. Wt.: 7.535 Kg



Dispensed By
(Store)

LBST-001 Revision No: R1

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(QA)

ID: DE-REC-2025-0019 - 14

Verified By
(Prod.)

Thu Jan 02 25 07:26:44



DISPENSED MATERIAL

Product: LITACOLD FLU (BMR - 978)
Batch No.: G17250103 | Batch Size: 1250000 Tablets



Item Code: RMAP0031 | Category: NA
Item Name: PHENYLEPHRINE HYDROCHLORIDE BP
Operation: Granulation

AR No.: QCR241906 | Retest Date: 19/11/25
Mfr: DIVOCOS LABORATORIES LTD. (V0014)

Lot No.: 4 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 6.25 Kg | Issd. Qty.: 5.012 Kg | Conv. Fa.: 1
Gr. Wt.: 1.291 Kg | Tr. Wt.: 0.038 Kg | Nt. Wt.: 1.253 Kg

Verified By
(Prod.)

Thu Jan 02 25 07:18:18

Checked By
(QA)

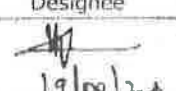
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BATCH MANUFACTURING RECORD

Page No.:

28 of 116

Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

6.01AFFIX DISPENSING CARD:

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets



Item Code: RMET0011 | Category: NA

Item Name: TARTRAZINE SUPRA INH

Operation: Granulation

AR No.: QCR241925 | Retest Date: 06/12/26

Mfr: STANDARDCON PVT. LTD. (V0227)

Lot No.: 4 | Pack 1 of 1 | Bal. Id.: ST/SRWB/002

Req. Qty.: 0.17 Kg | Issd. Qty.: 0.136 Kg | Conv. Fa.: 1

Gr. Wt.: 0.038 Kg | Tr. Wt.: 0.004 Kg | Nt. Wt.: 0.034 Kg



Dispensed By
(Store)

LBST:001 Revision No: R1

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(QA)

ID: DE-REC-2025-0019 - 40

Verified By
(Prod.)

Thu Jan 02 25 07:07:21

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets



Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241934 | Retest Date: 09/12/26

Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 4 | Pack 6 of 1 | Bal. Id.: ST/WB/189

Req. Qty.: 625.0 Kg | Issd. Qty.: 504.16 Kg | Conv. Fa.: 1

Gr. Wt.: 1.078 Kg | Tr. Wt.: 0.038 Kg | Nt. Wt.: 1.04 Kg

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(Store)

LBST:001 Revision No: R1

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(QA)

ID: DE-REC-2025-0019 - 76

Verified By
(Prod.)

Thu Jan 02 25 07:41:00



DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241934 | Retest Date: 09/12/26

Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 5 | Pack 5 of 1 | Bal. Id.: ST/WB/189

Req. Qty.: 625.0 Kg | Issd. Qty.: 629.16 Kg | Conv. Fa.: 1

Gr. Wt.: 25.25 Kg | Tr. Wt.: 0.25 Kg | Nt. Wt.: 25.0 Kg



Verified By
(Prod.)

Thu Jan 02 25 07:43:36

Checked By
(QA)

ID: DE-REC-2025-0019 - 70

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(Store)

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Signature			
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BATCH MANUFACTURING RECORD

Page No.: 29 of 116
Batch Size: 12,50,000 Tablets
Supersedes MFC No: ST/MFC/119/R5
Exp.Date: 12/2027

Brand Name: LITACOLD FLU TABLETS
Product ID No.: 978
Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets
MFC NO: ST/MFC/119/R6
Batch No.: G17250103
Mfg.Date: 01/2025

6.0KAFFIX DISPENSING CARD:

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)
Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMAP0030 | Category: NA
Item Name: PARACETAMOL BP
Operation: Granulation

AR No.: QCR241934 | Retest Date: 09/12/25
Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 5 | Pack 3 of 1 | Bal. Id.: ST/WB/189
Req. Qty.: 625.0 Kg | Issd. Qty.: 579.16 Kg | Conv. Fa.: 1
Gr. Wt.: 25.25 Kg | Tr. Wt.: 0.25 Kg | Ni. Wt.: 25.0 Kg

Dispensed By
(Store)
LBST:001 Revision No: R1

Checked By
(QA)
ID: DE-REC-2025-0019 - 77

Verified By
(Prod.)
Thu Jan 02 25 07:42:24

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)
Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMAP0030 | Category: NA
Item Name: PARACETAMOL BP
Operation: Granulation

AR No.: QCR241934 | Retest Date: 09/12/25
Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 5 | Pack 4 of 1 | Bal. Id.: ST/WB/189
Req. Qty.: 625.0 Kg | Issd. Qty.: 604.16 Kg | Conv. Fa.: 1
Gr. Wt.: 25.25 Kg | Tr. Wt.: 0.25 Kg | Ni. Wt.: 25.0 Kg

Dispensed By
(Store)
LBST:001 Revision No: R1

Checked By
(QA)
ID: DE-REC-2025-0019 - 78

Verified By
(Prod.)
Thu Jan 02 25 07:42:58

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)
Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMAP0030 | Category: NA
Item Name: PARACETAMOL BP
Operation: Granulation

AR No.: QCR241934 | Retest Date: 09/12/25
Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 5 | Pack 1 of 1 | Bal. Id.: ST/WB/189
Req. Qty.: 625.0 Kg | Issd. Qty.: 529.16 Kg | Conv. Fa.: 1
Gr. Wt.: 25.25 Kg | Tr. Wt.: 0.25 Kg | Ni. Wt.: 25.0 Kg

Verified By
(Prod.)

Checked By
(QA)

Dispensed By
(Store)

Thu Jan 02 25 07:41:29

ID: DE-REC-2025-0019 - 21

LBST:001 Revision No: R1

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Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			

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BATCH MANUFACTURING RECORD

Page No.:	30 of 116
Batch Size	12,50,000 Tablets
Supersedes MFC No:	ST/MFC/119/R5
Exp. Date:	12/2027

Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6
Batch No.:	G17250103	Mfg. Date:	01/2025

6.0 LAFFIX DISPENSING CARD:

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241934 | Retest Date: 09/12/25

Mir: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 5 | Pack 2 of 1 | Bal. Id.: ST/WB/189
Req. Qty.: 625.0 Kg | Issd. Qty.: 554.16 Kg | Conv. Fa.: 1
Gr. Wt.: 25.25 Kg | Tr. Wt.: 0.25 Kg | Nt. Wt.: 25.0 Kg

Dispensed By
(Store)
LBST-001 Revision No: R1

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(QA)
ID: DE-REC-2025-0019 - 76

Verified By
(Prod.)
Thu Jan 02 25 07:41:53

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMEP0046 | Category: NA

Item Name: PREGELATINIZED STARCH BP STARCH 1500

Operation: Granulation

AR No.: QCR241904 | Retest Date: 21/11/25

Mir: COLORCON ASIA PRIVATE LIMITED. (V0163)

Lot No.: 5 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 18.75 Kg | Issd. Qty.: 18.75 Kg | Conv. Fa.: 1
Gr. Wt.: 3.83 Kg | Tr. Wt.: 0.08 Kg | Nt. Wt.: 3.75 Kg

Dispensed By
(Store)
LBST-001 Revision No: R1

Checked By
(QA)
ID: DE-REC-2025-0019 - 26

Verified By
(Prod.)
Thu Jan 02 25 08:45:48

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMEM0031 | Category: NA

Item Name: MICROCRYSTALLINE CELLULOSE POWDER PH

Operation: Granulation

AR No.: QCR241887 | Retest Date: 21/11/25

Mir: SIGACHI INDUSTRIES PVT LTD. (V0162)

Lot No.: 5 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 30.92 Kg | Issd. Qty.: 25.53 Kg | Conv. Fa.: 1
Gr. Wt.: 5.186 Kg | Tr. Wt.: 0.08 Kg | Nt. Wt.: 5.106 Kg

Dispensed By
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(QA)

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LBST-001 Revision No: R1

ID: DE-REC-2025-0019 - 31

Thu Jan 02 25 08:55:50

Dispensed materials label pasted by (production sign/date):

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Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
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		Safetab Life Science			
BATCH MANUFACTURING RECORD				Page No.:	31 of 116
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO.:	ST/MFC/119/R6	Supersedes MFC No.:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

6.0MAFFIX DISPENSING CARD:

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

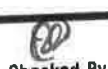
Item Code: RMEM0032 | Category: NA
Item Name: METHYL PARABEN SODIUM BP
Operation: Granulation

AR No.: QCR241875 | Retest Date: 02/12/26
Mir: ALTA LABORATORIES LTD. (V0013)

Lot No.: 5 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 0.625 Kg | Issd. Qty.: 0.625 Kg | Conv. Fa.: 1
Gr. Wt.: 0.129 Kg | Tr. Wt.: 0.004 Kg | Nt. Wt.: 0.125 Kg


Dispensed By
(Store)

LBST-001 Revision No: R1


Checked By
(QA)

ID: DE-REC-2025-0019 - 46


Verified By
(Prod.)

Thu Jan 02 25 07:02:55

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMEP0045 | Category: NA
Item Name: POVIDONE K 90 BP
Operation: Granulation

AR No.: QCR241854 | Retest Date: 22/08/26
Mir: HUANGSHAN BONSUN PHARMACEUTICALS (V01:9)

Lot No.: 5 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 15.625 Kg | Issd. Qty.: 15.625 Kg | Conv. Fa.: 1
Gr. Wt.: 3.205 Kg | Tr. Wt.: 0.08 Kg | Nt. Wt.: 3.125 Kg


Dispensed By
(Store)

LBST-001 Revision No: R1


Checked By
(QA)

ID: DE-REC-2025-0019 - 36


Verified By
(Prod.)

Thu Jan 02 25 06:49:33

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMAC0064 | Category: NA
Item Name: CHLORPHENIRAMINE MALEATE BP
Operation: Granulation

AR No.: QCR241903 | Retest Date: 18/11/25
Mir: SUPRIYA LIFE SCIENCE LIMITED. (V0067)

Lot No.: 5 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 2.5 Kg | Issd. Qty.: 2.505 Kg | Conv. Fa.: 1
Gr. Wt.: 0.529 Kg | Tr. Wt.: 0.028 Kg | Nt. Wt.: 0.501 Kg


Checked By
(QA)

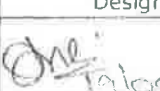
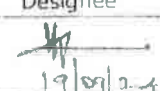
ID: DE-REC-2025-0019 - 5


Dispensed By
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LBST-001 Revision No: R1

Dispensed materials label pasted by (production sign/date):

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Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
UNCONTROLLED COPY		CONTROLLED COPY	



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BATCH MANUFACTURING RECORD

Page No.:	32 of 116
Batch Size	12,50,000 Tablets
Supersedes MFC No:	ST/MFC/119/R5
Exp.Date:	12/2027

Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6
Batch No.:	G17250103	Mfg.Date:	01/2025

6. ONAFFIX DISPENSING CARD:

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMAC0065 | Category: NA

Item Name: CAFFEINE ANHYDROUS BP

Operation: Granulation

AR No.: QCR241955 | Retest Date: 26/11/25

Mfr: AARTI PHARMALABS (V0443)

Lot No.: 5 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 37.5 Kg | Issd. Qty.: 37.675 Kg | Conv. Fa.: 1
Gr. Wt.: 7.695 Kg | Tr. Wt.: 0.16 Kg | Nt. Wt.: 7.535 Kg

Dispensed By
(Store)
LBST-001 Revision No: R1

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(QA)
ID: DE-REC-2025-0019 - 1E

Verified By
(Prod.)
Thu Jan 02 25 07:27:01

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMAP0031 | Category: NA

Item Name: PHENYLEPHRINE HYDROCHLORIDE BP

Operation: Granulation

AR No.: QCR241906 | Retest Date: 19/11/25

Mfr: DIVI OQS LABORATORIES LTD. (V0014)

Lot No.: 5 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 6.25 Kg | Issd. Qty.: 6.265 Kg | Conv. Fa.: 1
Gr. Wt.: 1.291 Kg | Tr. Wt.: 0.038 Kg | Nt. Wt.: 1.253 Kg

Dispensed By
(Store)
LBST-001 Revision No: R1

Checked By
(QA)
ID: DE-REC-2025-0019 - 10

Verified By
(Prod.)
Thu Jan 02 25 07:18:31

Dispensed materials label pasted by (production sign/date):

verified by (IPQA) sign/date:

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
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		Safetab Life Science			
BATCH MANUFACTURING RECORD				Page No.:	33 of 116
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

6.0-OAFFIX DISPENSING CARD:

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0) Tablets

Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241934 | Retest Date: 09/12/26

Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 5 | Pack 6 of 1 | Bal. Id.: ST/WB/189

Req. Qty.: 625.0 Kg | Issd. Qty.: 630.2 Kg | Conv. Fa.: 1

Gr. Wt.: 1.078 Kg | Tr. Wt.: 0.038 Kg | Nt. Wt.: 1.04 Kg

Dispensed By
(Store)

L88T:001 Revision No: R1

Checked By
(QA)

ID: DE-REC-2025-0019 - 80

Verified By
(Prod.)

Thu Jan 02 25 07:44:10

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0) Tablets

Item Code: RMEC0017 | Category: NA

Item Name: COLLOIDAL ANHYDROUS SILICA BP

Operation: Blending

AR No.: QCR241882 | Retest Date: 29/11/26

Mfr: CABOT SANMAR LIMITED. (V0131)

Lot No.: 1 | Pack 3 of 1 | Bal. Id.: ST/SRWB/001

Req. Qty.: 6.25 Kg | Issd. Qty.: 6.0 Kg | Conv. Fa.: 1

Gr. Wt.: 2.08 Kg | Tr. Wt.: 0.08 Kg | Nt. Wt.: 2.0 Kg

Dispensed By
(Store)

L88T:001 Revision No: R1

Checked By
(QA)

ID: DE-REC-2025-0019 - 6E

Verified By
(Prod.)

Thu Jan 02 25 06:59:08

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0) Tablets

Item Code: RMET0013 | Category: NA

Item Name: TARTRAZINE LAKE INH

Operation: Blending

AR No.: QCR241926 | Retest Date: 22/11/26

Mfr: STANDARDCON PVT. LTD. (V0227)

Lot No.: 1 | Pack 1 of 1 | Bal. Id.: ST/SRWB/002

Req. Qty.: 0.163 Kg | Issd. Qty.: 0.163 Kg | Conv. Fa.: 1

Gr. Wt.: 0.167 Kg | Tr. Wt.: 0.004 Kg | Nt. Wt.: 0.163 Kg

Checked By
(QA)

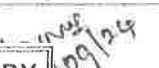
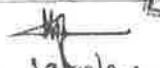
ID: DE-REC-2025-0019 - 51

Dispensed By
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Dispensed materials label pasted by (production sign/date):

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BATCH MANUFACTURING RECORD

Page No.:	34 of 116
Batch Size	12,500,000 Tablets
Supersedes MFC No:	ST/MFC/119/R5
Exp.Date:	12/2027

Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6
Batch No.:	G17250103	Mfg.Date:	01/2025

6.0 PAFFIX DISPENSING CARD:

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMEC0017 | Category: NA

Item Name: COLLOIDAL ANHYDROUS SILICA BP

Operation: Blending

AR No.: QCR241882 | Retest Date: 29/11/26

Mfr: CABOT SANMAR LIMITED. (V0131)

Lot No.: 1 | Pack 2 of 1 | Bal. Id.: ST/SRWB/001

Req. Qty.: 6.25 Kg | Issd. Qty.: 4.0 Kg | Conv. Fa.: 1

Gr. Wt.: 2.08 Kg | Tr. Wt.: 0.08 Kg | Nt. Wt.: 2.0 Kg

Dispensed By
(Store)

LBST:001 Revision No: R1

Checked By
(QA)

ID: DE-REC-2025-0019 - 54

Verified By
(Prod.)

Thu Jan 02 25 08:58:44

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMEC0017 | Category: NA

Item Name: COLLOIDAL ANHYDROUS SILICA BP

Operation: Blending

AR No.: QCR241882 | Retest Date: 29/11/26

Mfr: CABOT SANMAR LIMITED. (V0131)

Lot No.: 1 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001

Req. Qty.: 6.25 Kg | Issd. Qty.: 2.0 Kg | Conv. Fa.: 1

Gr. Wt.: 2.08 Kg | Tr. Wt.: 0.08 Kg | Nt. Wt.: 2.0 Kg

Dispensed By
(Store)

LBST:001 Revision No: R1

Checked By
(QA)

ID: DE-REC-2025-0019 - 50

Verified By
(Prod.)

Thu Jan 02 25 08:58:21

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMEC0017 | Category: NA

Item Name: COLLOIDAL ANHYDROUS SILICA BP

Operation: Blending

AR No.: QCR241882 | Retest Date: 29/11/26

Mfr: CABOT SANMAR LIMITED. (V0131)

Lot No.: 1 | Pack 4 of 1 | Bal. Id.: ST/SRWB/001

Req. Qty.: 6.25 Kg | Issd. Qty.: 6.25 Kg | Conv. Fa.: 1

Gr. Wt.: 0.33 Kg | Tr. Wt.: 0.08 Kg | Nt. Wt.: 0.25 Kg

Dispensed By
(Store)

LBST:001 Revision No: R1

Checked By
(QA)

ID: DE-REC-2025-0019 - 54

Verified By
(Prod.)

Thu Jan 02 25 07:00:03

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Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
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BATCH MANUFACTURING RECORD

Page No.:	35 of 116
Batch Size	12,50,000 Tablets
Supersedes MFC No:	ST/MFC/119/R5
Exp.Date:	12/2027

Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6
Batch No.:	G17250103	Mfg.Date:	01/2025

6.0Q-AFFIX DISPENSING CARD:

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMEM0033 | Category: NA
Item Name: MAGNESIUM STEARATE BP
Operation: Blending

AR No.: QCR241969 | Retest Date: 14/12/25
Mfr: ELITE CHEMICALS (V0456)

Lot No.: 1 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 7.5 Kg | Issd. Qty.: 7.5 Kg | Conv. Fa.: 1
Gr. Wt.: 7.50 Kg | Tr. Wt.: 0.08 Kg | NI. Wt.: 7.5 Kg

Dispensed By
(Store)

LBST-001 Revision No: R1

Checked By
(QA)

ID: DE-REC-2025-0019 - 02

Verified By
(Prod.)

Thu Jan 02 25 08:52:51

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMES0029 | Category: NA
Item Name: SODIUM STARCH GLYCOLATE BP
Operation: Blending

AR No.: QCR241867 | Retest Date: 16/11/25
Mfr: AMISHI DRUGS & CHEMICALS PVT. LTD. (V0134)

Lot No.: 1 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 21.25 Kg | Issd. Qty.: 21.25 Kg | Conv. Fa.: 1
Gr. Wt.: 21.41 Kg | Tr. Wt.: 0.16 Kg | NI. Wt.: 21.25 Kg

Dispensed By
(Store)

LBST-001 Revision No: R1

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(QA)

ID: DE-REC-2025-0019 - 46

Verified By
(Prod.)

Thu Jan 02 25 08:50:36

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets

Item Code: RMEP0046 | Category: NA

Item Name: PREGELATINIZED STARCH BP STARCH 1500

Operation: Blending

AR No.: QCR241904 | Retest Date: 21/11/25
Mfr: COLORCON ASIA PRIVATE LIMITED. (V0163)

Lot No.: 1 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 12.5 Kg | Issd. Qty.: 31.25 Kg | Conv. Fa.: 1
Gr. Wt.: 12.66 Kg | Tr. Wt.: 0.16 Kg | NI. Wt.: 12.5 Kg

Checked By
(QA)

ID: DE-REC-2025-0019 - 47

Verified By
(Prod.)

Thu Jan 02 25 08:46:09

Dispensed materials label pasted by (production sign/date)

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BATCH MANUFACTURING RECORD

Page No.: 36 of 116
Batch Size: 12,50,000 Tablets
Supersedes MFC No: ST/MFC/119/R5
Exp.Date: 12/2027

Brand Name: LITACOLD FLU TABLETS
Product ID No.: 978
Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets
MFC NO: ST/MFC/119/R6
Batch No.: G17250103
Mfg.Date: 01/2025

6.0R-AFFIX DISPENSING CARD:

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 1250000 Tablets



Item Code: RMET0012 | Category: NA

Item Name: PURIFIED TALC BP

Operation: Blending

AR No.: QCR241844 | Retest Date: 16/11/25

Mfr: NEELKANTH MINECHEM. (V0019)

Lot No.: 1 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001

Req. Qty.: 8.75 Kg | Issd. Qty.: 8.75 Kg | Conv. Fa.: 1

Gr. Wt.: 8.83 Kg | Tr. Wt.: 0.08 Kg | Nt. Wt.: 8.75 Kg



Dispensed By
(Store)

LBST:001 Revision No: R1

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(QA)

ID: DE-REC-2025-0019 - 48

Verified By
(Prod.)

Thu Jan 02 25 08:51:57

Dispensed materials label pasted by(production sign/date: 21/01/25

verified by(IPQA) sign/date: 21/01/25

Title	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature				
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DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0) Tablets



Item Code: RMEM0031 | Category: NA

Item Name: MICROCRYSTALLINE CELLULOSE POWDER PH

Operation: Granulation

AR No.: QCR241887 | Retest Date: 21/11/25

Mfr: SIGACHI INDUSTRIES PVT LTD. (V0162)

Lot No.: 3 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 30.92 Kg | Issd. Qty.: 15.318 Kg | Conv. Fa.: 1
Gr. Wt.: 5.186 Kg | Tr. Wt.: 0.08 Kg | NI. Wt.: 5.106 Kg

Dispensed By
(Store)

LBST-001 Revision No: R1

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(QA)

ID: DE-REC-2025-0019 - 28

Verified By
(Prod.)

Thu Jan 02 25 06:53:43

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0) Tablets



Item Code: RMEP0046 | Category: NA

Item Name: PREGELATINIZED STARCH BP STARCH 1500

Operation: Granulation

AR No.: QCR241904 | Retest Date: 21/11/25

Mfr: COLORCON ASIA PRIVATE LIMITED. (V0163)

Lot No.: 3 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 18.75 Kg | Issd. Qty.: 11.25 Kg | Conv. Fa.: 1
Gr. Wt.: 3.83 Kg | Tr. Wt.: 0.08 Kg | NI. Wt.: 3.75 Kg

Dispensed By
(Store)

LBST-001 Revision No: R1

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(QA)

ID: DE-REC-2025-0019 - 24

Verified By
(Prod.)

Thu Jan 02 25 06:45:18

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0) Tablets



Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241934 | Retest Date: 09/12/25

Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 3 | Pack 1 of 1 | Bal. Id.: ST/WB/189
Req. Qty.: 625.0 Kg | Issd. Qty.: 277.08 Kg | Conv. Fa.: 1
Gr. Wt.: 25.25 Kg | Tr. Wt.: 0.25 Kg | NI. Wt.: 25.0 Kg

Dispensed By
(Store)

LBST-001 Revision No: R1

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(QA)

ID: DE-REC-2025-0019 - 18

Verified By
(Prod.)

Thu Jan 02 25 07:35:30

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0) Tablets



Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241934 | Retest Date: 09/12/25

Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 3 | Pack 2 of 1 | Bal. Id.: ST/WB/189
Req. Qty.: 625.0 Kg | Issd. Qty.: 302.08 Kg | Conv. Fa.: 1
Gr. Wt.: 25.25 Kg | Tr. Wt.: 0.25 Kg | NI. Wt.: 25.0 Kg

Dispensed By
(Store)

LBST-001 Revision No: R1

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(QA)

ID: DE-REC-2025-0019 - 86

Verified By
(Prod.)

Thu Jan 02 25 07:35:48

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0) Tablets



Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241934 | Retest Date: 09/12/25

Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 3 | Pack 3 of 1 | Bal. Id.: ST/WB/189
Req. Qty.: 625.0 Kg | Issd. Qty.: 327.08 Kg | Conv. Fa.: 1
Gr. Wt.: 25.25 Kg | Tr. Wt.: 0.25 Kg | NI. Wt.: 25.0 Kg

Dispensed By
(Store)

LBST-001 Revision No: R1

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(QA)

ID: DE-REC-2025-0019 - 87

Verified By
(Prod.)

Thu Jan 02 25 07:36:06

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DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0) Tablets



Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241934 | Retest Date: 09/12/25

Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 2 | Pack 3 of 1 | Bal. Id.: ST/WB/189

Req. Qty.: 625.0 Kg | Issd. Qty.: 240.512 Kg | Conv. Fa.: 1

Gr. Wt.: 25.25 Kg | Tr. Wt.: 0.25 Kg | Nt. Wt.: 25.0 Kg



Dispensed By
(Store)

Checked By
(QA)

Verified By
(Prod.)

LBST:001 Revision No: R1

ID: DE-REC-2025-0019 - 64

Thu Jan 02 25 07:34:35

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0) Tablets



Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241934 | Retest Date: 09/12/25

Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 3 | Pack 6 of 1 | Bal. Id.: ST/WB/189

Req. Qty.: 625.0 Kg | Issd. Qty.: 378.12 Kg | Conv. Fa.: 1

Gr. Wt.: 1.078 Kg | Tr. Wt.: 0.038 Kg | Nt. Wt.: 1.04 Kg



Dispensed By
(Store)

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(Prod.)

LBST:001 Revision No: R1

ID: DE-REC-2025-0019 - 70

Thu Jan 02 25 07:37:53

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0) Tablets



Item Code: RMET0011 | Category: NA

Item Name: TARTRAZINE SUPRA INH

Operation: Granulation

AR No.: QCR241926 | Retest Date: 06/12/26

Mfr: STANDARDCON PVT. LTD. (V0227)

Lot No.: 3 | Pack 1 of 1 | Bal. Id.: ST/SRWB/002

Req. Qty.: 0.17 Kg | Issd. Qty.: 0.102 Kg | Conv. Fa.: 1

Gr. Wt.: 0.038 Kg | Tr. Wt.: 0.004 Kg | Nt. Wt.: 0.034 Kg



Dispensed By
(Store)

Checked By
(QA)

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(Prod.)

LBST:001 Revision No: R1

ID: DE-REC-2025-0019 - 38

Thu Jan 02 25 07:07:02



DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0) Tablets



Item Code: RMAP0031 | Category: NA

Item Name: PHENYLEPHRINE HYDROCHLORIDE BP

Operation: Granulation

AR No.: QCR241906 | Retest Date: 19/11/25

Mfr: DIVIÖÖS LABORATORIES LTD. (V0014)

Lot No.: 3 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001

Req. Qty.: 6.25 Kg | Issd. Qty.: 3.759 Kg | Conv. Fa.: 1

Gr. Wt.: 1.291 Kg | Tr. Wt.: 0.038 Kg | Nt. Wt.: 1.253 Kg

Dispensed By
(Store)

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LBST:001 Revision No: R1

ID: DE-REC-2025-0019 - 8

Thu Jan 02 25 07:18:04



DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0) Tablets



Item Code: RMAC0065 | Category: NA

Item Name: CAFFEINE ANHYDROUS BP

Operation: Granulation

AR No.: QCR241956 | Retest Date: 26/11/25

Mfr: AARTI PHARMALABS (V0443)

Lot No.: 3 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001

Req. Qty.: 37.5 Kg | Issd. Qty.: 22.605 Kg | Conv. Fa.: 1

Gr. Wt.: 7.695 Kg | Tr. Wt.: 0.16 Kg | Nt. Wt.: 7.535 Kg

Dispensed By
(Store)

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(QA)

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LBST:001 Revision No: R1

ID: DE-REC-2025-0019 - 13

Thu Jan 02 25 07:26:28

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DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0) Tablets



Item Code: RMAC0064 | Category: NA
Item Name: CHLORPHENIRAMINE MALEATE BP
Operation: Granulation

AR No.: QCR241903 | Retest Date: 18/11/25
Mfr: SUPRIYA LIFE SCIENCE LIMITED. (V0067)

Lot No.: 2 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 2.5 Kg | Issd. Qty.: 1.002 Kg | Conv. Fa.: 1
Gr. Wt.: 0.529 Kg | Tr. Wt.: 0.028 Kg | Nt. Wt.: 0.501 Kg



Dispensed By
(Store)

Checked By
(QA)

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LBST-001 Revision No: R1

ID: DE-REC-2025-0019 - 2

Thu Jan 02 25 07:14:27

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0) Tablets



Item Code: RMEP0045 | Category: NA
Item Name: POVIDONE K 90 BP
Operation: Granulation

AR No.: QCR241854 | Retest Date: 22/08/26
Mfr: HUANGSHAN BONSUN PHARMACEUTICALS (V01:9)

Lot No.: 2 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 15.625 Kg | Issd. Qty.: 6.25 Kg | Conv. Fa.: 1
Gr. Wt.: 3.205 Kg | Tr. Wt.: 0.08 Kg | Nt. Wt.: 3.125 Kg



Dispensed By
(Store)

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(QA)

Verified By
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LBST-001 Revision No: R1

ID: DE-REC-2025-0019 - 33

Thu Jan 02 25 08:41:30

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0) Tablets



Item Code: RMEM0032 | Category: NA
Item Name: METHYL PARABEN SODIUM BP
Operation: Granulation

AR No.: QCR241875 | Retest Date: 02/12/26
Mfr: ALTA LABORATORIES LTD. (V0013)

Lot No.: 2 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 0.625 Kg | Issd. Qty.: 0.25 Kg | Conv. Fa.: 1
Gr. Wt.: 0.129 Kg | Tr. Wt.: 0.004 Kg | Nt. Wt.: 0.125 Kg



Dispensed By
(Store)

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(Prod.)

LBST-001 Revision No: R1

ID: DE-REC-2025-0019 - 43

Thu Jan 02 25 07:02:11



DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0) Tablets



Item Code: RMEM0031 | Category: NA
Item Name: MICROCRYSTALLINE CELLULOSE POWDER PH
Operation: Granulation

AR No.: QCR241887 | Retest Date: 21/11/25
Mfr: SIGACHI INDUSTRIES PVT LTD. (V0162)

Lot No.: 2 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 30.92 Kg | Issd. Qty.: 10.212 Kg | Conv. Fa.: 1
Gr. Wt.: 5.186 Kg | Tr. Wt.: 0.08 Kg | Nt. Wt.: 5.106 Kg

Dispensed By
(Store)

Checked By
(QA)

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(Prod.)

ID: DE-REC-2025-0019 - 26

LBST-001 Revision No: R1

Thu Jan 02 25 06:30:31



DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0) Tablets



Item Code: RMEP0046 | Category: NA
Item Name: PREGELATINIZED STARCH BP STARCH 1500
Operation: Granulation

AR No.: QCR241904 | Retest Date: 21/11/25
Mfr: COLORCON ASIA PRIVATE LIMITED. (V0163)

Lot No.: 2 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001
Req. Qty.: 18.75 Kg | Issd. Qty.: 7.5 Kg | Conv. Fa.: 1
Gr. Wt.: 3.83 Kg | Tr. Wt.: 0.08 Kg | Nt. Wt.: 3.75 Kg

Dispensed By
(Store)

Checked By
(QA)

Verified By
(Prod.)

ID: DE-REC-2025-0019 - 23

LBST-001 Revision No: R1

Thu Jan 02 25 06:45:04

UNCONTROLLED COPY

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0 Tablets)



Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241933 | Retest Date: 26/11/25

Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 1 | Pack 4 of 1 | Bal. Id.: ST/WB/189
Req. Qty.: 625.0 Kg | Issd. Qty.: 100.0 Kg | Conv. Fa.: 1
Gr. Wt.: 25.25 Kg | Tr. Wt.: 0.25 Kg | Nt. Wt. 25.0 Kg



Dispensed By
(Store)

LBST:001 Revision No: R1

Checked By
(QA)

ID: DE-REC-2025-0019 - 58

Verified By
(Prod.)

Thu Jan 02 25 07:31:00

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0 Tablets)



Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241933 | Retest Date: 26/11/25

Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 1 | Pack 3 of 1 | Bal. Id.: ST/WB/189
Req. Qty.: 625.0 Kg | Issd. Qty.: 75.0 Kg | Conv. Fa.: 1
Gr. Wt.: 25.25 Kg | Tr. Wt.: 0.25 Kg | Nt. Wt. 25.0 Kg



Dispensed By
(Store)

LBST:001 Revision No: R1

Checked By
(QA)

ID: DE-REC-2025-0019 - 58

Verified By
(Prod.)

Thu Jan 02 25 07:30:08

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0 Tablets)



Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241933 | Retest Date: 26/11/25

Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 1 | Pack 5 of 1 | Bal. Id.: ST/WB/189
Req. Qty.: 625.0 Kg | Issd. Qty.: 125.0 Kg | Conv. Fa.: 1
Gr. Wt.: 25.25 Kg | Tr. Wt.: 0.25 Kg | Nt. Wt. 25.0 Kg



Dispensed By
(Store)

LBST:001 Revision No: R1

Checked By
(QA)

ID: DE-REC-2025-0019 - 60

Verified By
(Prod.)

Thu Jan 02 25 07:31:24



DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0 Tablets)



Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241934 | Retest Date: 09/12/25

Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 2 | Pack 4 of 1 | Bal. Id.: ST/WB/189
Req. Qty.: 625.0 Kg | Issd. Qty.: 252.08 Kg | Conv. Fa.: 1
Gr. Wt.: 11.728 Kg | Tr. Wt.: 0.16 Kg | Nt. Wt. 11.568 Kg

Verified By
(Prod.)

Thu Jan 02 25 07:35:06

Checked By
(QA)

ID: DE-REC-2025-0019 - 05

Dispensed By
(Store)

LBST:001 Revision No: R1



DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0 Tablets)



Item Code: RMAP0030 | Category: NA

Item Name: PARACETAMOL BP

Operation: Granulation

AR No.: QCR241933 | Retest Date: 26/11/25

Mfr: VALIANT LABORATORIES LIMITED (V0345)

Lot No.: 2 | Pack 2 of 1 | Bal. Id.: ST/WB/189
Req. Qty.: 625.0 Kg | Issd. Qty.: 165.512 Kg | Conv. Fa.: 1
Gr. Wt.: 14.632 Kg | Tr. Wt.: 0.16 Kg | Nt. Wt. 14.472 Kg

Verified By
(Prod.)

Thu Jan 02 25 07:38:18

Checked By
(QA)

ID: DE-REC-2025-0019 - 62

Dispensed By
(Store)

LBST:001 Revision No: R1

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DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0 Tablets)



Item Code: RMAC0065 | Category: NA

Item Name: CAFFEINE ANHYDROUS BP

Operation: Granulation

AR No.: QCR241955 | Retest Date: 26/11/25

Mfr: AARTI PHARMALABS (V0443)

Lot No.: 1 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001

Req. Qty.: 37.5 Kg | Issd. Qty.: 7.535 Kg | Conv. Fa.: 1

Gr. Wt.: 7.695 Kg | Tr. Wt.: 0.16 Kg | Nt. Wt.: 7.535 Kg

7.535 Kg

Dispensed By
(Store)

LBST-001 Revision No: R1

Checked By
(QA)

ID: DE-REC-2025-0019 - 11

Verified By
(Prod.)

Thu Jan 02 25 07:23:30

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0 Tablets)



Item Code: RMAC0064 | Category: NA

Item Name: CHLORPHENIRAMINE MALEATE BP

Operation: Granulation

AR No.: QCR241903 | Retest Date: 18/11/25

Mfr: SUPRIYA LIFE SCIENCE LIMITED. (V0067)

Lot No.: 1 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001

Req. Qty.: 2.5 Kg | Issd. Qty.: 0.501 Kg | Conv. Fa.: 1

Gr. Wt.: 0.529 Kg | Tr. Wt.: 0.028 Kg | Nt. Wt.: 0.501 Kg

0.501 Kg

Dispensed By
(Store)

LBST-001 Revision No: R1

Checked By
(QA)

ID: DE-REC-2025-0019 - 1

Verified By
(Prod.)

Thu Jan 02 25 07:13:36

DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0 Tablets)



Item Code: RMEP0045 | Category: NA

Item Name: POVIDONE K 90 BP

Operation: Granulation

AR No.: QCR241854 | Retest Date: 22/08/26

Mfr: HUANGSHAN BONSUN PHARMACEUTICALS (V0119)

Lot No.: 1 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001

Req. Qty.: 15.625 Kg | Issd. Qty.: 3.125 Kg | Conv. Fa.: 1

Gr. Wt.: 3.205 Kg | Tr. Wt.: 0.08 Kg | Nt. Wt.: 3.125 Kg

3.125 Kg

Dispensed By
(Store)

LBST-001 Revision No: R1

Checked By
(QA)

ID: DE-REC-2025-0019 - 32

Verified By
(Prod.)

Thu Jan 02 25 08:41:22



DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0 Tablets)

Item Code: RMEM0032 | Category: NA

Item Name: METHYL PARABEN SODIUM BP

Operation: Granulation

AR No.: QCR241875 | Retest Date: 07/12/26

Mfr: ALTA LABORATORIES LTD. (V0013)

Lot No.: 1 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001

Req. Qty.: 0.625 Kg | Issd. Qty.: 0.125 Kg | Conv. Fa.: 1

Gr. Wt.: 0.129 Kg | Tr. Wt.: 0.004 Kg | Nt. Wt.: 0.125 Kg

0.125 Kg

Verified By
(Prod.)

Thu Jan 02 25 07:01:58

Checked By
(QA)

ID: DE-REC-2025-0019 - 42

Dispensed By
(Store)

LBST-001 Revision No: R1



DISPENSED MATERIAL

Product: LITACOLD FLU (BMR-978)

Batch No.: G17250103 | Batch Size: 12500(0 Tablets)

Item Code: RMEM0031 | Category: NA

Item Name: MICROCRYSTALLINE CELLULOSE POWDER PH

Operation: Granulation

AR No.: QCR241887 | Retest Date: 21/11/25

Mfr: SIGACHI INDUSTRIES PVT. LTD. (N0162)

Lot No.: 1 | Pack 1 of 1 | Bal. Id.: ST/SRWB/001

Req. Qty.: 30.92 Kg | Issd. Qty.: 5.106 Kg | Conv. Fa.: 1

Gr. Wt.: 5.186 Kg | Tr. Wt.: 0.08 Kg | Nt. Wt.: 5.106 Kg

5.106 Kg

Verified By
(Prod.)

Thu Jan 02 25 06:58:18

Checked By
(QA)

ID: DE-REC-2025-0019 - 27

Dispensed By
(Store)

LBST-001 Revision No: R1

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Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.: 37 of 116
Batch Size: 12,50,000 Tablets
Supersedes MFC No: ST/MFC/119/R5
Exp.Date: 12/2027

Brand Name: LITACOLD FLU TABLETS
Product ID No.: 978
Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets
MFC NO: ST/MFC/119/R6
Batch No.: G17250103
Mfg.Date: 01/2025

7.0 GRANULATION:

7.1 LINE CLEARANCE CHECKS:

S.No	Check	Observation			
		Production		IPQA	
	DAY	I	II	I	II
1	Ensure that all empty containers, labels, used polybags, hand gloves of previous Product/ batch are removed from the area.	✓	✓	✓	✓
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	✓	✓	✓
3	Ensure that the previous batch BMR/documents are removed from the area.	✓	✓	✓	✓
4	Check the housekeeping general cleanliness of the floor, walls ceiling, tube light fixture, supply grills, riser grills, filters and electrical fixtures are clean.	✓	✓	✓	✓
5	Check the cleanliness of the doors, door view panel, SOP stand and compressed air filter outer surface.	✓	✓	✓	✓
6	Check for absence of previous batch/product from area below machine and inside the vessel.	✓	✓	✓	✓
7	Check whether the equipment body of Sifter, RMG, FBD and Multimill, Utensils are clean.	✓	✓	✓	✓
8	Ensure that the balances are cleaned and it's calibration status.	✓	✓	✓	✓
9	Check whether the Equipments/ Instruments to be used are within calibration/preventive maintenance due date.	✓	no	✓	no
10	Check the cleanliness of the utility line (compressed air, First RO water and purified water).	✓	✓	✓	✓
11	Check the cleanliness of the drain points.	✓	✓	✓	✓
12	Check the status board of the area is updated.	✓	✓	✓	✓
13	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.	✓	✓	✓	✓
14	Check the differential pressure of the area should be within the limit	✓	✓	✓	✓
15	Ensure the concurrent entries of log book.	✓	✓	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (Production) sign/date: 20/01/25

Verified by (IPQA) sign/date: V.P.H. 20/01/25

Equipment	Sifter	RMG	FBD	Multimill	Balance	AREA
Equipment ID No:	ST/PRVS/001	ST/PRMG/005	ST/PRFD/003	ST/PRML/001	ST/PRWB/001	
Previous Product:	Litacold Flu					
Batch No.	G1724209					
Cleaned by	msh					
Checked by	Production: <u>2</u>	IPQA: <u>V.P.H.</u>				

7.2 ENVIRONMENTAL CONDITIONS

	Date: <u>20/01/25</u>	Time: <u>15:00</u>	Date:	Time:
	Observation	Production Sign	Observation	Production Sign
Temperature: 23°C to 27°C	<u>26.4°C</u>	<u>2</u>		
Differential Pressure 0.5mm of water	<u>0.5mm</u>	<u>2</u>		
Relative Humidity: 45% to 55 %	<u>54%</u>	<u>2</u>		

7.3 APPROVAL FOR SIFTING, GRANULATION AND DRYING:

Production Sign/Date: <u>20/01/25</u>	IPQA Sign/Date: <u>V.P.H. 20/01/25</u>
---------------------------------------	--

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature	<u>20/01/25</u>	<u>20/01/25</u>	<u>20/01/25</u>

UNCONTROLLED COPY

CONTROLLED COPY

		Safetab Life Science			
BATCH MANUFACTURING RECORD				Page No.:	38 of 116
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

7.1A LINE CLEARANCE CHECKS:

S.No	Check	Observation			
		Production		IPQA	
	DAY	III	IV	III	IV
1	Ensure that all empty containers, labels, used polybags, hand gloves of previous Product/ batch are removed from the area.				
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.				
3	Ensure that the previous batch BMR/documents are removed from the area.				
4	Check the housekeeping general cleanliness of the floor, walls ceiling, tube light fixture, supply grills, riser grills, filters and electrical fixtures are clean.				
5	Check the cleanliness of the doors, door view panel, SOP stand and compressed air filter outer surface.				
6	Check for absence of previous batch/product from area below machine and inside the vessel.				
7	Check whether the equipment body of Sifter, RMG, FBD and Multimill, Utensils are clean.				
8	Ensure that the balances are cleaned and it's calibration status.				
9	Check whether the Equipments/ Instruments to be used are within calibration/preventive maintenance due date.				
10	Check the cleanliness of the utility line (compressed air, First RO water and purified water).				
11	Check the cleanliness of the drain points.				
12	Check the status board of the area is updated.				
13	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.				
14	Check the differential pressure of the area should be within the limit				
15	Ensure the concurrent entries of log book.				

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (Production) sign/date:

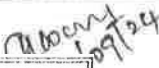
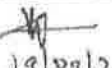
Verified by (IPQA) sign/date:

Equipment	Sifter	RMG	FBD	Multimill	Balance	AREA
Equipment ID No:						
Previous Product:						
Batch No.						
Cleaned by	20/01/24					
Checked by	Production:			IPQA:		

7.2A ENVIRONMENTAL CONDITIONS	Date:	Time:	Date:	Time:
	Observation	Production Sign	Observation	Production Sign
Temperature: 23°C to 27°C				
Differential Pressure 0.5mm of water				
Relative Humidity: 45% to 55 %				

7.3A APPROVAL FOR SIFTING, GRANULATION AND DRYING:

Production Sign/Date:	IPQA Sign/Date:
-----------------------------	-----------------------

Title Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	
Signature with Date				
UNCONTROLLED COPY				



Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.:	39 of 116
Batch Size	12,50,000 Tablets
Supersedes MFC No:	ST/MFC/119/R5
Exp.Date:	12/2027

Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6
Batch No.:	G17250103	Mfg.Date:	01/2025

7.1B LINE CLEARANCE CHECKS:

S.No	Check	Observation			
		Production		IPQA	
	DAY	V	VI	V	VI
1	Ensure that all empty containers, labels, used polybags, hand gloves of previous Product/ batch are removed from the area.				
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.				
3	Ensure that the previous batch BMR/documents are removed from the area.				
4	Check the housekeeping general cleanliness of the floor, walls ceiling, tube light fixture, supply grills, riser grills, filters and electrical fixtures are clean.				
5	Check the cleanliness of the doors, door view panel, SOP stand and compressed air filter outer surface.				
6	Check for absence of previous batch/product from area below machine and inside the vessel.				
7	Check whether the equipment body of Sifter, RMG, FBD and Multimill, Utensils are clean.				
8	Ensure that the balances are cleaned and it's calibration status.				
9	Check whether the Equipments/ Instruments to be used are within calibration/preventive maintenance due date.				
10	Check the cleanliness of the utility line (compressed air, First RO water and purified water).				
11	Check the cleanliness of the drain points.				
12	Check the status board of the area is updated.				
13	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.				
14	Check the differential pressure of the area should be within the limit				
15	Ensure the concurrent entries of log book.				

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (Production) sign/date:.....

Verified by (IPQA) sign/date:.....

Equipment	Sifter	RMG	FBD	Multimill	Balance	AREA
Equipment ID No:						
Previous Product:						
Batch No.						
Cleaned by						
Checked by	Production:			IPQA:		

7.2B ENVIRONMENTAL CONDITIONS

	Date:	Time:	Date:	Time:
	Observation	Production Sign	Observation	Production Sign
Temperature: 23°C to 27°C				
Differential Pressure 0.5mm of water				
Relative Humidity: 45% to 55 %				

7.3B APPROVAL FOR SIFTING, GRANULATION AND DRYING:

Production Sign/Date:	IPQA Sign/Date:
-----------------------	-----------------

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	<i>[Signature]</i> 19/01/25	<i>[Signature]</i> 19/01/25	<i>[Signature]</i> 19/01/25
UNCONTROLLED COPY		CONTROLLED COPY	

	Safetab Life Science				
	BATCH MANUFACTURING RECORD		Page No.:	40 of 116	
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

7.4 SIFTING INSTRUCTIONS:

S. NO	PROCESS INSTRUCTIONS
1	Check the cleanliness of the Vibro sifter.
2	Use hand gloves while handling the materials.
3	Carryout the sifting operation as per current version of SOP.
4	Check the integrity of sieve before and after sifting and record in the BMR.
5	Collect sifted materials in cleaned containers in polythene bag.

7.5 SIFTING RECORD: LOT I

S. No	Name of Ingredient	Size of sieve	Integrity checked before use*	Checked By Prod sign./date	Integrity checked after use*	Checked By Prod sign./date
1	Paracetamol BP	20#	OK/Not OK	<i>[Signature]</i> 20/01/25	OK/Not OK	<i>[Signature]</i> 20/01/25
2	Phenylephrine HCl, BP	40#	OK/Not OK	<i>[Signature]</i> 20/01/25	OK/Not OK	<i>[Signature]</i> 20/01/25
3	Chlorpheniramine Maleate BP	40#	OK/Not OK	<i>[Signature]</i> 20/01/25	OK/Not OK	<i>[Signature]</i> 20/01/25
4	Caffeine Anhydrous BP	40#	OK/Not OK	<i>[Signature]</i> 20/01/25	OK/Not OK	<i>[Signature]</i> 20/01/25
5	Pregelatinized Starch BP	40#	OK/Not OK	<i>[Signature]</i> 20/01/25	OK/Not OK	<i>[Signature]</i> 20/01/25
6	Microcrystalline Cellulose PH 101 BP	40#	OK/Not OK	<i>[Signature]</i> 20/01/25	OK/Not OK	<i>[Signature]</i> 20/01/25

LUBRICATION

7	Pregelatinized Starch BP	30#	OK/Not OK	<i>[Signature]</i> 22/10/17	OK/Not OK	<i>[Signature]</i> 22/10/17
8	Sodium Starch Glycolate BP	30#	OK/Not OK	<i>[Signature]</i> 22/10/17	OK/Not OK	<i>[Signature]</i> 22/10/17
9	Purified Talc BP	30#	OK/Not OK	<i>[Signature]</i> 22/10/17	OK/Not OK	<i>[Signature]</i> 22/10/17
10	Colloidal silicon Dioxide BP	30#	OK/Not OK	<i>[Signature]</i> 22/10/17	OK/Not OK	<i>[Signature]</i> 22/10/17
11	Half quantity of Pregelatinized Starch BP Tartrazine Lake INH	80#	OK/Not OK	<i>[Signature]</i> 22/10/17	OK/Not OK	<i>[Signature]</i> 22/10/17
12	Magnesium Stearate BP	60#	OK/Not OK	<i>[Signature]</i> 22/10/17	OK/Not OK	<i>[Signature]</i> 22/10/17

Note: If any discrepancy found, Initiate the deviation for corrective and preventive action and proceed to next step after QA approval.
 *Document the sieve integrity.

Title	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature	<i>[Signature]</i> 19/09/24	<i>[Signature]</i> 19/09/24	<i>[Signature]</i> 19/09/24	
UNCONTROLLED COPY				



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BATCH MANUFACTURING RECORD

Page No.: 41 of 116

Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12 50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

7.6 MANUFACTURING PROCESS: LOT I

Step No	Process Instructions	Date : 20/01/25		Done By	Checked by/Date
		Time			
		Started	Completed		
7.6.1	Sifting: Sift Paracetamol through 20# and Co sift Phenylephrine Hydrochloride, Chlorphenamine Maleate, Caffeine Anhydrous, Pregelatinized Starch, and Microcrystalline Cellulose PH 101 through 40#.	15.15	15.40	mnm	P 20/01/25
7.6.2	Dry mixing: Transfer the sifted material into 600 L RMG.	15.41	15.56	mnm	P 20/01/25
	Mix for 15minutes at slow/fast speed of impeller Amber reading. 29.61.	15.57	16.12	mnm	P 20/01/25
7.6.3	Binder preparation: Add Methyl Paraben Sodium, Tartrazine supra in Purified water and mix well to get clear solution. To this add Povidone K90 and mix well to get clear solution.	15.45	15.55	mnm	P 20/01/25
7.6.4	Granulation:(Wet mixing) Add the binder solution of step 7.6.3 into step of 7.6.2				
	Binder addition: 3-5 minutes mixing at slow/fast speed impeller and chopper 'ON' at slow/fast speed followed by racking Amber reading. 31.60	16.13	16.18	mnm	P 20/01/25
	Mixing: 2-5 minutes mixing at slow/fast speed impeller and chopper at slow/fast speed followed by racking.	16.19	16.24	mnm	P 20/01/25
	If required add additional Purified water and mix for 2-3mins to form a required granules. Additional Purified Water added _____ Kg				
	Discharge the wet granules in FBD bowl for drying.	16.25	16.27	mnm	P 20/01/25

7.7 DRYING: LOT I

Step No	Instructions	Done by	Checked by	Date
1	Use hand gloves, nose mask while handling the materials.			
2	Check the cleanliness of the FBD.	mnm	L	20/01/25
3	Carry out drying operation as per SOP.			
4	Load the wet granules .Dry the material by following steps.			

Title	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature				
UNCONTROLLED COPY		CONTROLLED COPY		



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BATCH MANUFACTURING RECORD

Page No.:

42 of 116

Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg. Date:	01/2025	Exp. Date:	12/2027

7.7.1 DRYING AND SIZING DETAILS: LOT I

Step	Process	Start Time	End Time	Done by	Checked by/date
1	Load the Wet granules into FBD and steam drying the granules at inlet temperature of 50°C -60°C with intermittent racking at every 10-15 mins to reach the LOD limit at 105°C.	Inlet temperature 60°C 16.25	Outlet temperature 55°C 17.50	msm	20/01/25
2	LOD%: limit 2.0%-3.0%.	Observed LOD%: 2.46%			
3	Sift the dried granules through 16#.	18.05	18.30	solm	20/01/25
4	16# Mesh integrity checks.	Before use OK/ Not OK	Checked by date 20/01/25	After use OK/ Not OK	20/01/25
5	Mill the retained granules through 1.5mm screen and pass through 16#.	18.31	18.50	msm	20/01/25
6	1.5mm Screen integrity checks.	Before use OK/ Not OK	Checked by date 20/01/25	After use OK/ Not OK	20/01/25

7.8 DRIED GRANULES WEIGHT RECORD: LOT I

Container No	Gross weight (Kg)	Tare weight (Kg)	Net weight (Kg)	Weighed By	Checked By/ Date
1	31.50	0.10	31.40	solm	20/01/25
2	32.70	0.10	32.60		
3	29.70	0.10	29.60		
4	28.70	0.10	28.60		
5	25.50	0.10	25.40		
6					
7					
Total weight of dried granules (Kg):			147.60		

7.9 SIFTING RECORD: LOT II

S. No	Name of Ingredient	Size of sieve	Integrity checked before use*	Checked By Prod sign./date	Integrity checked after use*	Checked By Prod sign./date
1	Paracetamol BP	20#	OK/Not OK	20/01/25	OK/Not OK	20/01/25
2	Phenylephrine HCL BP	40#	OK/Not OK	20/01/25	OK/Not OK	20/01/25
3	Chlorpheniramine Maleate BP	40#	OK/Not OK	20/01/25	OK/Not OK	20/01/25
4	Caffeine Anhydrous BP	40#	OK/Not OK	20/01/25	OK/Not OK	20/01/25
5	Pregelatinized Starch BP	40#	OK/Not OK	20/01/25	OK/Not OK	20/01/25
6	Microcrystalline Cellulose PH 101 BP	40#	OK/Not OK	20/01/25	OK/Not OK	20/01/25

Note: If any discrepancy found, Initiate the deviation for corrective and preventive action and proceed to next step after QA approval.

*Document the sieve integrity.

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature	19/09/24	19/09/24	19/09/24
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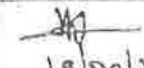
		Safetab Life Science			
BATCH MANUFACTURING RECORD				Page No.:	43 of 116
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg. Date:	01/2025	Exp. Date:	12/2027

7.10 MANUFACTURING PROCESS: LOT II

Step No	Process Instructions	Date : 20/01/25		Done By	Checked by/Date
		Time			
		Started	Completed		
7.10.1	Sifting: Sift Paracetamol through 20# and Co sift Phenylephrine Hydrochloride, Chlorphenamine Maleate, Caffeine Anhydrous, Pregelatinized Starch, and Microcrystalline Cellulose PH 101 through 40#.	19.00	19.30	Selva	20/01/25
7.10.2	Dry mixing: Transfer the sifted material into 600 L RMG.	19.31	19.46	Selva	20/01/25
	Mix for 15minutes at slow/fast speed of impeller Amber reading..29.81	19.47	20.12	Selva	20/01/25
7.10.3	Binder preparation: Add Methyl Paraben Sodium, Tartrazine supra in Purified water and mix well to get clear solution. To this add Povidone K90 and mix well to get clear solution.	19.31	19.49	Selva	20/01/25
7.10.4	Granulation:(Wet mixing) Add the binder solution by following steps:				
	Binder addition: 3-5 minutes mixing at slow/fast speed impeller and chopper 'ON' at slow/fast speed followed by racking. Amber reading...31.45	20.13	20.18	Selva	20/01/25
	Mixing:2-5 minutes mixing at slow/fast speed impeller and chopper at slow/fast speed followed by racking.	20.19	20.24	Selva	20/01/25
	If required add additional Purified water and mix for 2-3mins to form a required granules Additional Purified Water added _____ Kg				20/01/25
	Discharge the wet granules in FBD bowl for drying.	20.25	20.30	Selva	20/01/25

7.11 DRYING: LOT II

Step No	Instructions	Done by	Checked by	Date
1	Use hand gloves, nose mask while handling the materials.	Selva	20/01/25	20/01/25
2	Check the cleanliness of the FBD.			
3	Carry out drying operation as per SOP.			
4	Load the wet granules. Dry the material by following steps.			

Title	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature				
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		Safetab Life Science		Page No.: 44 of 116	
BATCH MANUFACTURING RECORD				Batch Size: 12,50,000 Tablets	
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Supersedes MFC No:	ST/MFC/119/R5
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Exp. Date:	12/2027
Batch No.:	G17250103	Mfg. Date:	01/2025		

7.11.1 DRYING AND SIZING DETAILS: LOT II

Step	Process	Start Time Inlet temperature	End Time Outlet temperature	Done by	Checked by/date
1	Load the Wet granules into FBD and steam drying the granules at inlet temperature of 50°C -60°C with intermittent racking at every 10-15 mins to reach the LOD limit at 105°C.	60°C 20-35	55°C 21-45	SEWU	20/01/25
2	LOD%: limit 2.0%-3.0%.	Observed LOD%: 2.42%			
3	Sift the dried granules through 16#.	21-55	22-15	SEWU	20/01/25
4	16# Mesh integrity checks.	Before use OK/ Not OK	Checked by date 20/01/25	After use OK/ Not OK	20/01/25
5	Mill the retained granules through 1.5mm screen and pass through 16#.	22-16	22-30	SEWU	20/01/25
6	1.5mm Screen integrity checks.	Before use OK/ Not OK	Checked by date 20/01/25	After use OK/ Not OK	20/01/25

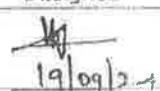
7.12 DRIED GRANULES WEIGHT RECORD: LOT II

Container No	Gross weight (Kg)	Tare weight (Kg)	Net weight (Kg)	Weighed By	Checked By/ Date
1	34.50	0.16	24.70	SEWU	20/01/25
2	26.76	0.16	26.60		
3	34.86	0.16	34.70		
4	36.76	0.16	36.60		
5	24.16	0.16	24.70		
6					
Total weight of dried granules (Kg):			147.30		

7.13 SIFTING RECORD: LOT III

S. No	Name of Ingredient	Size of sieve	Integrity checked before use*	Checked By Prod sign./date	Integrity checked after use*	Checked By Prod sign./date
1	Paracetamol BP	20#	OK/Not OK	20/01/25	OK/Not OK	20/01/25
2	Phenylephrine HCL BP	40#	OK/Not OK	20/01/25	OK/Not OK	20/01/25
3	Chlorpheniramine Maleate BP	40#	OK/Not OK	20/01/25	OK/Not OK	20/01/25
4	Caffeine Anhydrous BP	40#	OK/Not OK	20/01/25	OK/Not OK	20/01/25
5	Pregelatinized Starch BP	40#	OK/Not OK	20/01/25	OK/Not OK	20/01/25
6	Microcrystalline Cellulose PH 101 BP	40#	OK/Not OK	20/01/25	OK/Not OK	20/01/25

Note: If any discrepancy found, Initiate the deviation for corrective and preventive action and proceed to next step after QA approval.
*Document the sieve integrity.

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	 19/09/24	 19/09/24	 19/09/24

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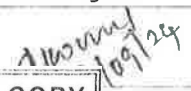
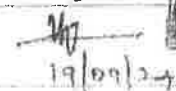
		Safetab Life Science		BATCH MANUFACTURING RECORD		Page No.: 45 of 116
Brand Name	LITACOLD FLU TABLETS	Product ID No.: 978	Batch Size 12,50,000 Tablets		Supersedes MFC No.: ST/MFC/119/R5	
Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO.: ST/MFC/119/R6	Mfg.Date: 01/2025	Exp.Date: 12/2027			
Batch No.: G17250103						

7.14 MANUFACTURING PROCESS: LOT III

Step No	Process Instructions	Date : 20/01/25		Done By	Checked by/Date
		Time			
		Started	Completed		
7.14.1	Sifting: Sift Paracetamol through 20# and Co sift Phenylephrine Hydrochloride, Chlorphenamine Maleate, Caffeine Anhydrous, Pregelatinized Starch, and Microcrystalline Cellulose PH 101 through 40#.	22.35	23.00	Selva	P 20/01/25
7.14.2	Dry mixing: Transfer the sifted material into 600 L RMG.	23.01	23.16	Selva	P 20/01/25
	Mix for 15minutes at slow/fast speed of impeller Amber reading: 29.86	23.17	23.32	Selva	P 20/01/25
7.14.3	Binder preparation: Add Methyl Paraben Sodium, Tartrazine supra in Purified water and mix well to get clear solution. To this add Povidone K90 and mix well to get clear solution.	23.00	23.20	Selva	P 20/01/25
7.14.4	Granulation:(Wet mixing) Add the binder solution by following steps:				
	Binder addition: 3-5 minutes mixing at slow/fast speed impeller and chopper 'ON' at slow/fast speed followed by racking. Amber reading: 31.56	23.33	23.38	Selva	P 20/01/25
	Mixing: 2-5 minutes mixing at slow/fast speed impeller and chopper at slow/fast speed followed by racking.	23.39	23.44	Selva	P 20/01/25
	If required add additional Purified water and mix for 2-3mins to form a required granules Additional Purified Water added _____ Kg				
	Discharge the wet granules in FBD bowl for drying.				

7.15 DRYING: LOT III

Step No	Instructions	Done by	Checked by	Date
1	Use hand gloves, nose mask while handling the materials.	Selva	P	20/01/25
2	Check the cleanliness of the FBD.			
3	Carry out drying operation as per SOP.			
4	Load the wet granules. Dry the material by following steps.			

Title Designation Signature with Date	Prepared by: QA Executive / Designee 	Checked by: Production Head / Designee 	Approved by: QA Head / Designee 	CONTROLLED COPY
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BATCH MANUFACTURING RECORD				Page No.:	46 of 116
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg. Date:	01/2025	Exp. Date:	12/2027

7.15.1 DRYING AND SIZING DETAILS: LOT III

Step	Process	Start Time	End Time	Done by	Checked by/date
1	Load the Wet granules into FBD and steam drying the granules at inlet temperature of 50°C -60°C with intermittent racking at every 10-15 mins to reach the LOD limit at 105°C.	Inlet temperature 60°C 23.45	Outlet temperature 55°C 01.05	Selm	21/01/25
2	LOD%: limit 2.0%-3.0%.	Observed LOD%: 2.82%			
3	Sift the dried granules through 16#.	01.15	01.35	Selm	21/01/25
4	16# Mesh integrity checks.	Before use OK/ Not OK	Checked by date 21/01/25	After use OK/ Not OK	21/01/25
5	Mill the retained granules through 1.5mm screen and pass through 16#.	01.38	01.49	Selm	21/01/25
6	1.5mm Screen integrity checks.	Before use OK/ Not OK	Checked by date 21/01/25	After use OK/ Not OK	21/01/25

7.16 DRIED GRANULES WEIGHT RECORD: LOT III

Container No	Gross weight (Kg)	Tare weight (Kg)	Net weight (Kg)	Weighed By	Checked By/ Date
1	34.86	0.16	34.70	Selm	21/01/25
2	34.78	0.16	34.60		
3	31.86	0.16	31.70		
4	26.76	0.16	26.60		
5	19.46	0.16	19.30		
6					
Total weight of dried granules (Kg):			146.90		

7.17 SIFTING RECORD: LOT IV

S. No	Name of Ingredient	Size of sieve	Integrity checked before use*	Checked By Prod sign./date	Integrity checked after use*	Checked By Prod sign./date
1	Paracetamol BP	20#	OK/Not OK	21/01/25	OK/Not OK	21/01/25
2	Phenylephrine HCL BP	40#	OK/Not OK	21/01/25	OK/Not OK	21/01/25
3	Chlorpheniramine Maleate BP	40#	OK/Not OK	21/01/25	OK/Not OK	21/01/25
4	Caffeine Anhydrous BP	40#	OK/Not OK	21/01/25	OK/Not OK	21/01/25
5	Pregelatinized Starch BP	40#	OK/Not OK	21/01/25	OK/Not OK	21/01/25
6	Microcrystalline Cellulose PH 101 BP	40#	OK/Not OK	21/01/25	OK/Not OK	21/01/25

Note: If any discrepancy found, Initiate the deviation for corrective and preventive action and proceed to next step after QA approval.

*Document the sieve integrity.

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	<i>[Signature]</i> 19/09/24	<i>[Signature]</i> 19/09/24	<i>[Signature]</i> 19/09/24
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BATCH MANUFACTURING RECORD

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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg. Date:	01/2025	Exp. Date:	12/2027

7.18 MANUFACTURING PROCESS: LOT IV

Step No	Process Instructions	Date : 21/01/25		Done By	Checked by/Date
		Time			
		Started	Completed		
7.18.1	Sifting: Sift Paracetamol through 20# and Co sift Phenylephrine Hydrochloride, Chlorphenamine Maleate, Caffeine Anhydrous, Pregelatinized Starch, and Microcrystalline Cellulose PH 101 through 40#.	06:30	06:50	Muth	21/01/25
7.18.2	Dry mixing: Transfer the sifted material into 600 L RMG.	06:55	07:10	Muth	21/01/25
	Mix for 15minutes at slow/fast speed of impeller Amber reading..... 0.5 to 1.0	07:15	07:30	Muth	21/01/25
7.18.3	Binder preparation: Add Methyl Paraben Sodium, Tartrazine supra in Purified water and mix well to get clear solution. To this add Povidone K90 and mix well to get clear solution.	07:30	07:30	Muth	21/01/25
7.18.4	Granulation:(Wet mixing) Add the binder solution by following steps:				
	Binder addition: 3-5 minutes mixing at slow/fast speed impeller and chopper 'ON' at slow/fast speed followed by racking. Amber reading..... 0.5 to 1.0	07:40	07:45	Muth	21/01/25
	Mixing: 2-5 minutes mixing at slow/fast speed impeller and chopper at slow/fast speed followed by racking.	07:50	07:55	Muth	21/01/25
	If required add additional Purified water and mix for 2-3mins to form a required granules Additional Purified Water added _____ Kg				
	Discharge the wet granules in FBD bowl for drying.				

7.19 DRYING: LOT IV

Step No	Instructions	Done by	Checked by	Date
1	Use hand gloves, nose mask while handling the materials.			
2	Check the cleanliness of the FBD.			
3	Carry out drying operation as per SOP.			
4	Load the wet granules. Dry the material by following steps.	Muth	21/01/25	21/01/25

Title	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	19/01/24	19/01/24	19/01/24	CONTROLLED COPY
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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg. Date:	01/2025	Exp. Date:	12/2027

7.19.1 DRYING AND SIZING DETAILS: LOT IV

Step	Process	Start Time	End Time	Done by	Checked by/date
1	Load the Wet granules into FBD and steam drying the granules at inlet temperature of 50°C -60°C with intermittent racking at every 10-15 mins to reach the LOD limit at 105°C.	Inlet temperature 60°C 08:00	Outlet temperature 45°C 09:30	Muk	21/01/25
2	LOD%: limit 2.0%-3.0%.	Observed LOD%: 2.467.			
3	Sift the dried granules through 16#.	09:10	10:10	Muk	21/01/25
4	16# Mesh integrity checks.	Before use OK/ Not OK	Checked by date 21/01/25	After use OK/ Not OK	21/01/25
5	Mill the retained granules through 1.5mm screen and pass through 16#.	10:15	11:00	Bala	21/01/25
6	1.5mm Screen integrity checks.	Before use OK/ Not OK	Checked by date 21/01/25	After use OK/ Not OK	21/01/25

7.20 DRIED GRANULES WEIGHT RECORD: LOT IV

Container No	Gross weight (Kg)	Tare weight (Kg)	Net weight (Kg)	Weighed By	Checked By/ Date
1	31.78	0.16	31.60	Bala	21/01/25
2	32.86	0.16	32.70		
3	34.76	0.16	34.60		
4	27.86	0.16	27.70		
5	20.98	0.16	20.80		
6					
Total weight of dried granules (Kg):			147.40		

7.21 SIFTING RECORD: LOT V

S. No	Name of Ingredient	Size of sieve	Integrity checked before use*	Checked By Prod sign./date	Integrity checked after use*	Checked By Prod sign./date
1	Paracetamol BP	20#	OK/Not OK	21/01/25	OK/Not OK	21/01/25
2	Phenylephrine HCL BP	40#	OK/Not OK	21/01/25	OK/Not OK	21/01/25
3	Chlorpheniramine Maleate BP	40#	OK/Not OK	21/01/25	OK/Not OK	21/01/25
4	Caffeine Anhydrous BP	40#	OK/Not OK	21/01/25	OK/Not OK	21/01/25
5	Pregelatinized Starch BP	40#	OK/Not OK	21/01/25	OK/Not OK	21/01/25
6	Microcrystalline Cellulose PH 101 BP	40#	OK/Not OK	21/01/25	OK/Not OK	21/01/25

Note: If any discrepancy found, Initiate the deviation for corrective and preventive action and proceed to next step after QA approval.

*Document the sieve integrity.

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	19/01/25	19/01/25	19/01/25
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BATCH MANUFACTURING RECORD

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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg. Date:	01/2025	Exp. Date:	12/2027

7.22 MANUFACTURING PROCESS: LOT V

Step No	Process Instructions	Date : 21/01/25		Done By	Checked by/Date
		Time			
		Started	Completed		
7.22.1	Sifting: Sift Paracetamol through 20# and Co sift Phenylephrine Hydrochloride, Chlorphenamine Maleate, Caffeine Anhydrous, Pregelatinized Starch, and Microcrystalline Cellulose PH 101 through 40#.	11:10	11:40	MUTH	21/01/25
7.22.2	Dry mixing: Transfer the sifted material into 600 L RMG.	11:45	11:55	MUTH	21/01/25
	Mix for 15minutes at slow/fast speed of impeller Amber reading..... 28.64	12:00	12:15	MUTH	21/01/25
7.22.3	Binder preparation: Add Methyl Paraben Sodium, Tartrazine supra in Purified water and mix well to get clear solution. To this add Povidone K90 and mix well to get clear solution.	12:10	12:20	MUTH	21/01/25
7.22.4	Granulation:(Wet mixing) Add the binder solution by following steps:				
	Binder addition: 3-5 minutes mixing at slow/fast speed impeller and chopper 'ON' at slow/fast speed followed by racking Amber reading..... 21.66	12:30	12:35	MUTH	21/01/25
	Mixing: 2-5 minutes mixing at slow/fast speed impeller and chopper at slow/fast speed followed by racking.	12:40	12:45	MUTH	21/01/25
	If required add additional Purified water and mix for 2-3mins to form a required granules Additional Purified Water added 10 Kg	 			

7.23 DRYING: LOT V

Step No	Instructions	Done by	Checked by	Date
1	Use hand gloves, nose mask while handling the materials.			
2	Check the cleanliness of the FBD.			
3	Carry out drying operation as per SOP.			
4	Load the wet granules .Dry the material by following steps.	MUTH	X	21/01/25

Title	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	19/01/24	19/01/24	19/01/24	
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BATCH MANUFACTURING RECORD				Page No.:	50 of 116
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

7.24.1 DRYING AND SIZING DETAILS: LOT V

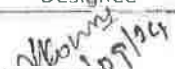
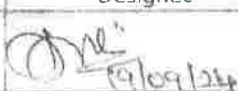
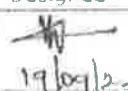
Step	Process	Start Time	End Time	Done by	Checked by/date
1	Load the Wet granules into FBD and steam drying the granules at inlet temperature of 50°C -60°C with intermittent racking at every 10-15 mins to reach the LOD limit at 105°C.	Inlet temperature 60°C 13:00	Outlet temperature 45°C 14:15	Mukta	21/01/24
2	LOD%: limit 2.0%-3.0%.	Observed LOD%: 2.46%			
3	Sift the dried granules through 16#.	14:20	14:45	Mukta	21/01/24
4	16# Mesh integrity checks.	Before use OK/ Not OK	Checked by date 21/01/24	After use OK/ Not OK	21/01/24
5	Mill the retained granules through 1.5mm screen and pass through 16#.	14:50	15:15	Mukta	21/01/24
6	1.5mm Screen integrity checks.	Before use OK/ Not OK	Checked by date 21/01/24	After use OK/ Not OK	21/01/24

7.25 DRIED GRANULES WEIGHT RECORD: LOT V

Container No	Gross weight (Kg)	Tare weight (Kg)	Net weight (Kg)	Weighed By	Checked By/ Date
1	31.7A	0.16	31.60	Mukta	21/01/24
2	32.66	0.16	32.40		
3	33.4A	0.16	33.30		
4	26.7A	0.16	26.60		
5	23.66	0.16	23.60		
6					
7					
Total weight of dried granules (Kg):			147.40	21/01/24	

7.26 YIELD OF DRIED GRANULES:

1.0	Weight of total in put material in granulation.	:	737.34	Kg
2.0	Weight of dried granules. [Lot I + Lot II + Lot III + Lot IV + Lot V]	:	736.60	Kg
3.0	Yield (NLT 99.00 %) {2.0 / 1.0 x 100}	:	99.89	%

Title Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee
Signature with Date			
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BATCH MANUFACTURING RECORD

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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

8.0 BLENDING AND LUBRICATION:

8.1 LINE CLEARANCE CHECKS:

S.No	Checks	Observation	
		production	IPQA
1	Ensure that all empty containers, used polybags, labels, hand gloves of previous Product/ batch are removed from the area.	✓	✓
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	✓
3	Ensure that the previous batch BMR / documents are removed from the area.	✓	✓
4	Check the housekeeping general cleanliness of the floor, walls ceiling, tube light fixture, supply grills, riser grills, filters and electrical fixtures are clean.	✓	✓
5	Check the cleanliness of the doors, door view panel and SOP stand.	✓	✓
6	Check the cleanliness of the utility line (compressed air, First RO water and purified water).	✓	✓
7	Check the cleanliness of the drain points.	✓	✓
8	Check for absence of previous batch/product from area below machine and inside machine by opening the guards of Octagonal blender.	✓	✓
9	Check whether the machine body and control panel of octagonal blender is clean.	✓	✓
10	Ensure that the balances are cleaned and it's calibration status.	✓	✓
11	Check whether the Equipments/ Instruments to be used are within calibration/preventive maintenance due date.	✓	✓
12	Check the status board of the area is updated with cleaned label.	✓	✓
13	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.	✓	✓
14	Check the differential pressure of the area should be within the limit.	✓	✓
15	Ensure the concurrent entries of log book.	✓	✓
16	Check the functioning and cleaning of return riser.	✓	✓
17	In case of materials / Intermediate products transferred between Block A and Block B, ensure that the containers received are clean and free from contamination.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (production) sign/date:.....

Verified by (IPQA) sign/date:.....

Equipment	Octagonal blender
Code No	ST/PL031001
Previous product	PL031001
Batch No	S 25114501A
Cleaned by:	Han
Checked by:	Production: ✓ IPQA: V.P.P.R.

8.2 ENVIRONMENTAL CONDITIONS:

	Date: 24/01/25 Time: 03:10		Date: Time:	
	Observation	Production Sign	Observation	Production Sign
Temperature: 23°C to 27°C	24.6°C	✓		
Differential pressure NLT 0.5mm of water	8	✓		
Relative Humidity: 45% to 55 %	57.1	✓		

8.3 APPROVAL FOR BLENDING AND LUBRICATION:

Production Sign/Date:.....	IPQA Sign/Date:.....
----------------------------	----------------------

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	Moumita 19/09/24	One 19/09/24	19/09/24

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	Safetab Life Science				
	BATCH MANUFACTURING RECORD		Page No.:	52 of 116	
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorpheniramine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg. Date:	01/2025	Exp. Date:	12/2027

8.4 BLENDING AND LUBRICATION INSTRUCTION:

Step No.	Process Instructions	Date: 02/01/25		Done by	Checked by/Date
		Time			
		Started	Completed		
8.4.1	Use hand gloves, nose mask while handling the materials.				
8.4.2	Operate the Octagonal Blender as per the current version of the SOP.				
8.4.3	Co sift Half quantity of Pregelatinized starch, Sodium starch glycolate, Talc, Colloidal silicon dioxide through 30#. Co sift remaining quantity of Pregelatinized starch and Tartrazin lake through 80#.	03:20	03:50	Kan	22/01/25
8.4.4	Load the sifted materials along with the dried granules (Lot I, Lot II, Lot III, Lot IV & Lot V) into the Octagonal blender.	04:00	04:20	Kan	22/01/25
8.4.5	The above sifted material are load into octagonal blender and mix for 20 minutes.	04:15	04:45	Ahu	22/01/25
8.4.6	Sift Magnesium Stearate through 60# and distribute / sprinkle over the blended material.	04:50	04:55	Ahu	22/01/25
8.4.7	The above sifted material are load into octagonal blender and mix for 5 minutes.	05:00	05:05	Ahu	22/01/25
8.4.8	Unload the final blend into suitable containers lined with double polythene bag container with proper label.	05:20	05:30	Ahu	22/01/25
8.4.9	Record the weight in below mentioned table.				

Title	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	M. Bhowmik 19/09/24	D. Mehta 14/09/24	[Signature] 19/09/24	
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BATCH MANUFACTURING RECORD

Page No.: 53 of 116
Batch Size: 12,50,000 Tablets
Supersedes MFC No: ST/MFC/119/R5
Exp.Date: 12/2027

Brand Name: LITACOLD FLU TABLETS
Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets
Batch No.: G17250103

Product ID No.: 978
MFC NO: ST/MFC/119/R6
Mfg.Date: 01/2025

8.5 WEIGHING OF FINAL BLEND: Date: 22/01/25

Container No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by/date	Container No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by/date
1	61.51	3.90	58.01	Kan	22/01/25	26					
2	62.00	3.40	58.60	Kan	22/01/25	27					
3	59.16	3.40	56.22	Kan	22/01/25	28					
4	62.77	3.40	59.37	Kan	22/01/25	29					
5	66.80	3.40	63.20	Kan	22/01/25	30					
6	61.40	3.40	58.00	Kan	22/01/25	31					
7	61.24	3.40	58.04	Kan	22/01/25	32					
8	65.12	3.40	61.62	Kan	22/01/25	33					
9	68.60	3.40	65.40	Kan	22/01/25	34					
10	68.27	3.40	64.87	Kan	22/01/25	35					
11	61.40	3.40	58.40	Kan	22/01/25	36					
12	47.60	3.40	44.10	Kan	22/01/25	37					
13	45.60	3.40	42.20	Kan	22/01/25	38					
14	32.60	2.60	30.00	Kan	22/01/25	39					
15	26.03	3.40	22.63	Kan	22/01/25	40					
16						41					
17						42					
18						43					
19						44					
20						45					
21						46					
22						47					
23						48					
24						49					
25						50					

Total weight of Lubricated granules: 791.50 kg

Intimate IPQA to draw the sample.

Sample withdrawn by IPQA

Production Sign: _____ Date: _____

IPQA Sign: NA Date: NA

Send Test request form for lubricated granules to QC department.

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	<u>22/01/25</u>	<u>22/01/25</u>	<u>19/01/24</u>

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	Safetab Life Science				
	BATCH MANUFACTURING RECORD		Page No.:	54 of 116	
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

8.6 RECONCILIATION:

1.0	Theoretical weight of blend		793.75	Kg
2.0	Actual weight of blend		791.50	Kg
3.0	In-process samples			
	A IPQA Samples		1.00	Kg
	B QC Samples		1.00	Kg
	C Validation Samples		1.00	Kg
	D Other		1.00	Kg
4.0	Total samples: (A + B + C + D)		4.00	Kg
5.0	Manufacturing Loss 1.0 = (2.0+3.0)		2.25	Kg
6.0	Total Qty: (2.0 + 3.0)		791.50	Kg
7.0	% Yield = $\frac{6.0}{1.0} \times 100$		79.71	%

If yield is out of limit, raise deviation and inform to QA. After QA, Investigation and approval proceed to the next stage.

Total rejects destroyed: 2.25 Kg (Rejected materials should be destroyed in the presence of QA)

Done by Production sign/Date: [Signature] 22/01/25 Checked by IPQA sign/Date: [Signature] 22/01/25

Reconciliation done by Production sign/Date: [Signature] 22/01/25 Checked by IPQA sign/Date: [Signature] 22/01/25

8.7 BLENDED GRANULES RELEASED FOR COMPRESSION:

Reconciliation checked and blended granules released for compression.

Production sign/Date: [Signature] 27/01/25

IPQA sign/Date: [Signature] 27/01/25

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	<u>[Signature]</u> 19/01/24	<u>[Signature]</u> 19/01/24	<u>[Signature]</u> 19/01/24

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BATCH MANUFACTURING RECORD

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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

9.0 COMPRESSION:

9.1 LINE CLEARANCE CHECKS:

S.No	Checks	Observation			
		production		IPQA	
		I	II	I	II
1	Ensure that all empty containers, used polybags, labels, hand gloves of previous Product/ batch are removed from the area.	✓	✓	✓	✓
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	✓	✓	✓
3	Ensure that the previous batch BMR / documents are removed from the area.	✓	✓	✓	✓
4	Check the housekeeping general cleanliness of the floor, walls, ceiling, tube light fixture, supply grills, riser grills, filters and electrical fixtures are clean.	✓	✓	✓	✓
5	Check the cleanliness of the doors, door view panel and compressed air filter outer surface.	✓	✓	✓	✓
6	Check whether the machine body and machine parts like hoppers, feed frame, and discharge chute and ejection chute and control panel are clean.	✓	✓	✓	✓
7	Check whether the dust collector main body and hosepipe of the dust collector is clean.	✓	✓	✓	✓
8	Ensure that the balances are cleaned and it's calibration status.	✓	✓	✓	✓
9	Check whether the Equipments/ Instruments to be used are within calibration/preventive maintenance due date.	✓	✓	✓	✓
10	Check the status board of the area is updated with cleaned label.	✓	✓	✓	✓
11	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.	✓	✓	✓	✓
12	Check the differential pressure of the area should be within the limit.	✓	✓	✓	✓
13	Ensure the concurrent entries of log book.	✓	✓	✓	✓
14	Check the Release Status of product Lubricated blend.	✓	✓	✓	✓
15	Check the calibration status of related IPQA Equipment like hardness tester, Vernier Caliper, DT apparatus, Friability etc.	✓	✓	✓	✓
16	Check the functioning and cleaning of return riser.	✓	✓	✓	✓
17	In case of materials / Intermediate products transferred between Block A and Block B, ensure that the containers received are clean and free from contamination.	✓	✓	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (production) sign/date: 27/01/25

Verified by (IPQA) sign/date: 27/01/25

Equipment	Single Rotary /Double Rotary Compression Machine	Balance	Area
Equipment ID No.:	ST/PRC/1005	51/105/102	
Area ID No.:			
Previous product:	Litacold FLU		
Batch No.	G1724 12109		

9.2 ENVIRONMENTAL CONDITIONS:

	Date: 27/01/25		Date:	
	Observation	Production Sign	Observation	Production sign
Temperature: 23°C to 27°C	24.3°C	27		
Differential Pressure NLT 0.5mm of water	8 mm	27		
Relative Humidity: 45% to 55 %	52%	27		

9.3 APPROVAL FOR COMPRESSION:

Production sign/Date: 27/01/25	IPQA sign/Date: 27/01/25
--------------------------------	--------------------------

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature	19/09/24	19/09/24	19/09/24
with Date			

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BATCH MANUFACTURING RECORD

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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

9.1A LINE CLEARANCE CHECKS:

S.No	Checks	Observation			
		production		IPQA	
		III	IV	III	IV
1	Ensure that all empty containers, used polybags, labels, hand gloves of previous Product/ batch are removed from the area.				
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.				
3	Ensure that the previous batch BMR / documents are removed from the area.				
4	Check the housekeeping general cleanliness of the floor, walls, ceiling, tube light fixture, supply grills, riser grills, filters and electrical fixtures are clean.				
5	Check the cleanliness of the doors, door view panel and compressed air filter outer surface.				
6	Check whether the machine body and machine parts like hoppers, feed frame, and discharge chute and ejection chute and control panel are clean.				
7	Check whether the dust collector main body and hosepipe of the dust collector is clean.				
8	Ensure that the balances are cleaned and it's calibration status.				
9	Check whether the Equipments/ Instruments to be used are within calibration/preventive maintenance due date.				
10	Check the status board of the area is updated with cleaned label.				
11	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.				
12	Check the differential pressure of the area should be within the limit.				
13	Ensure the concurrent entries of log book.				
14	Check the Release Status of product Lubricated blend.				
15	Check the calibration status of related IPQA Equipment like hardness tester, Vernier Caliper, DT apparatus, Friability etc.				
16	Check the functioning and cleaning of return riser.				
17	In case of materials / Intermediate products transferred between Block A and Block B, ensure that the containers received are clean and free from contamination.				

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (production) sign/date:.....

Verified by (IPQA) sign/date:.....

Equipment	Single Rotary /Double Rotary Compression Machine	Balance	Area
Equipment ID No.:			
Area ID No.:			
Previous product:			
Batch No.			

9.2A ENVIRONMENTAL CONDITIONS:

	Date:		Date:	
	Observation	Production Sign	Observation	Production sign
Temperature: 23°C to 27°C				
Differential Pressure NLT 0.5mm of water				
Relative Humidity: 45% to 55 %				

9.3A APPROVAL FOR COMPRESSION:

Production sign/Date:.....	IPQA sign/Date:.....
----------------------------	----------------------

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	<i>[Signature]</i> 19/09/24	<i>[Signature]</i> 19/09/24	<i>[Signature]</i> 19/09/24

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		Safetab Life Science			
BATCH MANUFACTURING RECORD				Page No.:	57 of 116
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

9.1B LINE CLEARANCE CHECKS:

S.No	Checks	Observation			
		production		IPQA	
		V	VI	V	VI
1	Ensure that all empty containers, used polybags, labels, hand gloves of previous Product/ batch are removed from the area.				
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.				
3	Ensure that the previous batch BMR / documents are removed from the area.				
4	Check the housekeeping general cleanliness of the floor, walls, ceiling, tube light fixture, supply grills, riser grills, filters and electrical fixtures are clean.				
5	Check the cleanliness of the doors, door view panel and compressed air filter outer surface.				
6	Check whether the machine body and machine parts like hoppers, feed frame, and discharge chute and ejection chute and control panel are clean.				
7	Check whether the dust collector main body and hosepipe of the dust collector is clean.				
8	Ensure that the balances are cleaned and it's calibration status.				
9	Check whether the Equipments/ Instruments to be used are within calibration/preventive maintenance due date.				
10	Check the status board of the area is updated with cleaned label.				
11	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.				
12	Check the differential pressure of the area should be within the limit.				
13	Ensure the concurrent entries of log book.				
14	Check the Release Status of product Lubricated blend.				
15	Check the calibration status of related IPQA Equipment like hardness tester, Vernier Caliper, DT apparatus, Friability etc.				
16	Check the functioning and cleaning of return riser.				
17	In case of materials / Intermediate products transferred between Block A and Block B, ensure that the containers received are clean and free from contamination.				

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (production) sign/date:

Verified by (IPQA) sign/date:

Equipment	Single Rotary /Double Rotary Compression Machine	Balance	Area
Equipment ID No.:			
Area ID No.:			
Previous product:			
Batch No.			

9.2B ENVIRONMENTAL CONDITIONS:

	Date:		Date:	
	Observation	Production Sign	Observation	Production sign
Temperature: 23°C to 27°C				
Differential Pressure NLT 0.5mm of water				
Relative Humidity: 45% to 55 %				

9.3B APPROVAL FOR COMPRESSION:

Production sign/Date:	IPQA sign/Date:
-----------------------------	-----------------------

Title Designation	Prepared by: QA Executive / Designee <i>A. B. M. S. / 19/09/24</i>	Checked by: Production Head / Designee <i>[Signature] / 19/09/24</i>	Approved by: QA Head / Designee <i>[Signature] / 19/09/24</i>
Signature with Date	UNCONTROLLED COPY		

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BATCH MANUFACTURING RECORD

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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg. Date:	01/2025	Exp. Date:	12/2027

9.4 PROCESS INSTRUCTIONS:

S. No	Process Instructions	Start Time	End Time	Done By	Checked by/date
1	Check the cleanliness of area and equipment.				
2	Ensure that the correct punch sets are issued as per the Punch issue record and ensure the cleanliness and verification of the punch and dies. Checked by/date(production): <i>Mh 29/01/25</i> verified by/date(IPQA): <i>ST 27/01/25</i>				
3	Set the 27/20 - station double/single rotary compression machine with Upper Punch: 12.70mm circular shape, flat beveled edge punch with break line Lower punch : 12.70mm circular shape, flat beveled edge punch plain Dies : 12.70mm	9:50	10:27	Bailan	<i>Mh 29/01/25</i>
4	Transfer the blend to compression cubicle. Load the granules in both the hoppers of the compression machine.	10:32	10:38	Bailan	<i>Mh 29/01/25</i>
5	Operate the 27/20 - station double/single rotary compression machine as per the current version of the SOP and reject tablets of the first three round which shall be destroyed as per SOP.	10:40	10:47	Bailan	<i>Mh 29/01/25</i>
6	Check the initial tablet for all the parameters as described below and set the machine accordingly.	10:52	11:27	Bailan	<i>Mh 29/01/25</i>
7	Collect the compressed tablets in polythene bag lined and labeled cleaned containers.	11:05	11:00	Ahlo	<i>ST 29/01/25</i>
8	Check and record the weight of the compressed tablets.				<i>29/01/25</i>

9.5 COMPRESSION SPECIFICATION/PARAMETERS:

S. No	Parameter	Limits	No. of tablets to be checked from each side	Frequency	
				Prod	IPQA
1	Appearance	Light yellow coloured flat, round beveled edged uncoated tablet with break line on one side and plain on another side.	20	Every 30 min	Every 1 hr
2	Average weight	635.000mg $\pm$ 3% (615.950mg to 654.050mg)	20	Every 30 min	Every 1 hr
3	Weight of 20 tablets	12.700g $\pm$ 3% (12.319g to 13.081g)	20	Every 30 min	Every 1 hr
4	Uniformity of weight	$\pm$ 5% of average weight (603.250mg to 666.750mg)	20	Every 1 hr	Every 2 hr
5	Hardness	100N-250N	5	Every 30 min	Every 1 hr
6	Disintegration time	NMT 15 mins at 37°C $\pm$ 2°C	6	Every 1 hr	Every 2 hr
7	Thickness	4.30mm $\pm$ 0.2mm (4.10mm to 4.50mm)	5	Every 30 min	Every 1 hr
8	Diameter	12.70 $\pm$ 0.2mm (12.50mm-12.90mm)	5	Initial	
9	Friability	NMT 1.0%	20	Every 1 hr	Every 2 hr

M/C set up done by (Operator): Date:

Bailan

29/01/25

M/C set up checked by (Production):

Mh

Date: *29/01/25*

M/C set up checked by IPQASign : Date:

ST

29/01/25

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature	<i>Mh</i> <i>29/01/25</i>	<i>ST</i> <i>29/01/25</i>	<i>Mh</i> <i>29/01/25</i>

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BATCH MANUFACTURING RECORD

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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

5.1 MACHINE SETTING FOR COMPRESSION: (UNIFORMITY OF WEIGHT AND THICKNESS)

Parameters	Instrument used	Observations of LHS		Observations of RHS		Limits
		Min	Max	Min	Max	
Uniformity of weight	Balance	622	647	620	649	±5% of average weight (603.250mg to 666.750mg)
Group weight of 20 tablets	Balance	12.725		12.706		12.700g±3% (12.319g to 13.081g)
Average weight	Balance	636		635		635.000mg±3% (615.950mg to 654.050mg)
Hardness	Hardness tester	128		118		100N - 250N
Thickness	Vernier	4.27		4.32		4.30mm ± 0.2mm (4.10mm to 4.50mm)
Friability	Friabilator	0.18		0.19		NMT 1.0%
DT	DT Apparatus	05 mm after		06 mm 07 sec		NMT 15 mins at 37°C±2°C
Appearance	visual	Complies		Complies		Light yellow coloured flat round beveled edged uncoated tablet with break line on one side and plain on another side.

LEFT HAND SIDE (LHS)						RIGHT HAND SIDE (RHS)					
Sr. No.	Weight	Thickness	Sr. No.	Weight	Thickness	Sr. No.	Weight	Thickness	Sr. No.	Weight	Thickness
1	636	4.27	25	631	4.21	1	636	4.31	25	635	4.21
2	635	4.31	26	635	4.31	2	635	4.27	26	634	4.31
3	632	4.24	27	632	4.24	3	631	4.26	27	635	4.32
4	634	4.21	28	631	4.23	4	632	4.29	28	631	4.24
5	635	4.27	29	632	4.24	5	631	4.32	29	635	4.27
6	632	4.32	30	631	4.21	6	635	4.34	30	632	4.31
7	636	4.32	31	632	4.27	7	636	4.32	31	632	4.34
8	635	4.32	32	636	4.31	8	635	4.27	32	641	4.32
9	636	4.37	33	637	4.33	9	636	4.32	33	635	4.32
10	635	4.32	34	635	4.32	10	635	4.31	34	641	4.27
11	634	4.31	35	632	4.37	11	636	4.27	35	637	4.26
12	632	4.24	36	630	4.37	12	637	4.31	36	634	4.32
13	637	4.26	37	632	4.37	13	635	4.32	37	631	4.31
14	632	4.27	38	636	4.32	14	635	4.36	38	635	4.36
15	630	4.26	39	636	4.37	15	636	4.31	39	636	4.32
16	632	4.27	40	635	4.32	16	635	4.27	40	632	4.32
17	636	4.26	41	631	4.37	17	636	4.26	41	636	4.27
18	637	4.26	42	635	4.32	18	636	4.21	42	637	4.32
19	635	4.27	43	636	4.37	19	635	4.27	43	631	4.34
20	636	4.21	44	637	4.32	20	630	4.27	44	620	4.32
21	632	4.27	45	631	4.27	21	630	4.32	45	627	4.37
22	636	4.26				22	647	4.36			
23	635	4.31				23	634	4.32			
24	632	4.27				24	636	4.36			

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
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BATCH MANUFACTURING RECORD

Page No.:	60 of 116
Batch Size	12,50,000 Tablets
Supersedes MFC No:	ST/MFC/119/R5
Exp.Date:	12/2027

Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6
Batch No.:	G17250103	Mfg.Date:	01/2025

Initial Setting done by(operator):	Baelen	DATE:	27/01/25
Initial Setting checked by Sign production:	nh	DATE:	27/01/25
Initial Setting checked by IPQA sign:	Ph	DATE:	27/01/25
Initial Setting tablets Destroyed by Sign/date(production):	nh	DATE:	27/01/25
Initial Setting tablets Destroyed by Sign/date(IPQA):	Ph	DATE:	27/01/25

Compression activity:

Day 1	Date	Name of the operator	Checked by	Day 2	Date	Name of the operator	Checked by
Shift I	27/01/25	Baelen	nh	Shift I			
Shift II	27/01/25	Anik	Ph	Shift II			
Shift III				Shift III			
Day 3	Date	Name of the operator	Checked by	Day 4	Date	Name of the operator	Checked by
Shift I				Shift I			
Shift II				Shift II			
Shift III				Shift III			
Day 5	Date	Name of the operator	Checked by	Day 6	Date	Name of the operator	Checked by
Shift I				Shift I			
Shift II				Shift II			
Shift III				Shift III			

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
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Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature	<i>[Signature]</i> 19/09/24	<i>[Signature]</i> 19/09/24	<i>[Signature]</i> 19/09/24

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BATCH MANUFACTURING RECORD

Page No. 8

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Brand Name	LITACOLD FLU TABLETS
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Product ID
No.:

978

Batch Size

12,50,000 Tablets

Generic Name: Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets

MFC NO:

ST/MFC/119/R6

Supersedes
MFC No:

ST/MFC/119/R5

Batch No.:

G17250103

Mfg.Date:

01/2025

Exp.Date:

12/2027

10.0B IN-PROCESS CHECKS: (EVERY 30 MINUTES) BY PRODUCTION:

*If appearance are satisfactory document as complies.

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	<i>[Signature]</i> 10/09/24	<i>[Signature]</i> 12/09/24	<i>[Signature]</i> 12/09/24

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BATCH MANUFACTURING RECORD

Page No.:

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Brand Name	LITACOLD FLU TABLETS
------------	----------------------

Product ID
No.:

978

Batch Size

12,50,000 Tablets

Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets
----------------------	---

MFC NO:

ST/MFC/119/R6

Supersedes
MFC No:

ST/MFC/119/R5

Batch No.: G17250103

Mfg.Date:

01/2025

Exp.Date:

12/2027

10.0D IN-PROCESS CHECKS: (EVERY 30 MINUTES) BY PRODUCTION:

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20/07/24

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BATCH MANUFACTURING RECORD

Page No.:

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Brand Name	LITACOLD FLU TABLETS
------------	----------------------

Product ID
No.:

978

Batch Size

12,50,000 Tablets

Generic Name:	Hydrocodone Bitartrate, Propoxyphene Hydrochloride, Chlorpheniramine Maleate and Caffeine Anhydrous Tablets
----------------------	---

MFC NO:

ST/MFC/119/R6

Supersedes
MFC No:

ST/MFC/119/R5

Batch No.: G17250103

Mfg.Date:

01/2025

Exp.Date:

12/2027

10.0E IN-PROCESS CHECKS: (EVERY 30 MINUTES) BY PRODUCTION:

*If appearance are satisfactory document as complies.

✓ In 29/02/25

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Signature	 19/09/24	 19/09/24	 19/09/24

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BATCH MANUFACTURING RECORD

Page No.:

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Brand Name

LITACOLD FLU TABLETS

Product ID
No.:

978

Batch Size

12,50,000 Tablets

Generic Name:

Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets

MFC NO. [redacted]

ST/MFC/119/R6

Supersedes
MFC No:

ST/MFC/119/R5

Batch No.:

G17250103

Mfg.Date:

01/2025

Exp.Date:

12/2027

10.0F IN-PROCESS CHECKS: (EVERY 30 MINUTES) BY PRODUCTION:

[illegible]

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Signature	<i>[Signature]</i> 19/09/24	<i>[Signature]</i> 19/09/24	<i>[Signature]</i> 19/09/24

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BATCH MANUFACTURING RECORD

Page No.:

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Brand Name

LITACOLD FLU TABLETS

Product ID No.:

978

Batch Size

12,50,000 Tablets

Generic Name:

Paracetamol, Phenylephrine Hydrochloride, Chlorpheniramine Maleate and Caffeine Anhydrous Tablets

MFC NO:

ST/MFC/119/R6

Supersedes MFC No:

ST/MFC/119/R5

Batch No.:

G17250103

Mfg.Date:

01/2025

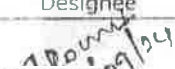
Exp.Date:

12/2027

11.0 IN-PROCESS CHECKS: (EVERY 1 HOUR) BY IPQA:

DATE	TIME	Group Wt: 12.700g±3% (12.319g to 13.081g) Avg. Wt: 635.000mg±3% (615.950mg to 654.050mg)				HARDNESS		THICKNESS		APPEARANCE		Done by IPQA
		L.H.S.		R.H.S.		100N-250N		4.30mm ± 0.2mm (4.10mm to 4.50mm)		Light yellow coloured flat round beveled edged uncoated tablet with break line on one side and plain on another side.		
		Weight of 20 Tab (g)	Avg. Weight (mg)	Weight of 20 Tab (g)	Avg. Weight (mg)	LHS	RHS	LHS	RHS	LHS	RHS	
27/01/25	11:43	12.724	636	12.682	634	147	126	4.28	4.29	Complete	Complete	V.Sig
27/01/25	12:27	12.708	635	12.713	636	153	144	4.27	4.24	Complete	Complete	V.Sig
27/01/25	13:32	12.736	639	12.707	635	121	128	4.28	4.25	Complete	Complete	V.Sig
27/01/25	14:25	12.706	635	12.719	636	129	138	4.27	4.25	Complete	Complete	V.Sig
27/01/25	15:33	12.723	636	12.703	635	130	126	4.25	4.25	Complete	Complete	V.Sig
27/01/25	16:30	12.702	635	12.721	636	129	132	4.24	4.27	Complete	Complete	V.Sig
27/01/25	17:32	12.705	635	12.707	635	130	128	4.25	4.25	Complete	Complete	V.Sig
27/01/25	18:21	12.723	636	12.722	636	132	135	4.27	4.28	Complete	Complete	V.Sig
n/c		Stopped at 18:50 due to batch completion										
V.Sig												

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BATCH MANUFACTURING RECORD

Page No.:

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Brand Name

LITACOLD FLU TABLETS

Product ID
No.:

978

Batch Size

12,50,000 Tablets

Generic Name:

Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets

MFC NO:

ST/MFC/119/R6

Supersedes
MFC No:

ST/MFC/119/R5

Batch No.:

G17250103

Mfg.Date:

01/2025

Exp.Date:

12/2027

11.0B IN-PROCESS CHECKS: (EVERY 1 HOUR) BY IPQA:

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BATCH MANUFACTURING RECORD

Page No.: 73 of 116
Batch Size: 12,50,000 Tablets
Supersedes MFC No.: ST/MFC/119/R5
Exp.Date: 12/2027

Brand Name: LITACOLD FLU TABLETS

Product ID No.: 978

Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorpheniramine Maleate and Caffeine Anhydrous Tablets

MFC NO: ST/MFC/119/R6

Batch No.: G17250103

Mfg.Date: 01/2025

12.0 IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

Date: 27/01/25 Time: 11:23		Upper % deviation = $\frac{\text{Maximum net fill weight} - \text{Average net fill weight}}{\text{Average net fill weight}} \times 100$ Lower % deviation = $\frac{\text{Minimum net fill weight} - \text{Average net fill weight}}{\text{Average net fill weight}} \times 100$	
LHS weight of 20 tablets: 12.719 gm		RHS weight of 20 tablets: 12.682 gm	
1 0.636	8 0.632	15 0.637	1 0.636
2 0.635	9 0.635	16 0.635	2 0.635
3 0.636	10 0.632	17 0.630	3 0.637
4 0.635	11 0.635	18 0.629	4 0.632
5 0.636	12 0.635	19 0.647	5 0.635
6 0.632	13 0.637	20 0.642	6 0.631
7 0.637	14 0.625		7 0.635
Limit: $\pm 5\%$ of average weight M/C Speed: 30 RPM		Limit: $\pm 5\%$ of average weight M/C Speed: 30 RPM	
Min. weight 0.625 g		Min. weight 0.621 g	
Max. weight 0.647 g		Max. weight 0.644 g	
Average weight of 20 Tablets: 0.636 g		Average weight of 20 Tablets: 0.635 g	
(Limit: 615.950.500mg-654.050mg)		(Limit: 615.950.500mg-654.050mg)	
Friability: 0.18		NMT 1.0 %	
Disintegration Time: 06 min 01 sec		NMT 15 mins at 37°C $\pm 2^\circ\text{C}$	
Done by: (Production)		Done by: (Production)	
Date: 27/01/25 Time: 12:25		Date: 27/01/25 Time: 12:25	
LHS weight of 20 tablets: 12.708 gm		RHS weight of 20 tablets: 12.672 gm	
1 0.636	8 0.637	15 0.632	1 0.636
2 0.635	9 0.637	16 0.637	2 0.632
3 0.632	10 0.632	17 0.631	3 0.635
4 0.635	11 0.637	18 0.637	4 0.631
5 0.637	12 0.635	19 0.620	5 0.635
6 0.637	13 0.631	20 0.632	6 0.631
7 0.632	14 0.632		7 0.637
Limit: $\pm 5\%$ of average weight M/C Speed: 30 RPM		Limit: $\pm 5\%$ of average weight M/C Speed: 30 RPM	
Min. weight 0.625 g		Min. weight 0.621 g	
Max. weight 0.647 g		Max. weight 0.646 g	
Average weight of 20 Tablets: 0.635 g		Average weight of 20 Tablets: 0.635 g	
(Limit: 615.950.500mg-654.050mg)		(Limit: 615.950.500mg-654.050mg)	
Friability: 0.18		NMT 1.0 %	
Disintegration Time: 06 min 11 sec		NMT 15 mins at 37°C $\pm 2^\circ\text{C}$	
Done by: (Production)		Done by: (Production)	
Date: 27/01/25 Time: 13:32		Date: 27/01/25 Time: 13:32	
LHS weight of 20 tablets: 12.712 gm		RHS weight of 20 tablets: 12.712 gm	
1 0.636	8 0.636	15 0.636	1 0.639
2 0.632	9 0.632	16 0.637	2 0.632
3 0.636	10 0.636	17 0.632	3 0.635
4 0.635	11 0.632	18 0.646	4 0.636
5 0.632	12 0.636	19 0.630	5 0.635
6 0.637	13 0.637	20 0.632	6 0.636
7 0.637	14 0.637		7 0.632
Limit: $\pm 5\%$ of average weight M/C Speed: 30 RPM		Limit: $\pm 5\%$ of average weight M/C Speed: 30 RPM	
Min. weight 0.625 g		Min. weight 0.625 g	
Max. weight 0.646 g		Max. weight 0.643 g	
Average weight of 20 Tablets: 0.636 g		Average weight of 20 Tablets: 0.636 g	
(Limit: 615.950.500mg-654.050mg)		(Limit: 615.950.500mg-654.050mg)	
Friability: 0.12		NMT 1.0 %	
Disintegration Time: 06 min 11 sec		NMT 15 mins at 37°C $\pm 2^\circ\text{C}$	
Done by: (Production)		Done by: (Production)	

Title	Prepared by:	Checked by:	Approved by:
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Signature			
Date	19/09/24	19/09/24	19/09/24

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BATCH MANUFACTURING RECORD

Page No.:

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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

12.0A IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

Date: 27.10.24 Time: 14:37	
LHS weight of 20 tablets: 12.684g	
RHS weight of 20 tablets: 12.748g	
1 0.640	8 0.634
2 0.640	9 0.635
3 0.630	10 0.634
4 0.631	11 0.631
5 0.630	12 0.630
6 0.637	13 0.631
7 0.635	14 0.630
15 0.645	16 0.640
17 0.637	18 0.635
19 0.634	20 0.630
Limit: 5% of actual average weight	
M/C Speed: 30 RPM	
Min. weight: 0.630g	Min. weight: 0.631g
Max. weight: 0.645g	Max. weight: 0.645g
Average weight of 20 Tablets: 0.634g	Average weight of 20 Tablets: 0.634g
Limit: (Limit: 615,950,500mg-654,050mg)	Limit: (Limit: 615,950,500mg-654,050mg)
Friability: 0.14	NMT 1.0 %
Disintegration Time: 06 min hole	NMT 15 mins at 37°C ± 2°C
Done by: P. J. (Production)	
Date: 27.10.24 Time: 15:44	
LHS weight of 20 tablets: 12.700g	
RHS weight of 20 tablets: 12.670g	
1 0.640	8 0.634
2 0.644	9 0.637
3 0.641	10 0.631
4 0.640	11 0.630
5 0.631	12 0.631
6 0.632	13 0.630
7 0.635	14 0.630
15 0.644	16 0.641
17 0.640	18 0.631
19 0.637	20 0.639
Limit: 5% of actual average weight	
M/C Speed: 30 RPM	
Min. weight: 0.631g	Min. weight: 0.627g
Max. weight: 0.644g	Max. weight: 0.645g
Average weight of 20 Tablets: 0.635g	Average weight of 20 Tablets: 0.633g
Limit: (Limit: 615,950,500mg-654,050mg)	Limit: (Limit: 615,950,500mg-654,050mg)
Friability: 0.14	NMT 1.0 %
Disintegration Time: 06 min hole	NA
Done by: P. J. (Production)	
Date: 27.10.24 Time: 16:44	
LHS weight of 20 tablets: 12.736g	
RHS weight of 20 tablets: 12.712g	
1 0.642	8 0.637
2 0.640	9 0.630
3 0.641	10 0.632
4 0.637	11 0.631
5 0.630	12 0.631
6 0.630	13 0.630
7 0.630	14 0.639
15 0.637	16 0.637
17 0.630	18 0.631
19 0.630	20 0.640
Limit: 5% of actual average weight	
M/C Speed: 30 RPM	
Min. weight: 0.630g	Min. weight: 0.629g
Max. weight: 0.647g	Max. weight: 0.647g
Average weight of 20 Tablets: 0.636g	Average weight of 20 Tablets: 0.635g
Limit: (Limit: 615,950,500mg-654,050mg)	Limit: (Limit: 615,950,500mg-654,050mg)
Friability: 0.14	NMT 1.0 %
Disintegration Time: 06 min hole	NMT 15 mins at 37°C ± 2°C
Done by: P. J. (Production)	

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	19/09/24	19/09/24	19/09/24
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BATCH MANUFACTURING RECORD

Page No.:

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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	10,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

12.0B IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

Date: 17/01/25 Time: 17:10	
LHS weight of 20 tablets: 127.88g	
RHS weight of 20 tablets: 12.62g	
1 0.636	8 0.632
2 0.634	9 0.630
3 0.630	10 0.631
4 0.634	11 0.630
5 0.637	12 0.631
6 0.642	13 0.630
7 0.642	14 0.640
15 0.640	16 0.640
17 0.637	18 0.635
19 0.640	20 0.637
Limit: 5% of actual average weight	
Min. weight: 0.630g	Max. weight: 0.642g
Average weight of 20 Tablets: 0.635g	Limit: (Limit: 615.950.500mg-654.050mg)
M / C Speed: 30 RPM	
Min. weight: 0.629g	Max. weight: 0.640g
Average weight of 20 Tablets: 0.630g	Limit: (Limit: 615.950.500mg-654.050mg)
Friability: 0.12%	
Disintegration Time: 06min 40sec	
Done by: (Production)	
Date: Time:	
LHS weight of 20 tablets:	
RHS weight of 20 tablets:	
1 8 15	1 8 15
2 9 16	2 9 16
3 10 17	3 10 17
4 11 18	4 11 18
5 12 19	5 12 19
6 13 20	6 13 20
7 14	7 14
Limit: 5% of actual average weight	
M / C Speed: RPM	
Min. weight: g	Max. weight: g
Average weight of 20 Tablets: g	Limit: (Limit: 615.950.500mg-654.050mg)
Friability: NMT 1.0 %	
Disintegration Time: NA	
Done by: (Production)	
Date: Time:	
LHS weight of 20 tablets:	
RHS weight of 20 tablets:	
1 8 15	1 8 15
2 9 16	2 9 16
3 10 17	3 10 17
4 11 18	4 11 18
5 12 19	5 12 19
6 13 20	6 13 20
7 14	7 14
Limit: 5% of actual average weight	
M / C Speed: RPM	
Min. weight: g	Max. weight: g
Average weight of 20 Tablets: g	Limit: (Limit: 615.950.500mg-654.050mg)
Friability: NMT 1.0 %	
Disintegration Time: NMT 15 mins at 37°C±2°C	
Done by: (Production)	

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	19/01/25	19/01/25	19/01/25

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BATCH MANUFACTURING RECORD

Page No.: 76 of 116

Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg. Date:	01/2025	Exp. Date:	12/2027

12.0C IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

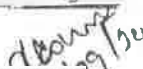
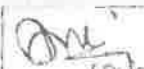
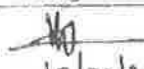
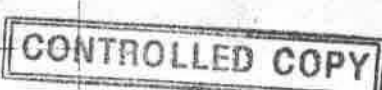
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M / C Speed: RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by:(Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M / C Speed: RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NA							
Done by:(Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M / C Speed: RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by:(Production)							

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	<i>[Signature]</i> 19/01/24	<i>[Signature]</i> 19/01/24	<i>[Signature]</i> 19/01/24
UNCONTROLLED COPY		CONTROLLED COPY	

		Safetab Life Science			
BATCH MANUFACTURING RECORD				Page No.:	77 of 116
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

12.0D IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

Date:..... Time:.....		LHS weight of 20 tablets:				RHS weight of 20 tablets:					
1	8	15		1	8	15		1	8	15	
2	9	16		2	9	16		2	9	16	
3	10	17		3	10	17		3	10	17	
4	11	18		4	11	18		4	11	18	
5	12	19		5	12	19		5	12	19	
6	13	20		6	13	20		6	13	20	
7	14			7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:.....RPM							
Min. weight.....g.....%				Min. weight.....g.....%							
Max. weight.....g.....%				Max. weight.....g.....%							
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g							
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)							
Friability : NMT 1.0 %											
Disintegration Time : NMT 15 mins at 37°C±2°C											
Done by:(Production)											
Date:..... Time:.....		LHS weight of 20 tablets:				RHS weight of 20 tablets:					
1	8	15		1	8	15		1	8	15	
2	9	16		2	9	16		2	9	16	
3	10	17		3	10	17		3	10	17	
4	11	18		4	11	18		4	11	18	
5	12	19		5	12	19		5	12	19	
6	13	20		6	13	20		6	13	20	
7	14			7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:.....RPM							
Min. weight.....g.....%				Min. weight.....g.....%							
Max. weight.....g.....%				Max. weight.....g.....%							
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g							
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)							
Friability : NMT 1.0 %											
Disintegration Time : NA											
Done by:(Production)											
Date:..... Time:.....		LHS weight of 20 tablets:				RHS weight of 20 tablets:					
1	8	15		1	8	15		1	8	15	
2	9	16		2	9	16		2	9	16	
3	10	17		3	10	17		3	10	17	
4	11	18		4	11	18		4	11	18	
5	12	19		5	12	19		5	12	19	
6	13	20		6	13	20		6	13	20	
7	14			7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:.....RPM							
Min. weight.....g.....%				Min. weight.....g.....%							
Max. weight.....g.....%				Max. weight.....g.....%							
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g							
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)							
Friability : NMT 1.0 %											
Disintegration Time : NMT 15 mins at 37°C±2°C											
Done by:(Production)											

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	 19/01/24	 19/01/24	 19/01/24
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BATCH MANUFACTURING RECORD

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Batch Size 12,50,000 Tablets

Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Supersedes MFC No:	ST/MFC/119/R5
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorpheniramine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Exp.Date:	12/2027
Batch No.:	G17250103	Mfg.Date:	01/2025		

12.DE IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by:(Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NA							
Done by:(Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by:(Production)							

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	19/09/24	19/09/24	19/09/24

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BATCH MANUFACTURING RECORD

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Brand Name

LITACOLD FLU TABLETS

Product ID No.:

978

Batch Size

12,50,000 Tablets

Generic Name:

Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets

MFC NO:

ST/MFC/119/R6

Supersedes MFC No:

ST/MFC/119/R5

Batch No.:

G17250103

Mfg. Date:

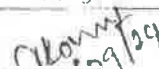
01/2025

Exp. Date:

12/2027

12.0F IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M/C Speed:..... RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability:.....				NMT 1.0 %			
Disintegration Time:.....				NMT 15 mins at 37°C±2°C			
Done by:.....(Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M/C Speed:..... RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability:.....				NMT 1.0 %			
Disintegration Time:.....				NA			
Done by:.....(Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M/C Speed:..... RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability:.....				NMT 1.0 %			
Disintegration Time:.....				NMT 15 mins at 37°C±2°C			
Done by:.....(Production)							

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	 19/09/24	 19/09/24	 19/09/24
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BATCH MANUFACTURING RECORD

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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

12.0G IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight.....g %				Min. weight.....g %			
Max. weight.....g %				Max. weight.....g %			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by:(Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight.....g %				Min. weight.....g %			
Max. weight.....g %				Max. weight.....g %			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NA							
Done by:(Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight.....g %				Min. weight.....g %			
Max. weight.....g %				Max. weight.....g %			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by:(Production)							

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
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BATCH MANUFACTURING RECORD

Page No.:

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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

12.0H IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M / C Speed:.....RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by:(Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M / C Speed:.....RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NA							
Done by:(Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M / C Speed:.....RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by:(Production)							

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	19/09/24	19/09/24	19/09/24

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Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.:

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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

12.01 IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight.....g %				Min. weight.....g %			
Max. weight.....g %				Max. weight.....g %			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by: (Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight.....g %				Min. weight.....g %			
Max. weight.....g %				Max. weight.....g %			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NA							
Done by: (Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight.....g %				Min. weight.....g %			
Max. weight.....g %				Max. weight.....g %			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by: (Production)							

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designer	QA Head / Designee
Signature	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
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Safetab Life Science

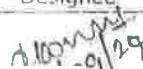
BATCH MANUFACTURING RECORD

Page No.: 83 of 116
Batch Size: 12,50,000 Tablets
Supersedes MFC No: ST/MFC/119/R5
Exp.Date: 12/2027

Brand Name: LITACOLD FLU TABLETS
Product ID No.: 978
Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets
MFC NO: ST/MFC/119/R6
Batch No.: G17250103
Mfg.Date: 01/2025

12.01 IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability: NMT 1.0 %							
Disintegration Time: NMT 15 mins at 37°C±2°C							
Done by:(Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability: NMT 1.0 %							
Disintegration Time: NA							
Done by:(Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability: NMT 1.0 %							
Disintegration Time: NMT 15 mins at 37°C±2°C							
Done by:(Production)							

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
with Date	19/09/24	19/09/24	19/09/24

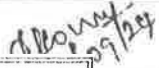
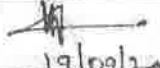
UNCONTROLLED COPY

CONTROLLED COPY

		Safetab Life Science		BATCH MANUFACTURING RECORD		Page No.: 84 of 116
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets	
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5	
Batch No.:	G17250103	Mfg. Date:	01/2025	Exp. Date:	12/2027	

12.0K IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

Date:..... Time:.....											
LHS weight of 20 tablets:						RHS weight of 20 tablets:					
1	8	15				1	8	15			
2	9	16				2	9	16			
3	10	17				3	10	17			
4	11	18				4	11	18			
5	12	19				5	12	19			
6	13	20				6	13	20			
7	14					7	14				
Limit: 5% of actual average weight						M / C Speed:..... RPM					
Min. weight.....g%						Min. weight.....g%					
Max. weight.....g%						Max. weight.....g%					
Average weight of 20 Tablets:.....g						Average weight of 20 Tablets:.....g					
Limit: (Limit: 615.950.500mg-654.050mg)						Limit: (Limit: 615.950.500mg-654.050mg)					
Friability : NMT 1.0 %											
Disintegration Time : NMT 15 mins at 37°C±2°C											
Done by: (Production)											
Date:..... Time:.....											
LHS weight of 20 tablets:						RHS weight of 20 tablets:					
1	8	15				1	8	15			
2	9	16				2	9	16			
3	10	17				3	10	17			
4	11	18				4	11	18			
5	12	19				5	12	19			
6	13	20				6	13	20			
7	14					7	14				
Limit: 5% of actual average weight						M / C Speed:..... RPM					
Min. weight.....g%						Min. weight.....g%					
Max. weight.....g%						Max. weight.....g%					
Average weight of 20 Tablets:.....g						Average weight of 20 Tablets:.....g					
Limit: (Limit: 615.950.500mg-654.050mg)						Limit: (Limit: 615.950.500mg-654.050mg)					
Friability : NMT 1.0 %											
Disintegration Time : NA											
Done by: (Production)											
Date:..... Time:.....											
LHS weight of 20 tablets:						RHS weight of 20 tablets:					
1	8	15				1	8	15			
2	9	16				2	9	16			
3	10	17				3	10	17			
4	11	18				4	11	18			
5	12	19				5	12	19			
6	13	20				6	13	20			
7	14					7	14				
Limit: 5% of actual average weight						M / C Speed:..... RPM					
Min. weight.....g%						Min. weight.....g%					
Max. weight.....g%						Max. weight.....g%					
Average weight of 20 Tablets:.....g						Average weight of 20 Tablets:.....g					
Limit: (Limit: 615.950.500mg-654.050mg)						Limit: (Limit: 615.950.500mg-654.050mg)					
Friability : NMT 1.0 %											
Disintegration Time : NMT 15 mins at 37°C±2°C											
Done by: (Production)											

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date			
UNCONTROLLED COPY CONTROLLED COPY			



Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.:

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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

12.01 IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability :.....				NMT 1.0 %			
Disintegration Time :.....				NMT 15 mins at 37°C±2°C			
Done by: (Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability :.....				NMT 1.0 %			
Disintegration Time :.....				NA			
Done by: (Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability :.....				NMT 1.0 %			
Disintegration Time :.....				NMT 15 mins at 37°C±2°C			
Done by: (Production)							

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
Date	19/09/24	19/09/24	19/09/24

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BATCH MANUFACTURING RECORD

Page No.:

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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

12.0M IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit:5%of actual average weight				M /C Speed:.....RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit:615.950.500mg-654.050mg)				Limit: (Limit:615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by:(Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit:5%of actual average weight				M /C Speed:.....RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit:615.950.500mg-654.050mg)				Limit: (Limit:615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NA							
Done by:(Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit:5%of actual average weight				M /C Speed:.....RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit:615.950.500mg-654.050mg)				Limit: (Limit:615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by:(Production)							

21/01/25

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
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Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.:

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Brand Name

LITACOLD FLU TABLETS

Product ID
No.:

078

Batch Size

12,50,000 Tablets

Generic Name:

Paracetamol, Phenylephrine
Hydrochloride, Chlorphenamine Maleate
and Caffeine Anhydrous Tablets

MFC NO:

ST/MFC/119/R6

Supersedes
MFC No:

ST/MFC/119/R5

Batch No.:

G17250103

Mfg.Date:

01/2025

Exp.Date:

12/2027

12.0N IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M / C Speed: RPM			
Min. weight g %				Min. weight g %			
Max. weight g %				Max. weight g %			
Average weight of 20 Tablets: g				Average weight of 20 Tablets: g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by: (Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M / C Speed: RPM			
Min. weight g %				Min. weight g %			
Max. weight g %				Max. weight g %			
Average weight of 20 Tablets: g				Average weight of 20 Tablets: g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NA							
Done by: (Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M / C Speed: RPM			
Min. weight g %				Min. weight g %			
Max. weight g %				Max. weight g %			
Average weight of 20 Tablets: g				Average weight of 20 Tablets: g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by: (Production)							

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
UNCONTROLLED COPY		CONTROLLED COPY	



Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.:

88 of 116

Brand Name

LITACOLD FLU TABLETS

Product ID No.:

978

Batch Size

12,50,000 Tablets

Generic Name:

Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets

MFC NO:

ST/MFC/119/R6

Supersedes MFC No:

ST/MFC/119/R5

Batch No.:

G17250103

Mfg.Date:

01/2025

Exp.Date:

12/2027

12.0 O IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M / C Speed: RPM			
Min. weight g %				Min. weight g %			
Max. weight g %				Max. weight g %			
Average weight of 20 Tablets: g				Average weight of 20 Tablets: g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by: (Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M / C Speed: RPM			
Min. weight g %				Min. weight g %			
Max. weight g %				Max. weight g %			
Average weight of 20 Tablets: g				Average weight of 20 Tablets: g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NA							
Done by: (Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M / C Speed: RPM			
Min. weight g %				Min. weight g %			
Max. weight g %				Max. weight g %			
Average weight of 20 Tablets: g				Average weight of 20 Tablets: g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by: (Production)							

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
UNCONTROLLED COPY			

CONTROLLED COPY



Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.: 89 of 116
Batch Size: 12,50,000 Tablets
Supersedes MFC No: ST/MFC/119/R5
Exp.Date: 12/2027

Brand Name: LITACOLD FLU TABLETS
Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets
Batch No.: G17250103

Product ID No.: 978
MFC NO: ST/MFC/119/R6
Mfg.Date: 01/2025

12.0P IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:.....RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by:(Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:.....RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NA							
Done by:(Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:.....RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by:(Production)							

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
UNCONTROLLED COPY		CONTROLLED COPY	



Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.: 90 of 116
Batch Size: 12,50,000 Tablets
Supersedes MFC No: ST/MFC/119/R5
Exp.Date: 12/2027

Brand Name: LITACOLD FLU TABLETS
Product ID No.: 978
Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets
MFC NO: ST/MFC/119/R5
Batch No.: G17250103
Mfg.Date: 01/2025

12.0 Q IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit:5%of actual average weight				M /C Speed:.....RPM			
Min. weight.....g		%		Min. weight.....g		%	
Max. weight.....g		%		Max. weight.....g		%	
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit:615.950.500mg-654.050mg)				Limit: (Limit:615.950.500mg-654.050mg)			
Friability :		NMT 1.0 %					
Disintegration Time :		NMT 15 mins at 37°C±2°C					
Done by:(Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit:5%of actual average weight				M /C Speed:.....RPM			
Min. weight.....g		%		Min. weight.....g		%	
Max. weight.....g		%		Max. weight.....g		%	
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit:615.950.500mg-654.050mg)				Limit: (Limit:615.950.500mg-654.050mg)			
Friability :		NMT 1.0 %					
Disintegration Time :		NA					
Done by:(Production)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit:5%of actual average weight				M /C Speed:.....RPM			
Min. weight.....g		%		Min. weight.....g		%	
Max. weight.....g		%		Max. weight.....g		%	
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit:615.950.500mg-654.050mg)				Limit: (Limit:615.950.500mg-654.050mg)			
Friability :		NMT 1.0 %					
Disintegration Time :		NMT 15 mins at 37°C±2°C					
Done by:(Production)							

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
UNCONTROLLED COPY		CONTROLLED COPY	
19/09/24		19/09/24	



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BATCH MANUFACTURING RECORD

Page No.:

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Brand Name

LITACOLD FLU TABLETS

Product ID
No.:

978

Batch Size

12,50,000 Tablets

Generic Name:

Paracetamol, Phenylephrine
Hydrochloride, Chlorphenamine Maleate
and Caffeine Anhydrous Tablets

MFC NO:

ST/MFC/119/R6

Supersedes
MFC No:

ST/MFC/119/R5

Batch No.:

G17250103

Mfg. Date:

01/2025

Exp. Date:

12/2027

13.0 IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BY IPQA:

Date: 27/10/25 Time: 12:09

Upper % deviation = $\frac{\text{Maximum net fill weight} - \text{Average net fill weight}}{\text{Average net fill weight}} \times 100$ Lower % deviation = $\frac{\text{Minimum net fill weight} - \text{Average net fill weight}}{\text{Average net fill weight}} \times 100$

LHS weight of 20 tablets: 12.665 g

RHS weight of 20 tablets: 12.684 g

1	0.627	8	0.634	15	0.631	1	0.636	8	0.634	15	0.633
2	0.631	9	0.632	16	0.632	2	0.632	9	0.632	16	0.624
3	0.627	10	0.633	17	0.626	3	0.635	10	0.634	17	0.629
4	0.634	11	0.632	18	0.643	4	0.630	11	0.624	18	0.645
5	0.642	12	0.620	19	0.638	5	0.641	12	0.624	19	0.632
6	0.636	13	0.629	20	0.636	6	0.632	13	0.632	20	0.634
7	0.632	14	0.630			7	0.632	14	0.635		

Limit: $\pm 5\%$ of average weight M / C Speed: 30 RPM

Min. weight: 0.626 g

71.10 %

Min. weight: 0.629 g

71.73 %

Max. weight: 0.643 g

71.38 %

Max. weight: 0.645 g

71.73 %

Average weight of 20 Tablets:

0.633 g

Average weight of 20 Tablets:

0.634 g

(Limit: 615.950.500mg-654.050mg)

(Limit: 615.950.500mg-654.050mg)

Friability: 0.157

NMT 1.0 %

Disintegration Time: 06 min 37 sec

NMT 15 mins at 37°C $\pm 2^\circ\text{C}$

Done by: (IPQA)

Date: 27/10/25 Time: 14:12

LHS weight of 20 tablets: 12.757 g

RHS weight of 20 tablets: 12.718 g

1	0.625	8	0.627	15	0.637	1	0.629	8	0.628	15	0.629
2	0.622	9	0.629	16	0.629	2	0.642	9	0.631	16	0.627
3	0.626	10	0.642	17	0.636	3	0.640	10	0.630	17	0.635
4	0.629	11	0.640	18	0.639	4	0.627	11	0.634	18	0.628
5	0.642	12	0.623	19	0.642	5	0.629	12	0.642	19	0.634
6	0.640	13	0.642	20	0.629	6	0.640	13	0.638	20	0.645
7	0.625	14	0.640			7	0.626	14	0.635		

Limit: $\pm 5\%$ of average weight

M / C Speed: 30 RPM

Min. weight: 0.627 g

71.72 %

Min. weight: 0.628 g

71.25 %

Max. weight: 0.642 g

71.35 %

Max. weight: 0.645 g

71.42 %

Average weight of 20 Tablets:

0.633 g

Average weight of 20 Tablets:

0.636 g

(Limit: 615.950.500mg-654.050mg)

(Limit: 615.950.500mg-654.050mg)

Friability: 0.167

NMT 1.0 %

Disintegration Time: 06 min 25 sec

NMT 15 mins at 37°C $\pm 2^\circ\text{C}$

Done by: (IPQA)

Date: 27/10/25 Time: 16:15

LHS weight of 20 tablets: 12.753 g

RHS weight of 20 tablets: 12.770 g

1	0.632	8	0.638	15	0.637	1	0.636	8	0.642	15	0.640
2	0.637	9	0.641	16	0.635	2	0.637	9	0.645	16	0.637
3	0.631	10	0.640	17	0.636	3	0.637	10	0.626	17	0.629
4	0.640	11	0.637	18	0.629	4	0.639	11	0.639	18	0.626
5	0.642	12	0.626	19	0.629	5	0.642	12	0.645	19	0.629
6	0.646	13	0.629	20	0.645	6	0.640	13	0.640	20	0.649
7	0.640	14	0.640			7	0.638	14	0.637		

Limit: $\pm 5\%$ of average weight

M / C Speed: 30 RPM

Min. weight: 0.626 g

71.88 %

Min. weight: 0.626 g

71.02 %

Max. weight: 0.646 g

71.25 %

Max. weight: 0.645 g

71.94 %

Average weight of 20 Tablets:

0.633 g

Average weight of 20 Tablets:

0.641 g

(Limit: 615.950.500mg-654.050mg)

(Limit: 615.950.500mg-654.050mg)

Friability: 0.157

NMT 1.0 %

Disintegration Time: 06 min 29 sec

NMT 15 mins at 37°C $\pm 2^\circ\text{C}$

Done by: (IPQA)

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
	UNCONTROLLED COPY		CONTROLLED COPY



Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.: 92 of 116
Batch Size: 12,50,000 Tablets
Supersedes MFC No: ST/MFC/119/R5
Exp.Date: 12/2027

Brand Name: LITACOLD FLU TABLETS

Product ID No.: 978

Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorpheniramine Maleate and Caffeine Anhydrous Tablets

MFC NO: ST/MFC/119/R6

Batch No.: G17250103

Mfg.Date: 01/2025

13.0A IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BYIPQA:

Date: 27/01/25, Time: 18:17							
LHS weight of 20 tablets: 17.7019				RHS weight of 20 tablets: 17.7559			
1	0.635	8	0.630	15	0.635	1	0.635
2	0.632	9	0.629	16	0.639	2	0.639
3	0.635	10	0.634	17	0.644	3	0.642
4	0.637	11	0.635	18	0.640	4	0.638
5	0.626	12	0.638	19	0.635	5	0.635
6	0.635	13	0.642	20	0.625	6	0.621
7	0.632	14	0.640			7	0.635
Limit: 5% of actual average weight				M/C Speed: 32 RPM			
Min. weight: 0.624 g				Min. weight: 0.621 g			
Max. weight: 0.644 g				Max. weight: 0.645 g			
Average weight of 20 Tablets: 0.635 g				Average weight of 20 Tablets: 0.638 g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability: 0.16%				NMT 1.0 %			
Disintegration Time: 06 min 19 sec				NMT 15 mins at 37°C±2°C			
Done by: (IPQA)							
Date: Time:							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1		8		15		1	
2		9		16		2	
3		10		17		3	
4		11		18		4	
5		12		19		5	
6		13		20		6	
7		14				7	
Limit: 5% of actual average weight				M/C Speed: RPM			
Min. weight: g				Min. weight: g			
Max. weight: g				Max. weight: g			
Average weight of 20 Tablets: g				Average weight of 20 Tablets: g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability: NMT 1.0 %							
Disintegration Time: NA							
Done by: (IPQA)							
Date: Time:							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1		8		15		1	
2		9		16		2	
3		10		17		3	
4		11		18		4	
5		12		19		5	
6		13		20		6	
7		14				7	
Limit: 5% of actual average weight				M/C Speed: RPM			
Min. weight: g				Min. weight: g			
Max. weight: g				Max. weight: g			
Average weight of 20 Tablets: g				Average weight of 20 Tablets: g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability: NMT 1.0 %							
Disintegration Time: NMT 15 mins at 37°C±2°C							
Done by: (IPQA)							

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
UNCONTROLLED COPY			CONTROLLED COPY



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BATCH MANUFACTURING RECORD

Page No.:

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Brand Name

LITACOLD FLU TABLETS

Product ID
No.:

978

Batch Size

12,50,000 Tablets

Generic Name:

Paracetamol, Phenylephrine
Hydrochloride, Chlorphenamine Maleate
and Caffeine Anhydrous Tablets

MFC NO:

ST/MFC/119/R6

Supersedes
MFC No:

ST/MFC/119/R5

Batch No.:

G17250103

Mfg.Date:

01/2025

Exp.Date:

12/2027

13.0C IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BYIPQA:

Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight:.....g %				Min. weight:.....g %			
Max. weight:.....g %				Max. weight:.....g %			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability:.....				NMT 1.0 %			
Disintegration Time:.....				NMT 15 mins at 37°C±2°C			
Done by: (IPQA)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight:.....g %				Min. weight:.....g %			
Max. weight:.....g %				Max. weight:.....g %			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability:.....				NMT 1.0 %			
Disintegration Time:.....				NA			
Done by: (IPQA)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight:.....g %				Min. weight:.....g %			
Max. weight:.....g %				Max. weight:.....g %			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability:.....				NMT 1.0 %			
Disintegration Time:.....				NMT 15 mins at 37°C±2°C			
Done by: (IPQA)							

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
UNCONTROLLED COPY		CONTROLLED COPY	



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BATCH MANUFACTURING RECORD

Page No.: 93 of 116
Batch Size: 12,50,000 Tablets
Supersedes MFC No: ST/MFC/119/R5
Exp.Date: 12/2027

Brand Name: LITACOLO FLU TABLETS
Product ID No.: 978
Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets
MFC NO: ST/MFC/119/R6
Batch No.: G17250103
Mfg.Date: 01/2025

13.0B IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BYIPQA:

Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed: RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:g				Average weight of 20 Tablets:g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by: (IPQA)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed: RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:g				Average weight of 20 Tablets:g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NA							
Done by: (IPQA)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed: RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:g				Average weight of 20 Tablets:g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by: (IPQA)							

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
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Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.: 95 of 116
Batch Size: 12,50,000 Tablets
Supersedes MFC No: ST/MFC/119/R5
Exp.Date: 12/2027

Brand Name: LITACOLD FLU TABLETS
Product ID No.: 978
Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets
MFC NO: ST/MFC/119/R6
Batch No.: G17250103
Mfg.Date: 01/2025

13.00 IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BYIPQA:

Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:.....RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by: (IPQA)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:.....RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NA							
Done by: (IPQA)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:.....RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by: (IPQA)							

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
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Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.:

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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

13.0E IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BYIPQA:

Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M/C Speed:.....RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability: NMT 1.0 %							
Disintegration Time: NMT 15 mins at 37°C±2°C							
Done by: (IPQA)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M/C Speed:.....RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability: NMT 1.0 %							
Disintegration Time: NA							
Done by: (IPQA)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M/C Speed:.....RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability: NMT 1.0 %							
Disintegration Time: NMT 15 mins at 37°C±2°C							
Done by: (IPQA)							

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
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Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.: 97 of 116
Batch Size: 12,50,000 Tablets
Supersedes MFC No: ST/MFC/119/R5
Exp.Date: 12/2027

Brand Name: LITACOLD FLU TABLETS
Product ID No.: 978
Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorpheniramine Maleate and Caffeine Anhydrous Tablets
MFC NO: ST/MFC/119/R6
Batch No.: G17250103
Mfg.Date: 01/2025

13. OF IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BY IPQA:

Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight.....g				Min. weight.....g			
Max. weight.....g				Max. weight.....g			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by: (IPQA)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight.....g				Min. weight.....g			
Max. weight.....g				Max. weight.....g			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NA							
Done by: (IPQA)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight.....g				Min. weight.....g			
Max. weight.....g				Max. weight.....g			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by: (IPQA)							

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
UNCONTROLLED COPY		CONTROLLED COPY	

		Safetab Life Science		Page No.: 98 of 116	
BATCH MANUFACTURING RECORD		Product ID No.: 978		Batch Size: 12,50,000 Tablets	
Brand Name: LITACOLD FLU TABLETS	Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO: ST/MFC/119/R6	Supersedes MFC No: ST/MFC/119/R5		
Batch No.: G17250103	Mfg.Date: 01/2025	Exp.Date: 12/2027			

13.0G IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BYIPQA:

Date:..... Time:.....											
LHS weight of 20 tablets:						RHS weight of 20 tablets:					
1	8	15				1	8	15			
2	9	16				2	9	16			
3	10	17				3	10	17			
4	11	18				4	11	18			
5	12	19				5	12	19			
6	13	20				6	13	20			
7	14					7	14				
Limit: 5% of actual average weight						M /C Speed:.....RPM					
Min. weight.....g%						Min. weight.....g%					
Max. weight.....g%						Max. weight.....g%					
Average weight of 20 Tablets:.....g						Average weight of 20 Tablets:.....g					
Limit: (Limit: 615.950.500mg-654.050mg)						Limit: (Limit: 615.950.500mg-654.050mg)					
Friability : NMT 1.0 %											
Disintegration Time : NMT 15 mins at 37°C±2°C											
Done by:(IPQA)											
Date:..... Time:.....											
LHS weight of 20 tablets:						RHS weight of 20 tablets:					
1	8	15				1	8	15			
2	9	16				2	9	16			
3	10	17				3	10	17			
4	11	18				4	11	18			
5	12	19				5	12	19			
6	13	20				6	13	20			
7	14					7	14				
Limit: 5% of actual average weight						M /C Speed:.....RPM					
Min. weight.....g%						Min. weight.....g%					
Max. weight.....g%						Max. weight.....g%					
Average weight of 20 Tablets:.....g						Average weight of 20 Tablets:.....g					
Limit: (Limit: 615.950.500mg-654.050mg)						Limit: (Limit: 615.950.500mg-654.050mg)					
Friability : NMT 1.0 %											
Disintegration Time : NA											
Done by:(IPQA)											
Date:..... Time:.....											
LHS weight of 20 tablets:						RHS weight of 20 tablets:					
1	8	15				1	8	15			
2	9	16				2	9	16			
3	10	17				3	10	17			
4	11	18				4	11	18			
5	12	19				5	12	19			
6	13	20				6	13	20			
7	14					7	14				
Limit: 5% of actual average weight						M /C Speed:.....RPM					
Min. weight.....g%						Min. weight.....g%					
Max. weight.....g%						Max. weight.....g%					
Average weight of 20 Tablets:.....g						Average weight of 20 Tablets:.....g					
Limit: (Limit: 615.950.500mg-654.050mg)						Limit: (Limit: 615.950.500mg-654.050mg)					
Friability : NMT 1.0 %											
Disintegration Time : NMT 15 mins at 37°C±2°C											
Done by:(IPQA)											

Title	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	

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Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.: 99 of 116
Batch Size: 17,40,000 Tablets
Supersedes MFC No: ST/MFC/119/R5
Exp.Date: 12/2027

Brand Name LITACOLD FLU TABLETS

Product ID No.: 978

Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets

MFC NO: ST/MFC/119/R6

Batch No.: G17250103

Mfg.Date: 01/2025

13.0H IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BYIPQA:

Date:..... Time:.....			
LHS weight of 20 tablets:			
1	8	15	
2	9	16	
3	10	17	
4	11	18	
5	12	19	
6	13	20	
7	14		
Limit: 5% of actual average weight			
Min. weight.....g		%	
Max. weight.....g		%	
Average weight of 20 Tablets:.....g		%	
Limit: (Limit: 615.950.500mg-654.050mg)			
Friability :		NMT 1.0 %	
Disintegration Time :		NMT 15 mins at 37°C±2°C	
Done by: (IPQA)			
Date:..... Time:.....			
LHS weight of 20 tablets:			
1	8	15	
2	9	16	
3	10	17	
4	11	18	
5	12	19	
6	13	20	
7	14		
Limit: 5% of actual average weight			
Min. weight.....g		%	
Max. weight.....g		%	
Average weight of 20 Tablets:.....g		%	
Limit: (Limit: 615.950.500mg-654.050mg)			
Friability :		NMT 1.0 %	
Disintegration Time :		NA	
Done by: (IPQA)			
Date:..... Time:.....			
LHS weight of 20 tablets:			
1	8	15	
2	9	16	
3	10	17	
4	11	18	
5	12	19	
6	13	20	
7	14		
Limit: 5% of actual average weight			
Min. weight.....g		%	
Max. weight.....g		%	
Average weight of 20 Tablets:.....g		%	
Limit: (Limit: 615.950.500mg-654.050mg)			
Friability :		NMT 1.0 %	
Disintegration Time :		NMT 15 mins at 37°C±2°C	
Done by: (IPQA)			

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
UNCONTROLLED COPY			

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BATCH MANUFACTURING RECORD

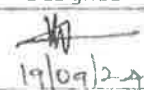
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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

13.01 IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BYIPQA:

Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight.....g		%		Min. weight.....g		%	
Max. weight.....g		%		Max. weight.....g		%	
Average weight of 20 Tablets:.....g		%		Average weight of 20 Tablets:.....g		%	
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability :		NMT 1.0 %					
Disintegration Time :		NMT 15 mins at 37°C±2°C					
Done by: (IPQA)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight.....g		%		Min. weight.....g		%	
Max. weight.....g		%		Max. weight.....g		%	
Average weight of 20 Tablets:.....g		%		Average weight of 20 Tablets:.....g		%	
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability :		NMT 1.0 %					
Disintegration Time :		NA					
Done by: (IPQA)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight.....g		%		Min. weight.....g		%	
Max. weight.....g		%		Max. weight.....g		%	
Average weight of 20 Tablets:.....g		%		Average weight of 20 Tablets:.....g		%	
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability :		NMT 1.0 %					
Disintegration Time :		NMT 15 mins at 37°C±2°C					
Done by: (IPQA)							

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
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Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.:

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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

13.01 IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BYIPQA:

Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M / C Speed:.....RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by: (IPQA)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M / C Speed:.....RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NA							
Done by: (IPQA)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M / C Speed:.....RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by: (IPQA)							

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
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Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.:

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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

13.0K IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BYIPQA:

Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by: (IPQA)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NA							
Done by: (IPQA)							
Date:..... Time:.....							
LHS weight of 20 tablets:				RHS weight of 20 tablets:			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Limit: 5% of actual average weight				M /C Speed:..... RPM			
Min. weight.....g.....%				Min. weight.....g.....%			
Max. weight.....g.....%				Max. weight.....g.....%			
Average weight of 20 Tablets:.....g				Average weight of 20 Tablets:.....g			
Limit: (Limit: 615.950.500mg-654.050mg)				Limit: (Limit: 615.950.500mg-654.050mg)			
Friability : NMT 1.0 %							
Disintegration Time : NMT 15 mins at 37°C±2°C							
Done by: (IPQA)							

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
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BATCH MANUFACTURING RECORD

Page No.:

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Brand Name

LITACOLD FLU TABLETS

Product ID
No.:

978

Batch Size

12,50,000 Tablets

Generic Name:

Paracetamol, Phenylephrine
Hydrochloride, Chlorphenamine Maleate
and Caffeine Anhydrous Tablets

MFC NO:

ST/MFC/119/R6

Supersedes
MFC No:

ST/MFC/119/R5

Batch No.:

G17250103

Mfg.Date:

01/2025

Exp.Date:

12/2027

14.0 WEIGHING RECORD OF COMPRESSED TABLETS:

Container No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by/date	Container No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by/date
1						26					
2						27					
3						28					
4						29					
5						30					
6						31					
7						32					
8						33					
9						34					
10						35					
11						36					
12						37					
13						38					
14						39					
15						40					
16						41					
17						42					
18						43					
19						44					
20						45					
21						46					
22						47					
23						48					
24						49					
25						50					

Total weight of compressed tablets:

kg

Intimate IPQA to draw the sample.

Sample withdrawn by IPQA.

Production Sign: Date:

IPQA Sign: Date:

Send Test Request Form for analysis of compressed tablets to QC department.

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
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BATCH MANUFACTURING RECORD

Page No.:

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Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

14.0A WEIGHING RECORD OF COMPRESSED TABLETS:

Container No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by/date	Container No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by/date
1	37.78	2.62	35.18	Darshan P.Je		26					
2	37.20	2.62	34.60	Darshan P.Je		27					
3	35.60	2.62	33.00	Darshan P.Je		28					
4	34.65	2.62	32.25	Darshan P.Je		29					
5	34.08	2.62	31.48	Darshan P.Je		30					
6	33.28	2.62	30.68	Darshan P.Je		31					
7	32.75	2.62	30.15	Darshan P.Je		32					
8	32.38	2.62	29.78	Darshan P.Je		33					
9	33.62	2.62	31.00	Darshan P.Je		34					
10	36.97	2.60	34.37	Ariane P.Je		35					
11	37.75	2.62	35.15	Ariane P.Je		36					
12	42.20	2.42	39.80	Ariane P.Je		37					
13	42.32	2.32	40.00	Ariane P.Je		38					
14	34.50	2.22	32.30	Ariane P.Je		39					
15	41.80	2.60	39.20	Ariane P.Je		40					
16	36.65	2.50	34.15	Ariane P.Je		41					
17	33.70	2.50	31.20	Ariane P.Je		42					
18	35.75	2.20	33.55	Ariane P.Je		43					
19	42.80	2.50	40.30	Ariane P.Je		44					
20	31.90	2.50	29.40	Ariane P.Je		45					
21	34.16	2.50	31.66	Ariane P.Je		46					
22	45.90	2.50	43.40	Ariane P.Je		47					
23	29.50	2.50	27.00	Ariane P.Je		48					
24	1					49					
25						50					

Total weight of compressed tablets:

780.30

kg

Intimate IPQA to draw the sample.

Sample withdrawn by IPQA.

Production Sign: P.Je Date: 27/01/25IPQA Sign: V. Sui Date: 27/01/25

Send Test Request Form for analysis of compressed tablets to QC department.

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature	<u>[Signature]</u> 27/01/25	<u>[Signature]</u> 27/01/25	<u>[Signature]</u> 19/01/25

UNCONTROLLED COPY

CONTROLLED COPY

		Safetab Life Science			
BATCH MANUFACTURING RECORD				Page No.:	105 of 116
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

15.0 RECONCILIATION:

1.0	Theoretical Weight of Compressed tablets	:	793.75	Kg	1250000 No's
2.0	Actual Qty of blend received for compression	:	791.50	Kg	1246456
3.0	Actual Weight of Compressed tablets	:	780.30		1228818
4.0	In-process samples				
	A IPQA Samples	:	0.44	Kg	700
	B QC Samples	:	0.06	Kg	100
	C Validation Samples	:	-	Kg	-
	D Others	:	-	Kg	-
5.0	Total samples: (A + B + C + D)	:	0.51	Kg	800
6.0	Total: (5.0 + 3.0)	:	780.81	Kg	1229622
7.0	Manufacturing Loss (1.0 - 6.0) (compression)		12.94		29377
8.0	Compression yield = $\frac{6.0}{2.0} \times 100$		98.64		%
9.0	% Yield = $\frac{6.0}{1.0} \times 100$ Limit: NLT 98.00% * (To be monitored)	:	98.36	%	

If yield is out of limit raise deviation and inform to QA, After QA investigation and approval proceed to the next stage.

Total rejects destroyed: 12.94 Kg Rejected materials shall be destroyed in the presence of QA.

Done by: Production sign/Date: [Signature] 27/01/25 Checked By IPQA sign/Date: [Signature] 27/01/25

Reconciliation Done by: Production sign/Date: [Signature] 27/01/25 Checked By IPQA sign/Date: [Signature] 27/01/25

15.1 COMPRESSED TABLETS RELEASED FOR INSPECTION:

Reconciliation checked and compression tablets are released for inspection.

Production sign/Date: [Signature] 19/01/25 IPQA sign/Date: [Signature] 19/01/25

Title Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee
Signature: [Signature]	[Signature] 09/04	[Signature] 19/01/25	[Signature] 19/01/25

UNCONTROLLED COPY

CONTROLLED COPY

		Safetab Life Science		BATCH MANUFACTURING RECORD		Page No.:	106 of 116
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets		
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5		
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027		

16.0 TABLET INSPECTION

16.1 LINE CLEARANCE CHECKS

S.No	Checks	Observation	
		Production	IPQA
1	Check whether the empty containers, polythene bags and documents of previous batch/product are removed from the area.	✓	✓
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	✓
3	Check the absence of tablets of previous batch/product in the container and surrounding area.	✓	✓
4	Check the area (floor, wall, ceiling, door, windows) are clean.	✓	✓
5	Check the tubelight fixture, supply grills, riser grills, filters and electrical fixtures are clean.	✓	✓
6	Check whether the daily records are updated and signed.	✓	✓
7	Check the environmental condition and record in BMR.	✓	✓
8	Check whether area and equipment status board is updated.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (production) sign/date: *P. J. 10/02/25* Verified by (IPQA) sign/date: *P. J. 10/02/25*

16.2 ENVIRONMENTAL CONDITIONS	Date: 10/02/25		Date:	
	Observation	Production Sign	Observation	Production Sign
Temperature: 23°C to 27°C	24.3°	P. J.	NA	
Differential pressure NLT 0.5mm of water or NMT 5 pascal	08	P. J.		
Relative Humidity: 45% to 55 %	49	P. J.		

16.3 APPROVAL FOR INSPECTION:

Production Sign/Date: *P. J. 10/02/25*
 Line clearance IPQA Sign./Date.: *P. J. 10/02/25*

S. No	Process Instructions
1	Carry out visual inspection of tablets on tablet manual inspection area.
2	Collect inspected tablets in containers lined with polythene bags. Weigh the containers and record the weight.
3	Intimate In-process Quality Assurance.

16.4 TABLETS VISUAL INSPECTION RECORD:

Types of rejection: broken tablets, damage edges, capping, sticking, foreign particle & any other rejections.								
Date	Container No		Time		Total Quantity Rejected	Type of Rejection	Tablets Inspection Done by/Date	Checked by/Date
	From	To	Started	Completed				
10/02/25	01	23	06:30	14:00	1.040	Half Tablet	chitra Anurag 10/02/25	P. J. 10/02/25

Title Designation Signature	Prepared by: QA Executive / Designee <i>chitra 10/02/25</i>	Checked by: Production Head / Designee <i>P. J. 10/02/25</i>	Approved by: QA Head / Designee <i>P. J. 10/02/25</i>
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Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.:

107 of 116

Brand Name

LITACOLD FLU TABLETS

Product ID No.:

978

Batch Size

12,50,000 Tablets

Generic Name:

Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets

MFC NO:

ST/MFC/119/R6

Supersedes MFC No:

ST/MFC/119/R5

Batch No.:

G17250103

Mfg.Date:

01/2025

Exp.Date:

12/2027

16.5 WEIGHING RECORD OF INSPECTED TABLETS:

Date: 10/02/25

Container No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by/date	Container No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by/date
1	37.70	2.60	35.10	Anurag	10/02/25	26					
2	37.10	2.60	34.50	Anurag	10/02/25	27					
3	35.50	2.50	33.00	Anurag	10/02/25	28					
4	34.80	2.60	32.20	Anurag	10/02/25	29					
5	34.00	2.60	31.40	Anurag	10/02/25	30					
6	33.20	2.60	30.60	Anurag	10/02/25	31					
7	32.70	2.60	30.10	Anurag	10/02/25	32					
8	32.30	2.60	29.70	Anurag	10/02/25	33					
9	33.50	2.60	30.90	Anurag	10/02/25	34					
10	36.90	2.60	34.30	Anurag	10/02/25	35					
11	37.70	2.20	35.50	Anurag	10/02/25	36					
12	42.10	2.00	40.10	Anurag	10/02/25	37					
13	42.15	2.40	39.75	Anurag	10/02/25	38					
14	34.48	2.20	32.28	Sulha	10/02/25	39					
15	41.75	2.60	39.15	Sulha	10/02/25	40					
16	36.62	2.50	34.12	Sulha	10/02/25	41					
17	33.68	2.50	31.18	Sulha	10/02/25	42					
18	36.02	2.50	33.52	Sulha	10/02/25	43					
19	43.72	2.50	41.22	Sulha	10/02/25	44					
20	31.88	2.50	29.38	Sulha	10/02/25	45					
21	33.54	2.50	31.04	Sulha	10/02/25	46					
22	45.85	2.50	43.35	Sulha	10/02/25	47					
23	29.45	2.50	26.95	Sulha	10/02/25	48					
24						49					
25						50					

Total weight of Inspected tablets:

779.260

kg

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
UNCONTROLLED COPY		CONTROLLED COPY	

		Safetab Life Science		BATCH MANUFACTURING RECORD		Page No.:	108 of 116
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets		
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5		
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027		

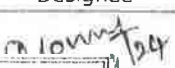
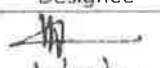
16.6 WEIGHING RECORD OF INSPECTED TABLETS:

Date:

Container No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by/date	Container No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by/date
51						76					
52						77					
53						78					
54						79					
55						80					
56						81					
57						82					
58						83					
59						84					
60						85					
61						86					
62						87					
63						88					
64						89					
65						90					
66						91					
67						92					
68						93					
69						94					
70						95					
71						96					
72						97					
73						98					
74						99					
75						100					

Total weight of Inspected tablets:

10/02/25 kg

Title Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee
Signature			
UNCONTROLLED COPY		CONTROLLED COPY	



Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.: 109 of 116

Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg. Date:	01/2025	Exp. Date:	12/2027

16.7 RECONCILIATION: (INSPECTION OF TABLETS)

1.0	Theoretical weight of tablets	793.75 kg	1250000 No's
2.0	Tablets transferred to inspection	780.300 kg	1228818 No's
3.0	Rejected tablets	1.040 kg	1637 No's
4.0	Total weight of good tablets	779.260 kg	1227181 No's
5.0	% Yield = $\frac{4.0}{1.0} \times 100$ (Limit- NLT 97.00%)	98.17 %	

If yield is out of limit, raise deviation and inform to QA. After QA, investigation and approval proceed to the next stage.

Total rejects destroyed: 1.040 Kg. Rejected materials shall be destroyed in the presence of QA

Done by Packing sign/Date: Pri 10/02/25 Checked by IPQA sign/Date: Pri 10/02/25

Reconciliation Done by Production sign/Date: Pri 10/02/25 Checked By IPQA sign/Date: Pri 10/02/25

17.0 RELEASE FOR PACKING

Compressed tablets report checked and released for packing.

Checked by Competent Staff Sign/Date: Pri 10/02/25

IPQA Sign/Date: Pri 11/02/25

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>

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CONTROLLED COPY



Safetab Life Science

BATCH MANUFACTURING RECORD

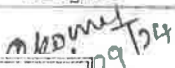
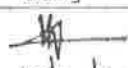
Page No.:

110 of 116

Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

18.0 PROCESS HISTORY

10/02/25

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature			
UNCONTROLLED COPY		CONTROLLED COPY	



Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.: 111 of 116
Batch Size: 12,50,000 Tablets
Supersedes MFC No: ST/MFC/119/R5
Exp.Date: 12/2027

Brand Name: LITACOLD FLU TABLETS
Product ID No.: 978
Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets
MFC NO: ST/MFC/119/R6
Batch No.: G17250103
Mfg.Date: 01/2025

19.0 Following the BMR records in additional attached.

		Checked by Production Head	Reviewed by QA Head
1	Raw Materials dispensed labels	✓	✓
2	Granulation stage analytical report	NA	NA
3	Compression stage analytical report	✓	✓
4	Blend container label	✓	✓
5	Compressed tablets container label	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply.

This Batch Manufacturing reviewed on date 11/02/25

Production Head sign/date: [Signature] 11/02/25

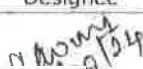
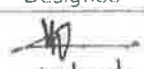
This Batch Manufacturing Record received, reviewed and batch is released for packing on date 11/02/2025

Reviewed by QA Head: [Signature] 11/02/2025

Title	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature	 11/02/25	 19/09/24	 19/09/24	
UNCONTROLLED COPY				

		Safetab Life Science			
BATCH MANUFACTURING RECORD				Page No.:	112 of 116
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12 50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

20.0 ABBREVIATIONS					
S.No.	Short Form	Abbreviation	S.No.	Short Form	Abbreviation
1	BP	British Pharmacopeia	19	A.R.No.	Analytical Report Number
2	API	Active Pharmaceutical Ingredients	20	IPQA	In Process Quality Assurance
3	BMR	Batch Manufacturing Record	21	L	Lakhs
4	MFG	Manufacturing	22	TRF	Test Request Form
5	EXP	Expiry	23	RMG	Rapid Mixer Granulator
6	QA	Quality Assurance	24	FBD	Fluid Bed Drier
7	Kg	Kilogram	25	SOP	Standard Operating Procedure
8	g	Gram	26	mm	Millimeter
9	lts	Liters	27	NLT	Not Less Than
10	Min	Minutes	28	NMT	Not More Than
11	Hrs	Hours	29	Tab	Tablet
12	M/C	Machine	30	RHS	Right Hand Side
13	Prod	Production	31	LHS	Left Hand Side
14	B.No	Batch number	32	Std	Standard
15	mg	Milligram	33	Avg	Average
16	Qty	Quantity	34	rpm	Rotation Per Minute
17	QC	Quality Control	35	No's	Numbers
18	LOD	Loss On Drying	36	Sign	Signature

Title	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	CONTROLLED COPY
Signature with Date				
UNCONTROLLED COPY				



Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.: 113 of 116
Batch Size: 12,50,000 Tablets
Supersedes MFC No: ST/MFC/119/R5
Exp.Date: 12/2027

Brand Name: LITACOLD FLU TABLETS
Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets
Batch No.: G17250103

Product ID No.: 978
MFC NO: ST/MFC/119/R6
Mfg.Date: 01/2025

BMR COPY/QUALITY CONTROL COPY

21.0 TEST REQUEST FORM FOR LUBRICATED GRANULES:

From: Manufacturing Department	To: Q.A. Department
To be filled by production	To be filled by IPQA
Date of Mfg : Date of exp :	Quantity Sampled :
Test Request for :	No. of containers :
TRF raised by : on date:	Sampled by : on date:
To be filled by QC	
TRF & Sample received Sign & Date :	
Sample tested on :	
Test Results	Limits
Analytical Reference no.:	
Analysed By : on :	Space for QC Approval (Stamping and Signing) 19/01/25

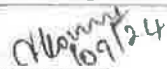
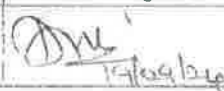
Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	19/01/24	19/01/24	19/01/24
UNCONTROLLED COPY		CONTROLLED COPY	

		Safetab Life Science			
BATCH MANUFACTURING RECORD				Page No.:	113 of 116
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg. Date:	01/2025	Exp. Date:	12/2027

BMR COPY/QUALITY CONTROL COPY

21.0 TEST REQUEST FORM FOR LUBRICATED GRANULES:

From: Manufacturing Department To be filled by production Date of Mfg: Date of exp: Test Request for : TRF raised by : on date:	To: Q.A. Department To be filled by IPQA Quantity Sampled : No. of containers : Sampled by : on date:
To be filled by QC TRF & Sample received Sign & Date : Sample tested on :	
Test Results	Limits
NO 22/01/25	
Analytical Reference no. : Analysed By : on :	Space for QC Approval (Stamping and Signing)

Title Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	CONTROLLED COPY
Signature with Date	 19/09/24	 19/09/24	 19/09/24	

UNCONTROLLED COPY



Safetab Life Science

BATCH MANUFACTURING RECORD

Page No.: 114 of 116
Batch Size: 120 ad 80% Tablets
Supersedes MFC No: ST/MFC/119/R5
Exp. Date: 12/2027

Brand Name: LITACOLD FLU TABLETS
Generic Name: Paracetamol, Phenylephrine Hydrochloride, Chlorpheniramine Maleate and Caffeine Anhydrous Tablets
Batch No.: G17250103
Product ID No.: 1/21
MFC NO: ST/MFC/119/R5
Mfg. Date: 01/2025

BMR COPY/QUALITY CONTROL COPY

22.0 TEST REQUEST FORM FOR BULK TABLETS:

From: Manufacturing Department	To: Q.A. Department
To be filled by production	To be filled by IPQA
Date of Mfg: 01/2025	Quantity Sampled: 100 Nos
Date of exp: 12/2027	No. of containers: 24
Test Request for: Control	Sampled by: N. S. J. on date: 27/01/25
TRF raised by: R. H. on date: 27/01/25	

To be filled by QC
TRF & Sample received Sign & Date: 27/01/25
Sample tested on: 27/01/25

Test Results	Limits
Each uncoated tablet contains:- As per:- Chlorpheniramine maleate - 2.0mg (100.8%) Phenylephrine HCl - 11.10mg (98.1%) Caffeine paracetamol dissolution:- Chlorpheniramine maleate - 90.6% Phenylephrine HCl - 94.8% Caffeine paracetamol - 98.4% Uniformity of content:- Chlorpheniramine maleate - 94.4% Phenylephrine HCl - 94.3%	Added substances i) single maximum: Unknown impurity - 0.004% ii) Total impurity - 0.006% Min Max Avg 95.7% 98.7% 97.2% 101.6% 99.8% 108.4% 104.1% 100.0% 100.4% 98.0% 96.0% 100.9% 99.4%

Analytical Reference no.: SIM260250	Space for QC Approval (Stamping and Signing)
Analysed By: on: 01/02/25	

Title	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designer	QA Head / Designee
Signature with Date	19/01/24	19/01/24	19/01/24

UNCONTROLLED COPY

CONTROLLED COPY

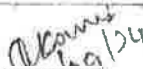
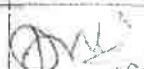
		Safetab Life Science			
BATCH MANUFACTURING RECORD				Page No.:	115 of 116
Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

23.0 BATCH MANUFACTURING RECORD REVIEW CHECK LIST

S.No. No.	CHECK POINTS	Status
1	The entire Page no: <u>1</u> to <u>116</u> are available, verified and found correct.	Yes / No
2	Batch numbers available in all pages verified and are correct.	Yes / No
3	Manufacturing and expiry is correctly allotted verified.	Yes / No
4	Dispensing carried out on calibrated balance verified.	Yes / No
5	Dispensing Cards attached.	Yes / No
6	Line clearance is taken prior to all dispensing and manufacturing activities.	Yes / No
7	Dispensing is carried out as per indent of raw materials are correct.	Yes / No
8	Environmental conditions comply during all the manufacturing steps.	Yes / No
9	All wrong entries if any have been strike out and signed and verified.	Yes / No
10	Actual equipment used is as specified and verified.	Yes / No
11	Blend, Compressed Tablet container labels are attached.	Yes / No
12	Lubrication, Compression and Inspection reconciliation is filled and variance is within acceptance limit.	Yes / No
13	If any deviation, change control or OOS initiated, related to this batch verified and corrective action implemented.	Yes / No / NA
Note:	If any abnormalities noticed during batch manufacturing record review it should be brought to the notice of QA Head.	

Batch Manufacturing Record reviewed by IPQA Sign/Date: 11/02/2025

QA Head Sign/Date: 11/02/2025

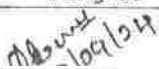
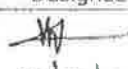
Title	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 11/02/2025	 11/02/2025	 11/02/2025	

UNCONTROLLED COPY

	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD				Page No.:	116 of 116
	Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	12,50,000 Tablets
	Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R6	Supersedes MFC No:	ST/MFC/119/R5
	Batch No.:	G17250103	Mfg.Date:	01/2025	Exp.Date:	12/2027

24.0 REVISION HISTORY:

Revision No.	Date of Revision	Changes Made	Effective Date
00		1. BMR Is Prepared. Refer Change control No.:ST/CC/22/242	09.12.2022
01	09/04/2024	1. Manufacturing from Safetab Life science to GHPL Loan Licence. Refer Change control No.:ST/CC/24/039	18/04/2024
02	19.09.2024	1. As per Approved Vendor List Vendor name has been included. Refer Change control No.:ST/CC/24/249	01/10/2024

Title	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 19/09/24	 19/09/24	 19/09/24	

UNCONTROLLED COPY