

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	1 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800C00 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg. Date:	06/2021	Exp. Date:	05/2024

BATCH MANUFACTURING RECORD COVER SHEET:

PRODUCT NAME	:	GENFORTE TABLET			
LABEL CLAIM	:	Each Uncoated tablet contains: Ibuprofen BP 400mg Paracetamol BP 500mg			
Pack Size	:	TP: 10x1x10's blister pack			
Storage Condition	:	Store in a cool dry place. Protect from light and moisture.			
SHELF LIFE	:	36 MONTHS			
CUSTOMER NAME	:	GENERIC HEALTHCARE PVT.LTD.			
EFFECTIVE BATCH NUMBER	:	GD210601	DATE:	01/06/2021	
MANUFACTURING LICENCE No.	:	07 13 1906			
MFG. DATE:	:	02/06/21 06/020 06/2021	BMR. No	STBMR:118/01	
EXP. DATE:	:	05/2024	Supersedes BMR.No	STBMR:118/00	
BMR ISSUED BY/DATE (QA)	:	02/06/2021			
BMR CHECKED & RECEIVED BY/DATE (PRODUCTION)	:	06/06/21			
Allotted By: QA Executive Sign/Date: 02/06/2021					
DATE OF COMMENCEMENT:		02/06/2021	DATE OF COMPLETION: 06/07/21		
This BMR contains 63 Pages + Annexure -1 + ML Additional Pages					
Checked by Competent Staff Sign/Date: 02/06/21					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	02/06/21	29/05/21	29/05/21

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				BATCH MANUFACTURING RECORD	
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Page No.:	2 of 63
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

1.0 LIST OF EQUIPMENTS:

S.No	Name of Equipment	Equipment ID No. to be used
1	Dispensing Booth	ST/SRWB/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/001 or ST/PRVS/001 or ST/PRVS/001
8	Rapid Mixer Granulator 600LTS	ST/PRRG/005
9	Fluid bed drier 250Kgs	ST/PRFD/003
10	Dry Co Mill	ST/PRDM/001 or ST/PRDM/001
11	Octagonal blender (2200L)	ST/PROB/001
12	Compression Machine	ST/PRCM/001 or ST/PRCM/003 or ST/PRC/004 or ST/PRCM/004
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/IPV/005
17	IR moisture Balance	ST/IPMB/001

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<i>[Signature]</i> 27/05/21	<i>[Signature]</i> 27/05/21	<i>[Signature]</i> 28/05/21	

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	BATCH MANUFACTURING RECORD			Page No.:	3 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

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.	✓	✓

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

Checked by (store) sign/date: *MA 02/06/21* Verified by (IPQA) sign/date: *N. M 02/06/21*

Equipment	Dispensing Booth	Weighing Balance			AREA
Equipment. ID No.	ST/SRDB/001	ST/SRWB/001 (30.0 Kg)	ST/SRWB/002 (620.0g)	ST/WB/189 (150.0 Kg)	
Previous Product & Batch No.	SIPRESIROL - S197904F				
Cleaned By	Bh	Bh	Bh	Bh	Bh
Checked by Stores Sign/Date	<i>MA 02/06/21</i>	<i>MA 02/06/21</i>	<i>MA 02/06/21</i>	<i>MA 02/06/21</i>	<i>MA 02/06/21</i>
Counter checked by IPQA/Sign/Date	<i>N. M 02/06/21</i>	<i>N. M 02/06/21</i>	<i>N. M 02/06/21</i>	<i>N. M 02/06/21</i>	<i>N. M 02/06/21</i>

2.2 ENVIRONMENTAL CONDITIONS:

	Observation	Stores Sign
Temperature: 23°C to 27°C	24.5°C	<i>MA</i>
Relative Humidity: 45% to 55 %	53 %	<i>MA</i>

2.3 APPROVAL FOR DISPENSING BY IPQA: Sign: *N. M* Date: *02/06/21*

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<i>R. K. 27/05/21</i>	<i>27/05/21</i>	<i>27/05/21</i>	

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Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil		
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024		

2.4 INDENT OF RAW MATERIALS:

2.4.1 INDENT OF ACTIVE PHARMACEUTICAL INGREDIENTS:

S.No	Name of the Ingredients	Material Code	Label claim per tablet in mg	Spec	Std Qty per batch (Kg)					Vendor
					Total	Lot I	Lot II	Lot III	Lot IV	
1	Paracetamol BP	RMAP0030	500.000	BP	400.000	100.000	100.000	100.000	100.000	Bharat Chemicals
2	Ibuprofen BP	RMAI0015	400.000	BP	320.000	80.000	80.000	80.000	80.000	IOL Chemicals and Pharmaceuticals Pvt Ltd.

2.4.2 INDENT OF EXCIPIENTS:

S. No	Name of the Ingredients	Material Code	Unit dose per tablet in mg	Spec	Std Qty per batch (Kg)					Vendor
					Total	Lot I	Lot II	Lot III	Lot IV	
3	Maize Starch BP	RMEM0034	55.920	BP	44.736	11.184	11.184	11.184	11.184	Roquette
4	Povidone K 90 BP	RMEP0045	26.000	BP	20.800	5.200	5.200	5.200	5.200	Haungshan Bonsun Pharmaceuticals
5	Propyl Paraben sodium BP	RMEP0048	0.440	BP	0.352	0.088	0.088	0.088	0.088	Rasula Pharmaceuticals and Fine Chemicals
6	Sunset Yellow supra INH	RMES0030	0.140	INH	0.112	0.028	0.028	0.028	0.028	Neelikon
7	Purified Water BP @	RMEP0033	175.000	BP	140.000	35.000	35.000	35.000	35.000	Inhouse
----			982.500	--	786.000	196.500	196.500	196.500	196.500	----
Lubrication										
8	Pregelatinized Starch 1500 BP	RMEP0046	40.000	BP	32.000	32.000				Colercon
9	Sodium Starch Glycolate BP	RMES0029	15.000	BP	12.000	12.000				Roquette
10	Magnesium Stearate BP	RMEM0033	2.500	BP	2.000	2.000				Nitika
----			1040	--	832	---				----

@ Does not appear in final product evaporates during processing.

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Designation Signature with Date	[Signature] 27/05/21	[Signature] 27/05/21	[Signature] 28/05/21	

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Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

2.5 DISPENSING OF RAW MATERIALS AGAINST RAW MATERIAL INDENT:

Dispensing Started at Date 01/06/21 Time 7-00

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	Checked by IPQA
1	Paracetamol BP	I	*	msp/2021/06/06/00985	25.250	0.250	25.000	Rh	ms	N.M
				msp/2021/06/06/00985	25.250	0.250	25.000	Rh	ms	N.M
				msp/2021/06/06/00985	25.250	0.250	25.000	Rh	ms	N.M
				msp/2021/06/06/00985	25.250	0.250	25.000	Rh	ms	N.M
				msp/2021/06/06/00985	0.130	0.020	0.110	Rh	ms	N.M
		II	*	msp/2021/06/06/00985	25.250	0.250	25.000	Rh	ms	N.M
				msp/2021/06/06/00985	25.250	0.250	25.000	Rh	ms	N.M
				msp/2021/06/06/00985	25.250	0.250	25.000	Rh	ms	N.M
				msp/2021/06/06/00985	25.250	0.250	25.000	Rh	ms	N.M
				msp/2021/06/06/00985	0.130	0.020	0.110	Rh	ms	N.M
		III	*	msp/2021/06/06/00985	25.250	0.250	25.000	Rh	ms	N.M
				msp/2021/06/06/00985	25.250	0.250	25.000	Rh	ms	N.M
				msp/2021/06/06/00985	25.250	0.250	25.000	Rh	ms	N.M
				msp/2021/06/06/00985	25.250	0.250	25.000	Rh	ms	N.M
				msp/2021/06/06/00985	0.130	0.020	0.110	Rh	ms	N.M

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Signature with Date	<u>Rshy 27/05/21</u>	<u>[Signature] 27/05/21</u>	<u>[Signature] 28/05/21</u>	



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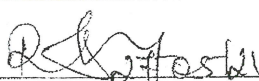
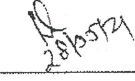
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Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

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	Checked by IPQA
2	Paracetamol BP	IV	*	msp/2021/06/06/00985	25.250	0.250	25.000	Rh	mt	N.M
				msp/2021/06/06/00985	25.250	0.250	25.000	Rh	mt	N.M
				msp/2021/06/06/00985	25.250	0.250	25.000	Rh	mt	N.M
				msp/2021/06/06/00985	25.250	0.250	25.000	Rh	mt	N.M
				msp/2021/06/06/00985	0.130	0.020	0.110	Rh	mt	N.M
	Ibuprofen BP	I	*	msp/2021/06/06/00812	56.400	6.400	50.000	Rh	mt	N.M
				msp/2021/06/06/00812	15.140	0.140	15.000	Rh	mt	N.M
				msp/2021/06/06/00812	15.728	0.140	15.588	Rh	mt	N.M
		II	*	msp/2021/06/06/00812	56.400	6.400	50.000	Rh	mt	N.M
				msp/2021/06/06/00812	15.140	0.140	15.000	Rh	mt	N.M
				msp/2021/06/06/00812	15.728	0.140	15.588	Rh	mt	N.M
		III	*	msp/2021/06/06/00812	56.400	6.400	50.000	Rh	mt	N.M
				msp/2021/06/06/00812	15.140	0.140	15.000	Rh	mt	N.M
				msp/2021/06/06/00812	15.728	0.140	15.588	Rh	mt	N.M
		IV	*	msp/2021/06/06/00812	56.400	6.400	50.000	Rh	mt	N.M
				msp/2021/06/06/00812	15.140	0.140	15.000	Rh	mt	N.M
				msp/2021/06/06/00812	15.728	0.140	15.588	Rh	mt	N.M

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Signature with Date				



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BATCH MANUFACTURING RECORD

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Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

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	Checked by IQQA
3	Maize Starch BP	I	**	msp/2021/veh/ur/00890	10.626	0.140	10.486	Ph	ms	N(m)
		II	**	msp/2021/veh/ur/00890	10.626	0.140	10.486	Ph	ms	N(m)
		III	**	msp/2021/veh/ur/00890	10.626	0.140	10.486	Ph	ms	N(m)
		IV	**	msp/2021/veh/ur/00890	10.626	0.140	10.486	Ph	ms	N(m)
4	Povidone K 90 BP	I	5.200	msp/2021/veh/ur/00996	5.260	0.060	5.200	Ph	ms	N(m)
		II	5.200	msp/2021/veh/ur/00996	5.260	0.060	5.200	Ph	ms	N(m)
		III	5.200	msp/2021/veh/ur/00996	5.260	0.060	5.200	Ph	ms	N(m)
		IV	5.200	msp/2021/veh/ur/00996	5.260	0.060	5.200	Ph	ms	N(m)

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
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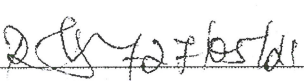
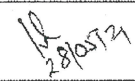
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Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

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	Checked by IPQA
5	Propyl Paraben sodium BP	I	0.088 0.080	msp/2002/bch/aur/00810	0.092	0.004	0.088	Bh	mb	N.M
		II	0.088 0.080	msp/2002/bch/aur/00810	0.092	0.004	0.088	Bh	mb	N.M
		III	0.088 0.080	msp/2002/bch/aur/00810	0.092	0.004	0.088	Bh	mb	N.M
		IV	0.088 0.080	msp/2002/bch/aur/00810	0.092	0.004	0.088	Bh	mb	N.M
6	Sunset Yellow supra INH	I	0.028	msp/1920/bch/aur/01009	0.032	0.004	0.028	Bh	mb	N.M
		II	0.028	msp/1920/bch/aur/01009	0.032	0.004	0.028	Bh	mb	N.M
		III	0.028	msp/1920/bch/aur/01009	0.032	0.004	0.028	Bh	mb	N.M
		IV	0.028	msp/1920/bch/aur/01009	0.032	0.004	0.028	Bh	mb	N.M

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Signature with Date	 27/05/21	 27/05/21	 28/05/21	

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Brand Name

GENFORTE TABLETS

Product ID No.:

977

Batch Size

800000 Tablets

Generic Name:

Ibuprofen (400mg) and Paracetamol (500mg) Tablets

MFC NO:

ST/MFC/118/R0

Supersedes MFC No:

Nil

Batch No.:

GD210601

Mfg.Date:

06/2021

Exp.Date:

05/2024

S.No	Name of the Ingredients	Actual Qty. per batch(Kg)	A.R No:	Gross Weight (Kg)	Tare Weight(Kg)	Net Weight(Kg)	Weighed By Stores	Checked by stores	Checked by IPQA
7	Pregelatinized Starch 1500 BP	32.000	msp/2021/06/06/00884	15.140	0.140	15.000	Rhr	ms	N.M
			msp/2021/06/06/00884	17.140	0.140	17.000	Rhr	ms	N.M
8	Sodium Starch Glycolate BP	12.000	msp/2021/06/06/01033	12.140	0.140	12.000	Rhr	ms	N.M
			-	-	-	-	-	-	-
9	Magnesium Stearate BP	2.000	msp/2021/06/06/00916	2.016	0.016	2.000	Rhr	ms	N.M
			-	-	-	-	-	-	-

Dispensing Completed at Date 07/06/21 Time 8.45

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>Rhr 27/05/21</u>	<u>27/05/21</u>	<u>28/05/21</u>	

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	BATCH MANUFACTURING RECORD			Page No.:	10 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

3.0 CALCULATION:

3.1 Potency calculation for Paracetamol :

Q.C AR.No. for Paracetamol	Expiry Date	Assay of Paracetamol on dried basis	LOD %
MSP/2021/06/01/00785	01/2026	100.600	0.110
—	—	—	—

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

$$500 \times 100 \times 100$$

Actual quantity of Paracetamol = -----mg/tablet

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

$$\frac{5000000}{9989} = 500.51 \text{ mg/tablet}$$

*Qty of Paracetamol to be added per batch = 400.441 Kg's

Lot I= 100.110 Kg's

Lot II= 100.110 Kg's

Lot III= 100.110 Kg's

Lot IV= 100.110 Kg's

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

Calculation done by(store)/date:

MA
02/06/21

checked by(production)/date:

MA
02/06/21

Verified by(QA)/date:

MA
02/06/21

Designation	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.:	11 of 63	
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

3.2 Potency calculation for Ibuprofen:

Q.C AR.No. for Ibuprofen	Expiry Date	Assay of Ibuprofen on dried basis	LOD %
12SP/2021/QCH/ALP/00812	10/2025	99.300	0.030

*The mentioned quantity of Ibuprofen is based on 100% assay on dried basis, and without LOD.
Actual quantity of Ibuprofen to be added is calculated as below.

$$400 \times 100 \times 100$$

Actual quantity of Ibuprofen = -----mg/tablet

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

$$= \frac{4000000}{99.2701} = 402.941 \text{ mg/tablet}$$

*Qty of Ibuprofen to be added per batch = 822.353 Kg's

Lot I= 80.588 Kg's

Lot II= 80.588 Kg's

Lot III= 80.588 Kg's

Lot IV= 80.588 Kg's

Quantity Maize starch varies based on assay content of Paracetamol and Ibuprofen for keeping the core tablet weight constant.
Hence,

** Qty of Maize starch to be added per batch = 41.942 Kg's

Lot I= 10.486 Kg's

Lot II= 10.486 Kg's

Lot III= 10.486 Kg's

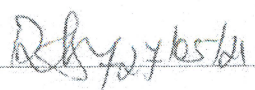
Lot IV= 10.486 Kg's

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

Calculation done by(store)/date:

checked by(production)/date:

Verified by(QA)/date:

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

	Safetab Life Science		MASTER COPY		
	BATCH MANUFACTURING RECORD		Page No.:	12 of 63	
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

4.0 VERIFICATION OF DISPENSED MATERIALS:

S.No	Name of the Ingredients	Lot	Gross weight in Kg	A.R.No.	Checked by Production Sign/Date	Checked by IPQA Sign/Date
1	Paracetamol BP	I	25.25	m8p/2021/aw/aw/00985	03/06/21	03/06/21
			25.25	m8p/2021/aw/aw/00985	03/06/21	03/06/21
			25.25	m8p/2021/aw/aw/00985	03/06/21	03/06/21
			25.25	m8p/2021/aw/aw/00985	03/06/21	03/06/21
			0.13	m8p/2021/aw/aw/00985	03/06/21	03/06/21
		II	25.25	m8p/2021/aw/aw/00985	03/06/21	03/06/21
			25.25	m8p/2021/aw/aw/00985	03/06/21	03/06/21
			25.25	m8p/2021/aw/aw/00985	03/06/21	03/06/21
			25.25	m8p/2021/aw/aw/00985	03/06/21	03/06/21
			0.13	m8p/2021/aw/aw/00985	03/06/21	03/06/21
		III	25.25	m8p/2021/aw/aw/00985	03/06/21	03/06/21
			25.25	m8p/2021/aw/aw/00985	03/06/21	03/06/21
			25.25	m8p/2021/aw/aw/00985	03/06/21	03/06/21
			25.25	m8p/2021/aw/aw/00985	03/06/21	03/06/21
			0.13	m8p/2021/aw/aw/00985	03/06/21	03/06/21
		IV	25.25	m8p/2021/aw/aw/00985	03/06/21	03/06/21
			25.25	m8p/2021/aw/aw/00985	03/06/21	03/06/21
			25.25	m8p/2021/aw/aw/00985	03/06/21	03/06/21
			25.25	m8p/2021/aw/aw/00985	03/06/21	03/06/21
			0.13	m8p/2021/aw/aw/00985	03/06/21	03/06/21
2	Ibuprofen BP	I	15.73	m8p/2021/aw/aw/00812	03/06/21	03/06/21
			15.14	m8p/2021/aw/aw/00812	03/06/21	03/06/21
			56.40	m8p/2021/aw/aw/00812	03/06/21	03/06/21
				N.A.	03/06/21	03/06/21
		II	15.14	m8p/2021/aw/aw/00812	03/06/21	03/06/21
			56.40	m8p/2021/aw/aw/00812	03/06/21	03/06/21
			15.73	m8p/2021/aw/aw/00812	03/06/21	03/06/21
				N.A.	03/06/21	03/06/21
		III	56.40	m8p/2021/aw/aw/00812	03/06/21	03/06/21
			15.14	m8p/2021/aw/aw/00812	03/06/21	03/06/21
			15.73	m8p/2021/aw/aw/00812	03/06/21	03/06/21
				N.A.	03/06/21	03/06/21
		IV	56.40	m8p/2021/aw/aw/00812	03/06/21	03/06/21
			15.73	m8p/2021/aw/aw/00812	03/06/21	03/06/21
			15.14			

Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	Signature with Date	Signature with Date	
<i>[Signature]</i> 27/05/21	<i>[Signature]</i> 27/05/21	<i>[Signature]</i> 28/05/21	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	13 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

S.No	Name of the Ingredients	Lot	Gross weight in Kg	A.R.No.	Checked by Production Sign/Date	Checked by IPQA Sign/Date
3	Maize Starch BP	I	10.63	mSP/2021/AW/AU/00890	S03/06/21	S03/06/21
			N.O	N.O	S03/06/21	NA
			N.O	N.O	S03/06/21	NA
		II	10.63	mSP/2021/AW/AU/00890	S03/06/21	S03/06/21
			N.O	N.O	S03/06/21	NA
			N.O	N.O	S03/06/21	NA
		III	10.63	mSP/2021/AW/AU/00890	S04/06/21	S04/06/21
			N.O	N.O	S04/06/21	NA
		IV	10.63	mSP/2021/AW/AU/00890	S04/06/21	S04/06/21
			N.O	N.O	S04/06/21	NA
		I	5.26	mSP/2021/AW/AU/00996	S03/06/21	S03/06/21
			N.O	N.O	S03/06/21	NA
			N.O	N.O	S03/06/21	NA
4	Povidone K 90 BP	II	5.26	mSP/2021/AW/AU/00996	S03/06/21	S03/06/21
			N.O	N.O	S03/06/21	NA
			N.O	N.O	S03/06/21	NA
		III	5.26	mSP/2021/AW/AU/00996	S03/06/21	S03/06/21
			N.O	N.O	S03/06/21	NA
			N.O	N.O	S03/06/21	NA
		IV	5.26	mSP/2021/AW/AU/00996	S04/06/21	S04/06/21
			N.O	N.O	S04/06/21	NA
			N.O	N.O	S04/06/21	NA
		I	0.09	mSP/2021/AW/AU/00810	S03/06/21	S03/06/21
			N.O	N.O	S03/06/21	NA
			N.O	N.O	S03/06/21	NA
5	Propyl Paraben sodium BP	II	0.09	mSP/2021/AW/AU/00810	S03/06/21	S03/06/21
			N.O	N.O	S03/06/21	NA
			N.O	N.O	S03/06/21	NA
		III	0.09	mSP/2021/AW/AU/00810	S03/06/21	S03/06/21
			N.O	N.O	S03/06/21	NA
			N.O	N.O	S03/06/21	NA
		IV	0.09	mSP/2021/AW/AU/00810	S04/06/21	S04/06/21
			N.O	N.O	S04/06/21	NA
			N.O	N.O	S04/06/21	NA
		I	0.09	mSP/2021/AW/AU/00810	S03/06/21	S03/06/21
			N.O	N.O	S03/06/21	NA
			N.O	N.O	S03/06/21	NA

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

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	14 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

S.No	Name of the Ingredients	Lot	Gross weight in Kg	A.R.No.	Checked by Production Sign/Date	Checked by IPQA Sign/Date
6	Sunset Yellow supra INH	I	0.03	msp/1920/qw/qw/01009	03/06/21	03/06/21
			N.A	N.A	03/06/21	NA
			N.A	N.A	03/06/21	NA
		II	0.03	msp/1920/qw/qw/01009	03/06/21	03/06/21
			N.A	N.A	03/06/21	NA
			N.A	N.A	03/06/21	NA
		III	0.03	msp/1920/qw/qw/01009	04/06/21	04/06/21
			N.A	N.A	04/06/21	NA
			N.A	N.A	04/06/21	NA
		IV	0.03	msp/1920/qw/qw/01009	04/06/21	04/06/21
			N.A	N.A	04/06/21	NA
			N.A	N.A	04/06/21	NA
7	Pregelatinized Starch 1500 BP		17.14	msp/2021/qw/qw/01009	04/06/21	04/06/21
			15.14	msp/2021/qw/qw/01009	04/06/21	04/06/21
			N.A	N.A	04/06/21	NA
			N.A	N.A	04/06/21	NA
8	Sodium Starch Glycolate BP		12.14	msp/2021/qw/qw/01009	04/06/21	04/06/21
			N.A	N.A	04/06/21	NA
			N.A	N.A	04/06/21	NA
			N.A	N.A	04/06/21	NA
9	Magnesium Stearate BP		2.02	msp/2021/qw/qw/01009	04/06/21	04/06/21
			N.A	N.A	04/06/21	NA
			N.A	N.A	04/06/21	NA
			N.A	N.A	04/06/21	NA
10	Purified water		0	N.A	04/06/21	NA
			N.A	N.A		
			N.A	N.A		
			N.A	N.A		

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.

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 27/05/21	 27/05/21	 28/05/21	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	15 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

5.0 GRANULATION:

5.1 LINE CLEARANCE CHECKS:

S.No	Check	Observation	
		Production	IPQA
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: 03/06/21

Verified by (IPQA) sign/date: 03/06/21

Equipment	Vibro sifter	Dry co mill	FBD	RMG	Balance
Equipment ID No:	STIPRVST001	STIPRDM 001	STIPRFDI 003	STIPRRG 1005	STIPRWB 1009
Previous Product:	Pulmoclear				
Batch No.	321108106E				
Cleaned by:	Vinoth				
Checked by:	Production: <u>B</u>		IPQA: <u>sh</u>		

5.2 ENVIRONMENTAL CONDITIONS	Date: <u>03/06/21</u>	Time: <u>14:00</u>	Date:	Time:
	Observation	Production Sign	Observation	Production Sign
Temperature: 23°C to 27°C	23.4°C	<u>B</u>		
Relative Humidity: 45% to 55 %	54%	<u>B</u>		

5.3 APPROVAL FOR SIFTING:

Production Sign/Date: 03/06/21

IPQA Sign/Date: 03/06/21

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>R. Sathish</u> 29/05/21	<u>S. Sathish</u> 29/05/21	<u>sh</u> 29/05/21	CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
BATCH MANUFACTURING RECORD			Page No.:	16 of 63	
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

5.4 SIFTING INSTRUCTIONS:

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

5.5 SIFTING RECORD: LOT I

S. No	Name of Ingredient	Size of sieve	Integrity checked before use*	Integrity checked after use*	Done by	Checked By/date
1	Paracetamol BP	30#	OK/ Not OK	OK/ Not OK	Vinora	03/06/24
2	Ibuprofen BP	30#	OK/ Not OK	OK/ Not OK	Vinora	03/06/24
3	Maize Starch BP	30#	OK/ Not OK	OK/ Not OK	Vinora	03/06/24
Lubrication						
4	Pregelatinized Starch 1500 BP	40#	OK/ Not OK	OK/ Not OK	Santhosh	03/06/24
5	Sodium Starch Glycolate BP	40#	OK/ Not OK	OK/ Not OK	Santhosh	03/06/24
6	Magnesium Stearate BP	60#	OK/ Not OK	OK/ Not OK	Santhosh	03/06/24

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 as¹.

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 07/05/24	 27/05/24	 30/5/24	

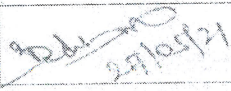
	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	17 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

5.6 MANUFACTURING PROCESS: LOT I

Step No	Process Instructions	Date : 03/06/24		Done By	Checked by/Date
		Time			
		Started	Completed		
5.6.1	Sifting: Co sift Paracetamol, Ibuprofen and Maize starch through 30#.	14:05	14:40	Vinoth	03/06/24
5.6.2	Dry mixing: Transfer the sifted material into 600 L RMG.	14:41	14:45	Vinoth	03/06/24
	Mix for 10minutes at slow/fast impeller speed and chopper ON at slow/fast speed.	14:50	15:00	Vinoth	03/06/24
5.6.3	Binder preparation: Add Propyl Paraben Sodium and Sunset Yellow supra in Purified water and dissolve until to get clear solution. To this add Povidone K90 and dissolve until to get clear coloured solution.	14:40	15:00	Sathish	03/06/24
5.6.4	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.	15:05	15:08	Vinoth	03/06/24
	Kneading:	15:09	15:10	Vinoth	03/06/24
	Mixing: 2-5 minutes mixing at fast/slow speed impeller/chopper ON at fast/slow speed.	15:12	15:14	Vinoth	03/06/24
	If required add additional Purified water and mix for 2-3minutes to form a required granules. Additional Purified Water added _____ Kg	NA	NA	NA	NA
	Discharge the wet granules in FBD bowl for drying.				

5.7 DRYING: LOT I

Step No	Instructions	Done by	Checked by	Date
1	Use hand gloves, nose mask while handling the materials.	VinOTH		03/06/24
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.			

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

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	18 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

5.7.1 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 drying the granules at inlet temperature of 50°C± 5 °C with intermittent racking between every 10-15 minutes to achieve LOD limit 0.6%-1.2%.	15:30	16:30	Vinoth	03/06/24
3	LOD%: limit 0.6%-1.2% on IR Moisture balance at 60°C.	Observed LOD%: 1.02%			
4	Sift the dried granules through 16#.	16:40	17:15	Sathish	03/06/24
5	Mesh integrity checks.	Before use OK/ Not OK	After use OK/ Not OK	Sathish	03/06/24
6	Mill the retained granules through 2.0mm screen and pass through 20#.	17:20	17:40	Sathish	03/06/24
7	Screen integrity checks.	Before use OK/ Not OK	After use OK/ Not OK	Sathish	03/06/24

5.8 DRIED GRANULES WEIGHT RECORD: LOT I

Container No	Gross weight (Kg)	Tare weight (Kg)	Net weight (Kg)	Weighed By	Checked By/ Date
1	42.31	0.16	42.15	Sathish	03/06/24
2	39.12	0.16	38.96		
3	41.28	0.16	41.12		
4	40.26	0.16	40.10		
5	33.96	0.16	33.79		
6	1				
7		NA			
Total weight of dried granules (Kg):			196.12		

5.9 SIFTING RECORD: LOT II

S. No	Name of Ingredient	Size of sieve	Integrity checked before use*	Integrity checked after use*	Done by	Checked By/date
1	Paracetamol BP	30#	OK/ Not OK	OK/ Not OK	Vinoth	03/06/24
2	Ibuprofen BP	30#	OK/ Not OK	OK/ Not OK	Vinoth	03/06/24
3	Maize Starch BP	30#	OK/ Not OK	OK/ Not OK	Vinoth	03/06/24

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 asv.

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

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	19 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

5.10 MANUFACTURING PROCESS: LOT II

Step No	Process Instructions	Date : 06/06/21		Done By	Checked by/Date
		Time			
		Started	Completed		
5.10.1	Sifting: Co sift Paracetamol, Ibuprofen and Maize starch through 30#.	06:10	06:50	Sriron	06/06/21
5.10.2	Dry mixing: Transfer the sifted material into 600 L RMG.	06:52	07:00	Sriron	06/06/21
	Mix for 10minutes at slow/fast impeller speed and chopper ON at slow/fast speed.	07:02	07:12	Sriron	06/06/21
5.10.3	Binder preparation: Add Propyl Paraben Sodium and Sunset Yellow supra in Purified water and dissolve until to get clear solution. To this add Povidone K90 and dissolve until to get clear coloured solution.	06:20	06:40	Sriron	06/06/21
5.10.4	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.	07:15	07:18	Sriron	06/06/21
	Kneading:	07:20	07:22	Sriron	06/06/21
	Mixing: 2-5 minutes mixing at fast/slow speed impeller/chopper ON at fast/slow speed.	07:23	07:25	Sriron	06/06/21
	If required add additional Purified water and mix for 2-3minutes to form a required granules. Additional Purified Water added <u>Nil</u> Kg	Nil	Nil	Nil	Nil
	Discharge the wet granules in FBD bowl for drying.				

5.11 DRYING: LOT II

Step No	Instructions	Done by	Checked by	Date
1	Use hand gloves, nose mask while handling the materials.	Sriron	06/06/21	06/06/21
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.			

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 06/06/21	 27/05/21	 28/05/21	CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	20 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

5.11.1 DRYING AND SIZING DETAILS: LOT II

Step	Process	Start Time	End Time	Done by	Checked by/date
1	Load the Wet granules into FBD and drying the granules at inlet temperature of 50°C± 5 °C with intermittent racking between every 10-15 minutes to achieve LOD limit 0.6%-1.2%.	07:30	08:30	Snoth	29/05/21
3	LOD%: limit 0.6%-1.2% on IR Moisture balance at 60°C.	Observed LOD%: 0.927.			
4	Sift the dried granules through 16#.	08:35	09:05	Srinan	29/05/21
5	Mesh integrity checks.	Before use OK/ Not OK	After use OK/ Not OK	Srinan	29/05/21
6	Mill the retained granules through 2.0mm screen and pass through 20#.	09:08	09:28	Sathish	29/05/21
7	Screen integrity checks.	Before use OK/ Not OK	After use OK/ Not OK	Sathish	29/05/21

5.12 DRIED GRANULES WEIGHT RECORD: LOT II

Container No	Gross weight (Kg)	Tare weight (Kg)	Net weight (Kg)	Weighed By	Checked By/ Date
1	45.31	0.16	45.15	Sanna	29/05/21
2	44.35	0.16	44.19		
3	40.08	0.16	39.92		
4	35.86	0.16	35.10		
5	31.31	0.16	31.15		
6	1				
7		NA			
Total weight of dried granules (Kg):			195.51g		

5.13 SIFTING RECORD: LOT III

S. No	Name of Ingredient	Size of sieve	Integrity checked before use*	Integrity checked after use*	Done by	Checked By/date
1	Paracetamol BP	30#	OK/ Not OK	OK/ Not OK	Sathish	29/05/21
2	Ibuprofen BP	30#	OK/ Not OK	OK/ Not OK	Sathish	29/05/21
3	Maize Starch BP	30#	OK/ Not OK	OK/ Not OK	Sathish	29/05/21

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 asv.

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 29/05/21	 29/05/21	 28/05/21	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	21 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

5.14 MANUFACTURING PROCESS: LOT III

Step No	Process Instructions	Date : 01/06/21		Done By	Checked by/Date
		Time			
		Started	Completed		
5.14.1	Sifting: Co sift Paracetamol, Ibuprofen and Maize starch through 30#.	09:30	10:05	Sahish	01/06/21
5.14.2	Dry mixing: Transfer the sifted material into 600 L RMG.	10:08	10:12	Sahish	01/06/21
	Mix for 10minutes at slow/fast impeller speed and chopper ON at slow/fast speed.	10:14	10:24	Sahish	01/06/21
5.14.3	Binder preparation: Add Propyl Paraben Sodium and Sunset Yellow supra in Purified water and dissolve until to get clear solution. To this add Povidone K90 and dissolve until to get clear coloured solution.	10:10	10:30	Vijayabala	01/06/21
5.14.4	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.	10:32	10:35	Sirm	01/06/21
	Kneading:	10:36	10:38	Sirm	01/06/21
	Mixing: 2-5 minutes mixing at fast/slow speed impeller/chopper ON at fast/slow speed.	10:40	10:42	Sirm	01/06/21
	If required add additional Purified water and mix for 2-3minutes to form a required granules. Additional Purified Water added <u>NA</u> Kg	NA	NA	NA	NA
	Discharge the wet granules in FBD bowl for drying.				

5.15 DRYING: LOT III

Step No	Instructions	Done by	Checked by	Date
1	Use hand gloves, nose mask while handling the materials.	Vijayabala	S	01/06/21
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.			

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 27/05/21	 27/05/21	 28/05/21	CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	22 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC No:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

5.15.1 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 drying the granules at inlet temperature of 50°C± 5 °C with intermittent racking between every 10-15 minutes to achieve LOD limit 0.6%-1.2%.	10:50	11:50	Srijata	Kaibab
3	LOD%: limit 0.6%-1.2% on IR Moisture balance at 60°C.	Observed LOD%: 1.031.			
4	Sift the dried granules through 16#.	12:00	12:25	Satish	Kaibab
5	Mesh integrity checks.	Before use OK/ Not OK	After use OK/ Not OK	Satish	Kaibab
6	Mill the retained granules through 2.0mm screen and pass through 20#.	12:30	13:05	Sriram	Kaibab
7	Screen integrity checks.	Before use OK/ Not OK	After use OK/ Not OK	Sriram	Kaibab

5.16 DRIED GRANULES WEIGHT RECORD: LOT III

Container No	Gross weight (Kg)	Tare weight (Kg)	Net weight (Kg)	Weighed By	Checked By/ Date
1	31.08	0.16	30.92	Sriram	Kaibab
2	hh.39	0.16	hh.23		
3	h6.88	0.16	h6.72		
4	33.58	0.16	33.42		
5	39.06	0.16	38.89		
6	1				
7		NA		Kaibab	
Total weight of dried granules (Kg):			19h.18		

5.17 SIFTING RECORD: LOT IV

S. No	Name of Ingredient	Size of sieve	Integrity checked before use*	Integrity checked after use*	Done by	Checked By/date
1	Paracetamol BP	30#	OK/ Not OK	OK/ Not OK	Sriram	04/06/24
2	Ibuprofen BP	30#	OK/ Not OK	OK/ Not OK	Sriram	04/06/24
3	Maize Starch BP	30#	OK/ Not OK	OK/ Not OK	Sriram	04/06/24

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 asv.

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	Rajy 27/05/24	27/05/24	28/05/24

CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	23 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC No.:	ST/MFC/118/R0	Supersedes MFC No.:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

5.18 MANUFACTURING PROCESS: LOT IV

Step No	Process Instructions	Date : 04/06/24		Done By	Checked by/Date
		Time			
		Started	Completed		
5.18.1	Sifting: Co sift Paracetamol, Ibuprofen and Maize starch through 30#.	13:30	14:15	Srisom	04/06/24
5.18.2	Dry mixing: Transfer the sifted material into 600 L RMG.	14:16	14:20	Srisom	04/06/24
	Mix for 10minutes at slow/fast impeller speed and chopper ON at slow/fast speed.	14:25	14:35	Srisom	04/06/24
5.18.3	Binder preparation: Add Propyl Paraben Sodium and Sunset Yellow supra in Purified water and dissolve until to get clear solution. To this add Povidone K90 and dissolve until to get clear coloured solution.	14:00	14:20	Vinorh	04/06/24
5.18.4	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.	14:37	14:40	Vinorh	04/06/24
	Kneading:	14:41	14:43	Vinorh	04/06/24
	Mixing: 2-5 minutes mixing at fast/slow speed impeller/chopper ON at fast/slow speed.	14:45	14:47	Vinorh	04/06/24
	If required add additional Purified water and mix for 2-3minutes to form a required granules. Additional Purified Water added _____ Kg	NA	NA	NA	NA
	Discharge the wet granules in FBD bowl for drying.				

5.19 DRYING: LOT IV

Step No	Instructions	Done by	Checked by	Date
1	Use hand gloves, nose mask while handling the materials.	Vinorh	04/06/24	04/06/24
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.			

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 27/05/24	 27/05/24	 28/05/24	CONTROLLED COPY

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	BATCH MANUFACTURING RECORD			Page No.:	24 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

5.19.1 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 drying the granules at inlet temperature of 50°C± 5 °C with intermittent racking between every 10-15 minutes to achieve LOD limit 0.6%-1.2%.	15:00	16:05	Sriram	04/06/24
3	LOD%: limit 0.6%-1.2% on IR Moisture balance at 60°C.	Observed LOD%: 1.10%			
4	Sift the dried granules through 16#.	16:20	16:50	Visayabala	04/06/24
5	Mesh integrity checks.	Before use	After use	Visayabala	04/06/24
		OK/ Not OK	OK/ Not OK		
6	Mill the retained granules through 2.0mm screen and pass through 20#.	16:55	17:25	Visayabala	04/06/24
7	Screen integrity checks.	Before use	After use	Visayabala	04/06/24
		OK/ Not OK	OK/ Not OK		

5.20 DRIED GRANULES WEIGHT RECORD: LOT IV

Container No	Gross weight (Kg)	Tare weight (Kg)	Net weight (Kg)	Weighed By	Checked By/ Date
1	49.34	0.16	49.18	Visayabala	04/06/24
2	39.06	0.16	38.90		
3	44.80	0.16	44.64		
4	32.31	0.16	32.15		
5	31.55	0.16	31.39		
6	1				
7					
Total weight of dried granules (Kg):			196.264		

Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	Signature with Date	Signature with Date	
<i>[Signature]</i> 27/05/24	<i>[Signature]</i> 27/05/24	<i>[Signature]</i> 28/05/24	

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BATCH MANUFACTURING RECORD				Page No.:	25 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

6.0 BLENDING AND LUBRICATION:

6.1 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.	✓	✓

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

Checked by (production) sign/date: *[Signature]* 27/06/21

Verified by (IPQA) sign/date: *[Signature]* 27/06/21

Equipment	Octagonal blender (2200L)		
Code No	ST/PROB/001		
Previous product	Suresh to 1		
Batch No	S2127 924E		
Cleaned by:	<i>[Signature]</i>		
Checked by:	Production: <i>[Signature]</i>	IPQA: <i>[Signature]</i>	

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	<i>[Signature]</i> 27/06/21	<i>[Signature]</i> 27/06/21	<i>[Signature]</i> 28/06/21

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	BATCH MANUFACTURING RECORD		Page No.:	26 of 63	
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

6.2 ENVIRONMENTAL CONDITIONS:	Date: 04/06/24	Time: 18:30	Date:	Time:
	Observation	Production Sign	Observation	Production Sign
Temperature: 23°C to 27°C	24.16	X		
Relative Humidity: 45% to 55 %	51 %	X		X
6.3 APPROVAL FOR BLENDING AND LUBRICATION:				
Production Sign/Date: X 04/06/24		IPQA Sign/Date: X 04/06/24		

6.4 BLENDING AND LUBRICATION INSTRUCTION:

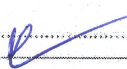
Step No.	Process Instructions	Date: 04/06/24		Done by	Checked by/Date
		Time			
		Started	Completed		
1	Use hand gloves, nose mask while handling the materials.				
2	Operate the Octagonal Blender as per the current version of the SOP.				
3	Co sift Pregelatinized starch and Sodium starch glycolate through 40#.	18:40	18:54	Balaji	X 04/06/24
4	Load the sifted materials along with the dried granules into the Octagonal blender.	18:55	19:19	Balaji	X 04/06/24
5	Mix for 15minutes.	19:20	19:45	Balaji	X 04/06/24
6	Sift Magnesium Stearate through 60# and distribute / sprinkle over the blended material.	19:46	19:51	Balaji	X 04/06/24
7	Mix for 5 minutes.	19:52	19:57	Balaji	X 04/06/24
8	Unload the final blend into suitable containers lined with double polythene bag container with proper label.	20:00	20:15	Balaji	X 04/06/24
9	Record the weight in below mentioned table.				

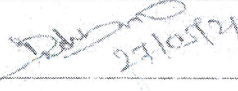
	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	R. S. 27/05/24	[Signature] 27/05/24	[Signature] 28/05/24	

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Brand Name	GENFORTE TABLETS	Product ID No.:	577	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

6.5 WEIGHING OF FINAL BLEND: Date: 04/06/21

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	39.32	2.50	36.82	Sriram	04/06/21	31					
2	45.50	2.50	43.00	Sriram	04/06/21	32					
3	32.85	2.50	30.35	Sriram	04/06/21	33					
4	41.22	2.50	38.72	Sriram	04/06/21	34					
5	44.42	2.50	41.92	Sriram	04/06/21	35					
6	43.92	2.50	41.42	Sriram	04/06/21	36					
7	42.02	2.50	39.52	Sriram	04/06/21	37					
8	44.33	2.50	41.83	Sriram	04/06/21	38					
9	43.38	2.50	40.88	Sriram	04/06/21	39					
10	45.92	2.50	43.42	Sriram	04/06/21	40					
11	38.56	2.50	36.06	Sriram	04/06/21	41					
12	41.48	2.50	38.98	Sriram	04/06/21	42					
13	39.03	2.50	36.53	Sriram	04/06/21	43					
14	50.83	2.50	48.33	Sriram	04/06/21	44					
15	55.65	2.50	53.15	Sriram	04/06/21	45					
16	34.65	2.50	32.15	Sriram	04/06/21	46					
17	53.13	2.50	50.63	Sriram	04/06/21	47					
18	50.62	2.50	48.12	Sriram	04/06/21	48					
19	42.55	2.50	40.05	Sriram	04/06/21	49					
20	21.24	2.50	18.74	Sriram	04/06/21	50					
21						51					
22						52					
23						53					
24						54					
25						55					
26						56					
27						57					
28						58					
29						59					
30						60					
Total weight of Lubricated granules:							824.67 kg				

Intimate IPQA to draw the sample.		Sample withdrawn by IPQA	
Production Sign: 	Date: 04/06/21	IPQA Sign: 	Date: 04/06/21
Send Test request form for lubricated granules to QC department.			

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

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Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

7.0 RECONCILIATION:

1.0	Theoretical weight of blend	:	832.000 Kg
2.0	Actual weight of blend	:	824.67 Kg
3.0	Manufacturing Loss (1.0 - 6.0)	:	6.66 Kg
4.0	In-process samples	:	
	A IPQA Samples	:	Nil Kg
	B QC Samples	:	0.05 Kg
	C Validation Samples + Hotel trace study	:	0.12 + 0.50 Kg
5.0	Total samples: (A + B + C)	:	0.67 Kg
6.0	Total: (2.0 + 5.0)	:	825.34 Kg
7.0	% Yield = $\frac{6.0}{1.0} \times 100$ (Limit- NLT 99.00%)*	:	99.20 %

*Tentative limit

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: 6.66 Kg (Rejected materials should be destroyed in the presence of QA)

Done by Production sign/Date: [Signature] 25/06/21

Checked by IPQA sign/Date: [Signature] 25/06/21

Reconciliation done by Production sign/Date: [Signature] 25/06/21

Checked by IPQA sign/Date: [Signature] 25/06/21

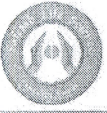
7.1 BLENDED GRANULES RELEASED FOR COMPRESSION:

Reconciliation checked and blended granules released for compression.

Production sign/Date: [Signature] 23/06/21

IPQA sign/Date: [Signature] 23/06/21

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	[Signature] 25/06/21	[Signature] 27/06/21	[Signature] 28/06/21	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	29 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

8.0 COMPRESSION:

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 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.	✓	✓

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

Checked by (production) sign/date: S. Pi 23/06/2021

Verified by (IPQA) sign/date: G. 23/06/21

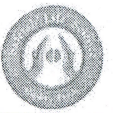
Equipment	Double Rotary/Single Rotary Compression Machine	Balance	Area
Equipment ID No.:	ST/PRCM/001 or ST/PRCM/003 or ST/PRC/004	ST/WB/202	
Previous product:	Ace-2		
Batch No.	S2196002F		

8.2 ENVIRONMENTAL CONDITIONS:	Date: <u>23/06/2021</u>		Date:	
	Observation	Production Sign	Observation	Production sign
Temperature: 23°C to 27°C	24°C	S. Pi	NA	
Relative Humidity: 45% to 55 %	52%	S. Pi		

8.3 APPROVAL FOR COMPRESSION:

Production sign/Date: S. Pi 23/06/2021 IPQA sign/Date: G. 23/06/21

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>[Signature]</u> 27/05/21	<u>[Signature]</u> 27/05/21	<u>[Signature]</u> 28/05/21	CONTROLLED COPY

		Safetab Life Science		BATCH MANUFACTURING RECORD		Page No.: 30 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets	
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	NT	
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024	

8.4 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): <u>S. Pi 23/06/21</u> verified by/date(IPQA): <u>Q. 23/06/21</u>				
3	Set the 27/20 - station double/single rotary compression machine with Upper Punch : 19.3x9.0mm oval shape biconcave with score. Lower punch : 19.3x9.0mm oval shape biconcave plain. Dies : 19.3x9.0mm.				
4	Transfer the blend to compression cubicle. Load the granules in both the hoppers of the compression machine.	17:00	19:00	Baskar	S. Pi 23/06/21
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.	19:10	19:25	Baskar	S. Pi 23/06/21
6	Check the initial tablet for all the parameters as described below and set the machine accordingly.	20:00	20:20	Baskar	S. Pi 23/06/21
7	Collect the compressed tablets in polythene bag lined and labeled cleaned containers.	20:25	20:35	Baskar	S. Pi 23/06/21
8	Check and record the weight of the compressed tablets.	20:45	20:55	Baskar	S. Pi 23/06/21

8.5 COMPRESSION SPECIFICATION/PARAMETERS:

S. No	Parameter	Limits	No. of tablets to be checked from each side	Frequency	
				Prod	IPQA
1	Appearance	Light orange coloured oval shape biconvex uncoated tablets with half break line on one side and plain on another side.	20	Every 30 min	Every 1 hr
2	Average weight	1040mg $\pm$ 3.00% (1008.800mg-1071.200mg)	20	Every 30 min	Every 1 hr
3	Weight of 20 tablets	20.800g $\pm$ 3.00% (20.176g to 21.424g)	20	Every 30 min	Every 1 hr
4	Uniformity of weight	$\pm$ 5% of average weight (988.000mg to 1092.000mg)	20	Every 1 hr	Every 2 hr
5	Hardness	160 N to 230 N (To be monitored)	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	7.90mm $\pm$ 0.3mm (7.60mm to 8.20 mm) (To be monitored)	5	Every 30 min	Every 1 hr
8	Friability	NMT 1.0%	20	Every 1 hr	Every 2 hr

M/C set up done by (Operator): Baskar Date: 23/06/21
 M/C set up checked by (Production): S. Pi Date: 23/06/21
 M/C set up checked by IPQA Sign: [Signature] Date: 23/06/21

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	<u>[Signature]</u> 23/06/21	<u>[Signature]</u> 23/06/21	<u>[Signature]</u> 23/06/21

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	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	31 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

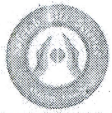
8.5.1 MACHINE SETTING FOR COMPRESSION: (UNIFORMITY OF WEIGHT AND THICKNESS)

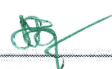
Parameters	Instrument used	Observations of LHS		Observations of RHS		Limits
		Min	Max	Min	Max	
Uniformity of weight	Balance	1024	1065	1026	1064	±5% of average weight (988.000mg to 1092.000mg)
Group weight of 20 tablets	Balance	20.802		20.824		20.800g±3.00% (20.176g to 21.424g)
Average weight	Balance	1040		1041		1040mg± 3.00% (1008.800mg-1071.200mg)
Hardness	Hardness tester	201		200		160 N to 230 N (To be monitored)
Thickness	Vernier	7.81 mm		7.80 mm		7.90mm± 0.3mm (7.60mm to 8.20 mm) (To be monitored)
Friability	Friabilator	0.13%		0.14%		NMT 1.0%
DT	DT Apparatus	01 minutes 49 sec		01 minutes 40 sec		NMT 15 mins at 37°C±2°C
Appearance	visual	Complies		Complies		Light orange coloured oval shape biconvex uncoated tablets with half break line on one side and plain on another side.

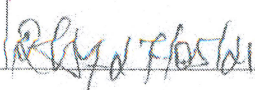
LEFT HAND SIDE (LHS)						RIGHT HAND SIDE (RHS)					
Sr. No.	Weight	Thickness	Sr. No.	Weight	Thickness	Sr. No.	Weight	Thickness	Sr. No.	Weight	Thickness
1	1041	7.81	25	1046	7.71	1	1040	7.82	25	1051	7.71
2	1045	7.85	26	1048	7.74	2	1042	7.84	26	1050	7.80
3	1046	7.77	27	1050	7.75	3	1040	7.87	27	1044	7.81
4	1047	7.76	28	1049	7.76	4	1045	7.85	28	1040	7.82
5	1041	7.75	29	1050	7.78	5	1048	7.77	29	1045	7.76
6	1039	7.85	30	1047	7.77	6	1026	7.75	30	1048	7.74
7	1038	7.84	31	1048	7.80	7	1055	7.74	31	1050	7.72
8	1041	7.82	32	1049	7.81	8	1045	7.73	32	1047	7.70
9	1040	7.80	33	1040	7.79	9	1048	7.72	33	1049	7.69
10	1041	7.81	34	1037	7.74	10	1064	7.70	34	1047	7.70
11	1040	7.84	35	1039	7.76	11	1065	7.71	35	1048	7.72
12	1045	7.75	36	1024	7.82	12	1064	7.72	36	1049	7.70
13	1039	7.72	37	1027	7.90	13	1063	7.70	37	1040	7.90
14	1038	7.74	38	1035	7.92	14	1062	7.75	38	1042	7.95
15	1041	7.72	39	1065	7.90	15	1064	7.76	39	1045	7.75
16	1037	7.70	40	1060	7.82	16	1063	7.72	40	1048	7.77
17	1039	7.75	41	1054	7.85	17	1064	7.74	41	1040	7.78
18	1041	7.76	42	1040	7.86	18	1060	7.75	42	1047	7.77
19	1040	7.76	43	1045	7.82	19	1040	7.74	43	1049	7.80
20	1037	7.77	44	1048	7.84	20	1045	7.72	44	1047	7.85
21	1039	7.75	45	1050	7.86	21	1048	7.70	45	1045	7.87
22	1040	7.70				22	1050	7.74			
23	1042	7.78				23	1051	7.75			
24	1045	7.80				24	1052	7.76			

	Prepared by:	Checked by:	Approved By:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date			

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	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	32 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

Initial Setting done by(operator):	Baskin	DATE:	23/06/2021				
Initial Setting checked by Sign production:	S. Pi	DATE:	23/06/2021				
Initial Setting checked by IPQA sign:		DATE:	28/06/21.				
Initial Setting tablets Destroyed by Sign/date(production):	S. Pi 23/06/2021	DATE:	23/06/2021				
Initial Setting tablets Destroyed by Sign/date(IPQA):		DATE:	28/06/21.				
Compression activity:							
Day 1	Date	Name of the operator	Checked by	Day 2	Date	Name of the operator	Checked by
Shift I	23/06/2021	Baskin	S. Pi	Shift I			
Shift II				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		24/06/21	
Shift II				Shift II			
Shift III				Shift III			

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 28/06/21	 28/06/21	 28/06/21	

BATCH MANUFACTURING RECORD

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Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

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

DATE	TIME	Group Wt: 20.800g±3.00% (20.176g to 21.424g) Avg. Wt: 1040mg± 3.00% (1008.800mg-1071.200mg)				HARDNESS		THICKNESS		APPEARANCE		Done by Production
		L.H.S.		R.H.S.		160 N to 230 N (To be monitored)		7.90mm± 0.3mm (7.60mm to 8.20 mm) (To be monitored)		Light orange coloured oval shape biconvex uncoated tablets with half 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)							
23/06/24	20:55	20.802	1040	20.820	1041	200	201	7.79	7.79	OK	OK	S.R.
23/06/24	21:30	20.802	1041	20.806	1040	200	204	7.81	7.75	OK	OK	S.R.
23/06/24	22:00	20.841	1042	20.842	1042	201	201	7.82	7.76	OK	OK	✓
23/06/24	22:30	20.782	1039	20.842	1041	199	202	7.89	7.74	OK	OK	✓
23/06/24	23:00	20.821	1041	20.829	1041	202	200	7.82	7.77	OK	OK	✓
23/06/24	23:30	20.842	1041	20.826	1041	204	202	7.84	7.82	OK	OK	✓
MIC stopped at 00:00 to 00:10 due to tea break -												
24/06/24	00:20	20.802	1040	20.807	1041	204	201	7.79	7.79	OK	OK	✓
24/06/24	00:50	20.809	1041	20.809	1040	202	200	7.79	7.79	OK	OK	✓
24/06/24	01:20	20.806	1040	20.849	1042	201	204	7.81	7.75	OK	OK	✓
24/06/24	01:50	20.789	1039	20.842	1042	204	206	7.82	7.74	OK	OK	✓
24/06/24	02:20	20.809	1041	20.789	1039	203	207	7.79	7.74	OK	OK	✓
24/06/24	02:50	20.809	1040	20.786	1039	202	200	7.79	7.76	OK	OK	✓
24/06/24	03:20	20.809	1040	20.809	1040	204	206	7.82	7.79	OK	OK	✓
24/06/24	03:50	20.782	1039	20.849	1042	201	207	7.84	7.76	OK	OK	✓
MIC stopped at 04:00 to 04:10 due to tea break -												
24/06/24	04:20	20.806	1040	20.809	1042	201	204	7.84	7.77	OK	OK	✓
24/06/24	04:50	20.809	1041	20.849	1040	202	202	7.84	7.76	OK	OK	✓
24/06/24	05:20	20.809	1041	20.806	1042	201	202	7.82	7.76	OK	OK	✓
MIC stopped at 05:30 due to Batch completed -												
NA												
24/06/24												

*If appearance are satisfactory document as complies.

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	CONTROLLED COPY
Signature with Date	 28/05/21	 28/05/21	 28/05/21	

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Brand Name

GENFORTE TABLETS

Product ID
No.:

977

Batch Size

800000 Tablets

Generic Name:

**Ibuprofen (400mg) and
Paracetamol (500mg) Tablets**

MFC NO:

ST/MFC/118/R0

Supersedes MFC
No:

Nil

Batch No.:

GD210601

Mfg. Date:

06/2021

Exp.Date:

05/2024

9.0A IN-PROCESS CHECKS: (EVERY 30 MINUTES) BY PRODUCTION:

[illegible]

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Brand Name

GENFORTE TABLETS

Product ID
No.:

977

Batch Size

800000 Tablets

Generic Name:

**Ibuprofen (400mg) and
Paracetamol (500mg) Tablets**

MFC NO:

ST/MFC/118/R0

Supersedes MFC
No:

Nii

Batch No.:

GD210601

Mfg.Date:

06/2021

Exp.Date:

05/2024

9.0B IN-PROCESS CHECKS: (EVERY 30 MINUTES) BY PRODUCTION:

[illegible]

*If appearance are satisfactory document as complies.

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Signature with Date	 27/05/24	 27/05/24	 28/05/24	

BATCH MANUFACTURING RECORD

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Brand Name

GENFORTE TABLETS

Product ID
No.:

977

Batch Size

800000 Tablets

Generic Name:

**Ibuprofen (400mg) and
Paracetamol (500mg) Tablets**

MFC NO:

ST/MFC/118/R0

Supersedes MFC
No:

NII

Batch No.:

GD210601

Mfg.Date:

06/2021

Exp.Date:

05/2024

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

DATE	TIME	Group Wt: 20.800g±3.00% (20.176g to 21.424g) Avg. Wt: 1040mg± 3.00% (1008.800mg-1071.200mg)				HARDNESS		THICKNESS		APPEARANCE		Done by IPQA
		L.H.S.		R.H.S.		160 N to 230 N (To be monitored)		7.90mm± 0.3mm (7.60mm to 8.20 mm) (To be monitored)		Light orange coloured oval shape biconvex uncoated tablets with half 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	
23/06/21	22:15	20.814	1040	20.841	1042	198	204	7.82	7.79	OK	OK	
23/06/21	22:15	20.827	1041	20.826	1041	202	210	7.80	7.78	OK	OK	
23/06/21	23:15	20.794	1039	20.810	1040	196	200	7.83	7.80	OK	OK	
M/c Stopped at 00:00 to 00:10 due to tes break												
24/06/21	00:20	20.810	1040	20.827	1041	198	198	7.78	7.81	OK	OK	
24/06/21	01:20	20.767	1038	20.818	1040	204	205	7.80	7.80	OK	OK	
24/06/21	02:25	20.845	1042	20.832	1041	200	196	7.81	7.79	OK	OK	
24/06/21	03:25	20.817	1040	20.803	1040	205	212	7.82	7.80	OK	OK	
M/c Stopped at 04:00 to 04:10 due to tes break												
24/06/21	04:35	20.84	1040	20.828	1041	208	205	7.80	7.78	OK	OK	
M/c Stopped at 05:30 due to Batch Completed												
24/06/21												

*If appearance are satisfactory document as complies.

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	CONTROLLED COPY
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800000 Tablets

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05/2024

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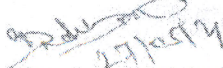
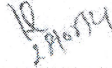
12
28/05/24

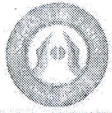
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	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	38 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

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

Date: 23/06/2021 Time: 21:05											
LHS weight of 20 tablets: 20.860 gm						RHS weight of 20 tablets: 20.924 gm					
1	1.029	8	1.035	15	1.035	1	1.035	8	1.051	15	1.050
2	1.035	9	1.029	16	1.038	2	1.038	9	1.045	16	1.051
3	1.040	10	1.058	17	1.042	3	1.032	10	1.048	17	1.060
4	1.042	11	1.045	18	1.042	4	1.042	11	1.045	18	1.030
5	1.040	12	1.042	19	1.052	5	1.045	12	1.044	19	1.040
6	1.035	13	1.040	20	1.058	6	1.047	13	1.047	20	1.041
7	1.039	14	1.029			7	1.050	14	1.048		
Limit: 5% of actual average weight (988.000mg to 1092.000mg) M/C Speed: 17 RPM											
Min. weight: 1.029 g 98.65 %						Min. weight: 1.030 g 98.56 %					
Max. weight: 1.058 g 101.43 %						Max. weight: 1.060 g 101.43 %					
Average weight of 20 Tablets: 1.043 g						Average weight of 20 Tablets: 1.045 g					
Friability: 0.14 % NMT 1.0 %						Equipment Code No.: ST/IPF/001					
Disintegration Time: 01 min 40 sec NMT 15 mins at 37°C ± 2°C						Equipment Code No.: ST/IPDT/002					
Done by: S. M. (Production)											
Date: 23/06/2021 Time: 22:10											
LHS weight of 20 tablets: 20.817 gm						RHS weight of 20 tablets: 20.807 gm					
1	1.032	8	1.048	15	1.040	1	1.034	8	1.049	15	1.040
2	1.039	9	1.036	16	1.041	2	1.036	9	1.047	16	1.041
3	1.034	10	1.039	17	1.042	3	1.039	10	1.039	17	1.041
4	1.036	11	1.034	18	1.046	4	1.037	11	1.036	18	1.036
5	1.039	12	1.039	19	1.047	5	1.037	12	1.037	19	1.037
6	1.041	13	1.032	20	1.041	6	1.036	13	1.030	20	1.036
7	1.042	14	1.034			7	1.039	14	1.036		
Limit: 5% of actual average weight (988.000mg to 1092.000mg) M/C Speed: 17 RPM											
Min. weight: 1.032 g 99.23 %						Min. weight: 1.034 g 99.32 %					
Max. weight: 1.048 g 100.76 %						Max. weight: 1.049 g 100.76 %					
Average weight of 20 Tablets: 1.040 g						Average weight of 20 Tablets: 1.041 g					
Friability: 0.74 % NMT 1.0 %						Equipment Code No.: ST/IPF/001					
Disintegration Time: 01 min 40 sec NMT 15 mins at 37°C ± 2°C						Equipment Code No.: ST/IPDT/002					
Done by: (Production)											
Date: 23/06/2021 Time: 23:20											
LHS weight of 20 tablets: 20.869 gm						RHS weight of 20 tablets: 20.906 gm					
1	1.029	8	1.058	15	1.050	1	1.030	8	1.060	15	1.060
2	1.029	9	1.049	16	1.050	2	1.037	9	1.060	16	1.050
3	1.032	10	1.046	17	1.058	3	1.039	10	1.047	17	1.060
4	1.036	11	1.050	18	1.047	4	1.036	11	1.046	18	1.047
5	1.032	12	1.047	19	1.047	5	1.029	12	1.050	19	1.047
6	1.031	13	1.047	20	1.046	6	1.036	13	1.051	20	1.046
7	1.032	14	1.032			7	1.039	14	1.050		
Limit: 5% of actual average weight (988.000mg to 1092.000mg) M/C Speed: 17 RPM											
Min. weight: 1.029 g 98.65 %						Min. weight: 1.030 g 98.56 %					
Max. weight: 1.058 g 101.43 %						Max. weight: 1.060 g 101.43 %					
Average weight of 20 Tablets: 1.043 g						Average weight of 20 Tablets: 1.045 g					
Friability: 0.10 % NMT 1.0 %						Equipment Code No.: ST/IPF/001					
Disintegration Time: 01 min 50 sec NMT 15 mins at 37°C ± 2°C						Equipment Code No.: ST/IPDT/002					
Done by: (Production)											

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

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	39 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

11.0A IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

Date: <u>24/06/21</u> Time: <u>00:30</u>											
LHS weight of 20 tablets: <u>20.767g</u>						RHS weight of 20 tablets: <u>20.846g</u>					
1	1.030	8	1.046	15	1.040	1	1.034	8	1.050	15	1.050
2	1.036	9	1.042	16	1.042	2	1.039	9	1.042	16	1.050
3	1.039	10	1.043	17	1.042	3	1.036	10	1.046	17	1.047
4	1.040	11	1.042	18	1.042	4	1.041	11	1.041	18	1.041
5	1.042	12	1.039	19	1.041	5	1.046	12	1.042	19	1.034
6	1.041	13	1.041	20	1.042	6	1.049	13	1.039	20	1.041
7	1.046	14	1.042			7	1.041	14	1.036		
Limit: 5% of actual average weight (988.000mg to 1092.000mg) M/C Speed: <u>17</u> RPM											
Min. weight: <u>1.030</u> g <u>99.22</u> %						Min. weight: <u>1.034</u> g <u>99.23</u> %					
Max. weight: <u>1.046</u> g <u>100.77</u> %						Max. weight: <u>1.050</u> g <u>100.76</u> %					
Average weight of 20 Tablets: <u>1.038</u> g						Average weight of 20 Tablets: <u>1.042</u> g					
Friability: <u>0.12%</u> NMT 1.0 %						Equipment Code No.: ST/IPF/001					
Disintegration Time: <u>0 mins 40 secs</u> NMT 15 mins at 37°C ± 2°C						Equipment Code No.: ST/IPDT/002					
Done by: <u>[Signature]</u> (Production)											
Date: <u>24/06/21</u> Time: <u>01:40</u>											
LHS weight of 20 tablets: <u>20.816g</u>						RHS weight of 20 tablets: <u>20.769g</u>					
1	1.031	8	1.049	15	1.040	1	1.030	8	1.046	15	1.040
2	1.039	9	1.042	16	1.041	2	1.032	9	1.042	16	1.040
3	1.036	10	1.042	17	1.042	3	1.037	10	1.042	17	1.042
4	1.034	11	1.041	18	1.039	4	1.036	11	1.041	18	1.046
5	1.036	12	1.042	19	1.036	5	1.034	12	1.036	19	1.039
6	1.042	13	1.041	20	1.036	6	1.042	13	1.037	20	1.036
7	1.046	14	1.042			7	1.040	14	1.039		
Limit: 5% of actual average weight (988.000mg to 1092.000mg) M/C Speed: <u>17</u> RPM											
Min. weight: <u>1.031</u> g <u>99.13</u> %						Min. weight: <u>1.030</u> g <u>99.22</u> %					
Max. weight: <u>1.049</u> g <u>100.86</u> %						Max. weight: <u>1.046</u> g <u>100.77</u> %					
Average weight of 20 Tablets: <u>1.040</u> g						Average weight of 20 Tablets: <u>1.038</u> g					
Friability: <u>0.13%</u> NMT 1.0 %						Equipment Code No.: ST/IPF/001					
Disintegration Time: <u>01 mins 30 secs</u> NA						Equipment Code No.: ST/IPDT/002					
Done by: <u>[Signature]</u> (Production)											
Date: <u>24/06/21</u> Time: <u>02:40</u>											
LHS weight of 20 tablets: <u>20.769g</u>						RHS weight of 20 tablets: <u>20.796g</u>					
1	1.030	8	1.046	15	1.040	1	1.031	8	1.047	15	1.037
2	1.036	9	1.040	16	1.040	2	1.039	9	1.042	16	1.046
3	1.039	10	1.039	17	1.040	3	1.036	10	1.042	17	1.042
4	1.037	11	1.041	18	1.046	4	1.036	11	1.046	18	1.046
5	1.034	12	1.042	19	1.042	5	1.032	12	1.042	19	1.046
6	1.032	13	1.032	20	1.046	6	1.034	13	1.046	20	1.047
7	1.031	14	1.037			7	1.036	14	1.039		
Limit: 5% of actual average weight (988.000mg to 1092.000mg) M/C Speed: <u>17</u> RPM											
Min. weight: <u>1.030</u> g <u>99.22</u> %						Min. weight: <u>1.031</u> g <u>99.23</u> %					
Max. weight: <u>1.046</u> g <u>100.77</u> %						Max. weight: <u>1.047</u> g <u>100.76</u> %					
Average weight of 20 Tablets: <u>1.038</u> g						Average weight of 20 Tablets: <u>1.039</u> g					
Friability: <u>0.12%</u> NMT 1.0 %						Equipment Code No.: ST/IPF/001					
Disintegration Time: <u>01 mins 40 secs</u> NMT 15 mins at 37°C ± 2°C						Equipment Code No.: ST/IPDT/002					
Done by: <u>[Signature]</u> (Production)											

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	<u>[Signature]</u> <u>27/06/21</u>	<u>[Signature]</u> <u>27/06/21</u>	<u>[Signature]</u> <u>28/06/21</u>

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BATCH MANUFACTURING RECORD

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Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

11.0B IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

Date: 24/06/21 Time: 03:40											
LHS weight of 20 tablets: 20.769g						RHS weight of 20 tablets: 20.847g					
1	1.030	8	1.046	15	1.040	1	1.034	8	1.050	15	1.050
2	1.037	9	1.046	16	1.040	2	1.039	9	1.040	16	1.042
3	1.036	10	1.042	17	1.046	3	1.036	10	1.042	17	1.049
4	1.034	11	1.037	18	1.042	4	1.037	11	1.042	18	1.046
5	1.039	12	1.037	19	1.041	5	1.026	12	1.041	19	1.042
6	1.037	13	1.036	20	1.040	6	1.037	13	1.042	20	1.042
7	1.036	14	1.032			7	1.036	14	1.042		
Limit: 5% of actual average weight (988.000mg to 1092.000mg) M/C Speed: 17 RPM											
Min. weight: 1.030 g 99.22 %						Min. weight: 1.024 g 99.23 %					
Max. weight: 1.046 g 100.77 %						Max. weight: 1.050 g 100.76 %					
Average weight of 20 Tablets: 1.038 g						Average weight of 20 Tablets: 1.042 g					
Friability: 0.12%						NMT 1.0 %					
Disintegration Time: 00mins 40secs						NMT 15 mins at 37°C ± 2°C					
Equipment Code No.: ST/IPF/001						Equipment Code No.: ST/IPDT/002					
Done by: (Production)											
Date: 24/06/21 Time: 04:40											
LHS weight of 20 tablets: 20.817g						RHS weight of 20 tablets: 20.769g					
1	1.034	8	1.048	15	1.040	1	1.030	8	1.046	15	1.046
2	1.039	9	1.036	16	1.042	2	1.042	9	1.040	16	1.040
3	1.036	10	1.037	17	1.046	3	1.042	10	1.042	17	1.042
4	1.039	11	1.036	18	1.036	4	1.041	11	1.036	18	1.046
5	1.042	12	1.029	19	1.036	5	1.040	12	1.037	19	1.040
6	1.042	13	1.040	20	1.042	6	1.042	13	1.036	20	1.047
7	1.046	14	1.042			7	1.036	14	1.032		
Limit: 5% of actual average weight (988.000mg to 1092.000mg) M/C Speed: 17 RPM											
Min. weight: 1.034 g 99.32 %						Min. weight: 1.030 g 99.22 %					
Max. weight: 1.048 g 100.67 %						Max. weight: 1.046 g 100.77 %					
Average weight of 20 Tablets: 1.047 g						Average weight of 20 Tablets: 1.038 g					
Friability: 0.12%						NMT 1.0 %					
Disintegration Time: 00mins 10secs						NMT 15 mins at 37°C ± 2°C					
Equipment Code No.: ST/IPF/001						Equipment Code No.: ST/IPDT/002					
Done by: (Production)											
Date: 24/06/21 Time: 05:00											
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 (988.000mg to 1092.000mg) 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					
Friability: %						NMT 1.0 %					
Disintegration Time: %						NMT 15 mins at 37°C ± 2°C					
Equipment Code No.: ST/IPF/001						Equipment Code No.: ST/IPDT/002					
Done by: (Production)											

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	28/05/21	27/05/21	28/05/21

CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	41 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

11.0C 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 (988.000mg to 1092.000mg) 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					
Friability : NMT 1.0 %						Equipment Code No.: ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C±2°C						Equipment Code No.: ST/IPDT/002					
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 (988.000mg to 1092.000mg) 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					
Friability : NMT 1.0 %						Equipment Code No.: ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C±2°C						Equipment Code No.: ST/IPDT/002					
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 (988.000mg to 1092.000mg) 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					
Friability : NMT 1.0 %						Equipment Code No.: ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C±2°C						Equipment Code No.: ST/IPDT/002					
Done by:(Production)											

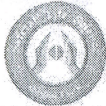
	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<i>[Signature]</i> 27/06/24	<i>[Signature]</i> 27/06/24	<i>[Signature]</i> 28/06/24	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	42 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

11.0D IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

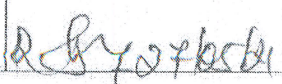
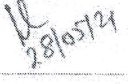
Date:..... Time:.....											
LHS weight of 20 tablets:						RHS weight of 20 tablets:					
1		8		15		1		8		15	
2		9		16		2		9		16	
3		10		17		3		10		17	
4		11		18		4		11		18	
5		12		19		5		12		19	
6		13		20		6		13		20	
7		14				7		14			
Limit: 5% of actual average weight (988.000mg to 1092.000mg) 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					
Friability : NMT 1.0 %						Equipment Code No.: ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C±2°C						Equipment Code No.: ST/IPDT/002					
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 (988.000mg to 1092.000mg) 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					
Friability : NMT 1.0 %						Equipment Code No.: ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C±2°C						Equipment Code No.: ST/IPDT/002					
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 (988.000mg to 1092.000mg) 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					
Friability : NMT 1.0 %						Equipment Code No.: ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C±2°C						Equipment Code No.: ST/IPDT/002					
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 (988.000mg to 1092.000mg) 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					
Friability : NMT 1.0 %						Equipment Code No.: ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C±2°C						Equipment Code No.: ST/IPDT/002					
Done by:(Production)											

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Signature with Date	<i>R. S. 27/05/21</i>	<i>[Signature] 27/05/21</i>	<i>[Signature] 28/05/21</i>	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	43 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

11.0E 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(988.000mg to 1092.000mg) 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					
Friability : NMT 1.0 %						Equipment Code No.:ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C±2°C						Equipment Code No.:ST/IPDT/002					
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(988.000mg to 1092.000mg) 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					
Friability : NMT 1.0 %						Equipment Code No.:ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C±2°C						Equipment Code No.:ST/IPDT/002					
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(988.000mg to 1092.000mg) 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					
Friability : NMT 1.0 %						Equipment Code No.:ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C±2°C						Equipment Code No.:ST/IPDT/002					
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(988.000mg to 1092.000mg) 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					
Friability : NMT 1.0 %						Equipment Code No.:ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C±2°C						Equipment Code No.:ST/IPDT/002					
Done by:(Production)											

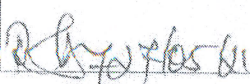
	Prepared by:	Checked by:	Approved By:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date			

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	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	44 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

11.0F IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

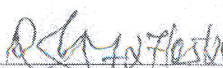
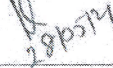
Date:..... Time:.....											
LHS weight of 20 tablets:						RHS weight of 20 tablets:					
1	8	15				1	8	15			
2	9	16				2	9	16			
3	10	17				3	10	17			
4	11	18				4	11	18			
5	12	19				5	12	19			
6	13	20				6	13	20			
7	14					7	14				
Limit:5%of actual average weight(988.000mg to 1092.000mg) M /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					
Friability : NMT 1.0 %						Equipment Code No.:ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C±2°C						Equipment Code No.:ST/IPDT/002					
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(988.000mg to 1092.000mg) 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					
Friability : NMT 1.0 %						Equipment Code No.:ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C±2°C						Equipment Code No.:ST/IPDT/002					
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(988.000mg to 1092.000mg) 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					
Friability : NMT 1.0 %						Equipment Code No.:ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C±2°C						Equipment Code No.:ST/IPDT/002					
Done by:(Production)											

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

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	45 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

11.0G 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 (988.000mg to 1092.000mg) 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					
Friability :						NMT 1.0 %			Equipment Code No.:ST/IPF/001		
Disintegration Time :						NMT 15 mins at 37°C±2°C			Equipment Code No.:ST/IPDT/002		
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 (988.000mg to 1092.000mg) 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					
Friability :						NMT 1.0 %			Equipment Code No.:ST/IPF/001		
Disintegration Time :						NMT 15 mins at 37°C±2°C			Equipment Code No.:ST/IPDT/002		
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 (988.000mg to 1092.000mg) 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					
Friability :						NMT 1.0 %			Equipment Code No.:ST/IPF/001		
Disintegration Time :						NMT 15 mins at 37°C±2°C			Equipment Code No.:ST/IPDT/002		
Done by:(Production)											

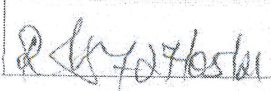
	Prepared by:	Checked by:	Approved By:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date			

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	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	46 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

11.0H 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(988.000mg to 1092.000mg) 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					
Friability : NMT 1.0 %						Equipment Code No.:ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C±2°C						Equipment Code No.:ST/IPDT/002					
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(988.000mg to 1092.000mg) 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					
Friability : NMT 1.0 %						Equipment Code No.:ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C±2°C						Equipment Code No.:ST/IPDT/002					
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(988.000mg to 1092.000mg) 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					
Friability : NMT 1.0 %						Equipment Code No.:ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C±2°C						Equipment Code No.:ST/IPDT/002					
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(988.000mg to 1092.000mg) 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					
Friability : NMT 1.0 %						Equipment Code No.:ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C±2°C						Equipment Code No.:ST/IPDT/002					
Done by:(Production)											

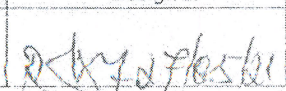
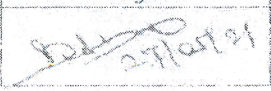
	Prepared by:	Checked by:	Approved By:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date			

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	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	47 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg. Date:	06/2021	Exp. Date:	05/2024

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

Date: 20/06/21 Time: 21:25															
LHS weight of 20 tablets: 20.814g						RHS weight of 20 tablets: 20.828g									
1	1.038	8	1.032	15	1.040	1	1.038	8	1.037	15	1.040				
2	1.040	9	1.039	16	1.037	2	1.040	9	1.040	16	1.040				
3	1.042	10	1.040	17	1.032	3	1.040	10	1.039	17	1.038				
4	1.048	11	1.048	18	1.040	4	1.039	11	1.039	18	1.039				
5	1.039	12	1.040	19	1.037	5	1.040	12	1.038	19	1.040				
6	1.040	13	1.032	20	1.048	6	1.039	13	1.039	20	1.039				
7	1.038	14	1.039			7	1.039	14	1.042						
Limit: 5% of actual average weight (988.000mg to 1092.000mg) M/C Speed: 17 RPM															
Min. weight: 1.032g				99.23%				Min. weight: 1.039g				99.32%			
Max. weight: 1.048g				100.76%				Max. weight: 1.049g				100.76%			
Average weight of 20 Tablets: 1.040g								Average weight of 20 Tablets: 1.041g							
Friability: 0.15%				NMT 1.0 %				Equipment Code No.: ST/IPF/001							
Disintegration Time: 0.1 mins 49 Sec				NMT 15 mins at 37°C ± 2°C				Equipment Code No.: ST/IPDT/002							
Done by: (IPQA)															
Date: 20/06/21 Time: 23:20															
LHS weight of 20 tablets: 20.765g						RHS weight of 20 tablets: 20.816g									
1	1.040	8	1.041	15	1.040	1	1.040	8	1.040	15	1.037				
2	1.038	9	1.038	16	1.037	2	1.040	9	1.048	16	1.040				
3	1.042	10	1.042	17	1.040	3	1.039	10	1.040	17	1.039				
4	1.040	11	1.042	18	1.040	4	1.042	11	1.038	18	1.038				
5	1.046	12	1.040	19	1.036	5	1.040	12	1.039	19	1.040				
6	1.039	13	1.039	20	1.040	6	1.042	13	1.040	20	1.040				
7	1.036	14	1.042			7	1.045	14	1.040						
Limit: 5% of actual average weight (988.000mg to 1092.000mg) M/C Speed: 17 RPM															
Min. weight: 1.030g				99.22%				Min. weight: 1.039g				99.22%			
Max. weight: 1.046g				100.77%				Max. weight: 1.046g				100.76%			
Average weight of 20 Tablets: 1.038g								Average weight of 20 Tablets: 1.042g							
Friability: 0.16%				NMT 1.0 %				Equipment Code No.: ST/IPF/001							
Disintegration Time: 0.1 mins 55 Sec				NMT 15 mins at 37°C ± 2°C				Equipment Code No.: ST/IPDT/002							
Done by: (IPQA)															
Date: 20/06/21 Time: 01:35															
LHS weight of 20 tablets: 20.815g						RHS weight of 20 tablets: 20.794g									
1	1.038	8	1.040	15	1.031	1	1.030	8	1.047	15	1.039				
2	1.042	9	1.049	16	1.037	2	1.038	9	1.040	16	1.040				
3	1.040	10	1.037	17	1.040	3	1.042	10	1.039	17	1.038				
4	1.046	11	1.038	18	1.042	4	1.042	11	1.036	18	1.042				
5	1.049	12	1.040	19	1.038	5	1.038	12	1.035	19	1.042				
6	1.038	13	1.031	20	1.040	6	1.031	13	1.040	20	1.039				
7	1.031	14	1.037			7	1.040	14	1.042						
Limit: 5% of actual average weight (988.000mg to 1092.000mg) M/C Speed: 17 RPM															
Min. weight: 1.031g				99.13%				Min. weight: 1.031g				99.22%			
Max. weight: 1.049g				100.86%				Max. weight: 1.049g				100.76%			
Average weight of 20 Tablets: 1.040g								Average weight of 20 Tablets: 1.039g							
Friability: 0.14%				NMT 1.0 %				Equipment Code No.: ST/IPF/001							
Disintegration Time: 0.1 mins 58 Sec				NMT 15 mins at 37°C ± 2°C				Equipment Code No.: ST/IPDT/002							
Done by: (IPQA)															

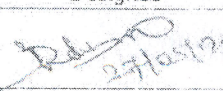
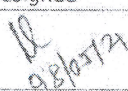
Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date			

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	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	48 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC No:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

12.0A IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BY IPQA:

Date: 24/06/21 Time: 03:38											
LHS weight of 20 tablets: 20.8159						RHS weight of 20 tablets: 20.8679					
1	1.042	8	1.034	15	1.046	1	1.040	8	1.040	15	1.040
2	1.040	9	1.038	16	1.040	2	1.038	9	1.039	16	1.037
3	1.037	10	1.040	17	1.037	3	1.043	10	1.042	17	1.040
4	1.039	11	1.040	18	1.039	4	1.035	11	1.051	18	1.040
5	1.042	12	1.037	19	1.040	5	1.040	12	1.046	19	1.037
6	1.048	13	1.040	20	1.040	6	1.042	13	1.039	20	1.038
7	1.038	14	1.042			7	1.039	14	1.042		
Limit: 5% of actual average weight (988.000mg to 1092.000mg) M/C Speed: 15 RPM											
Min. weight: 1.034 g 99.32 %						Min. weight: 1.035 g 99.22 %					
Max. weight: 1.048 g 100.67 %						Max. weight: 1.051 g 100.75 %					
Average weight of 20 Tablets: 1.041 g						Average weight of 20 Tablets: 1.043 g					
Friability: 0.14 % NMT 1.0 %						Equipment Code No.: ST/IPF/001					
Disintegration Time: 01 min 45 sec NMT 15 mins at 37°C ± 2°C						Equipment Code No.: ST/IPDT/002					
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 (988.000mg to 1092.000mg) 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					
Friability: NMT 1.0 %						Equipment Code No.: ST/IPF/001					
Disintegration Time: NMT 15 mins at 37°C ± 2°C						Equipment Code No.: ST/IPDT/002					
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 (988.000mg to 1092.000mg) 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					
Friability: NMT 1.0 %						Equipment Code No.: ST/IPF/001					
Disintegration Time: NMT 15 mins at 37°C ± 2°C						Equipment Code No.: ST/IPDT/002					
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 (988.000mg to 1092.000mg) 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					
Friability: NMT 1.0 %						Equipment Code No.: ST/IPF/001					
Disintegration Time: NMT 15 mins at 37°C ± 2°C						Equipment Code No.: ST/IPDT/002					
Done by: (IPQA)											

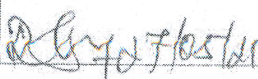
Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date			

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	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	49 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC No:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

12.0B 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 (988.000mg to 1092.000mg) 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					
Friability : NMT 1.0 %						Equipment Code No.:ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C±2°C						Equipment Code No.:ST/IPDT/002					
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 (988.000mg to 1092.000mg) 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					
Friability : NMT 1.0 %						Equipment Code No.:ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C±2°C						Equipment Code No.:ST/IPDT/002					
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 (988.000mg to 1092.000mg) 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					
Friability : NMT 1.0 %						Equipment Code No.:ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C±2°C						Equipment Code No.:ST/IPDT/002					
Done by:(IPQA)											

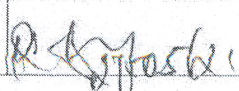
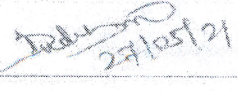
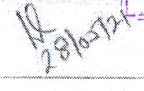
	Prepared by:	Checked by:	Approved By:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date			

CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	50 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

12.0C IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BY IPQA:

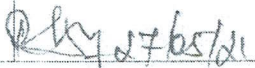
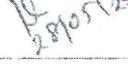
Date:..... Time:.....											
LHS weight of 20 tablets:						RHS weight of 20 tablets:					
1	8	15	1	8	15						
2	9	16	2	9	16						
3	10	17	3	10	17						
4	11	18	4	11	18						
5	12	19	5	12	19						
6	13	20	6	13	20						
7	14		7	14							
Limit: 5% of actual average weight (988.000mg to 1092.000mg)						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					
Friability : NMT 1.0 %						Equipment Code No.: ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C ± 2°C						Equipment Code No.: ST/IPDT/002					
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 (988.000mg to 1092.000mg)						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					
Friability : NMT 1.0 %						Equipment Code No.: ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C ± 2°C						Equipment Code No.: ST/IPDT/002					
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 (988.000mg to 1092.000mg)						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					
Friability : NMT 1.0 %						Equipment Code No.: ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C ± 2°C						Equipment Code No.: ST/IPDT/002					
Done by: (IPQA)											

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

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	51 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

12.0D 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 (988.000mg to 1092.000mg) 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					
Friability : NMT 1.0 %						Equipment Code No.:ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C±2°C						Equipment Code No.:ST/IPDT/002					
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 (988.000mg to 1092.000mg) 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					
Friability : NMT 1.0 %						Equipment Code No.:ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C±2°C						Equipment Code No.:ST/IPDT/002					
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 (988.000mg to 1092.000mg) 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					
Friability : NMT 1.0 %						Equipment Code No.:ST/IPF/001					
Disintegration Time : NMT 15 mins at 37°C±2°C						Equipment Code No.:ST/IPDT/002					
Done by:(IPQA)											

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date			

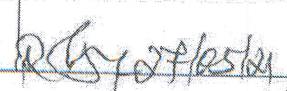
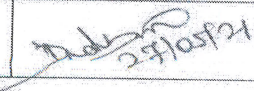
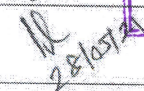
CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	52 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

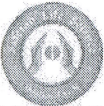
13.0 WEIGHING RECORD OF COMPRESSED TABLETS:

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	30.03	2.50	27.53	Basker	02/10/21	31					
2	30.11	2.50	27.61	Basker	02/10/21	32					
3	30.40	2.50	27.90	Basker	02/10/21	33					
4	29.64	2.50	27.14	Basker	02/10/21	34					
5	29.40	2.50	27.00	Basker	02/10/21	35					
6	28.69	2.50	26.19	Basker	02/10/21	36					
7	31.40	2.50	28.90	Basker	02/10/21	37					
8	33.04	2.50	30.54	Basker	02/10/21	38					
9	31.00	2.50	28.50	Basker	02/10/21	39					
10	27.97	2.50	25.47	Basker	02/10/21	40					
11	28.38	2.50	25.88	Basker	02/10/21	41					
12	29.82	2.50	27.32	Basker	02/10/21	42					
13	28.77	2.50	26.27	Basker	02/10/21	43					
14	26.00	2.50	23.50	Basker	02/10/21	44					
15	31.73	2.50	29.23	Basker	02/10/21	45					
16	32.50	2.50	30.00	Basker	02/10/21	46					
17	35.71	2.50	33.21	Basker	02/10/21	47					
18	32.50	2.50	30.00	Basker	02/10/21	48					
19	34.94	2.50	32.44	Basker	02/10/21	49					
20	33.26	2.50	30.76	Basker	02/10/21	50					
21	33.86	2.50	31.36	Basker	02/10/21	51					
22	36.18	2.50	33.68	Basker	02/10/21	52					
23	35.50	2.50	33.00	Basker	02/10/21	53					
24	31.52	2.50	29.02	Basker	02/10/21	54					
25	28.78	2.50	26.28	Basker	02/10/21	55					
26	36.26	2.50	33.76	Basker	02/10/21	56					
27	25.38	2.50	22.88	Basker	02/10/21	57					
28	42.13	2.50	39.63	Basker	02/10/21	58					
29						59					
30						60					
Total weight of Compressed tablets:							815.00		kg		

Intimate IPQA to draw the sample.		Sample withdrawn by IPQA.	
Production Sign: 	Date: 24/06/21	IPQA Sign: 	Date: 24/06/21
Send Test Request Form for analysis of compressed tablets to QC department.			

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	 27/05/21	 27/05/21	 28/05/21

CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	53 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

14.0 RECONCILIATION:

1	Theoretical Weight of Compressed tablets	:	832.000Kg	800000 No's
2	Actual Weight of Compressed tablets	:	815.00 Kg	783653
3	Manufacturing Loss (1.0 – 6.0)	:	14.62 Kg	14051
4	In-process samples			
	A IPQA Samples	:	0.62 Kg	600
	B QC Samples	:	0.10 Kg	100
	C Validation Samples	:	0.83 + 0.83 Kg	800 + 800
5	Total samples: (A + B + C)	:	2.38 Kg	21288
6	Total: (5.0 + 2.0)	:	817.38 Kg	785942
7	% Yield = $\frac{6.0}{1.0} \times 100$ Limit: NLT 98.00%*	:	98.24	%

*Tentative limit

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: 14.62 Kg Rejected materials shall be destroyed in the presence of QA.

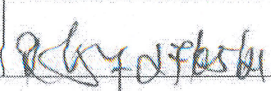
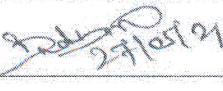
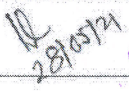
Done by Production sign/Date: S. Di. 24/06/21 Checked By IPQA sign/Date: V. 24/06/21

Reconciliation Done by Production sign/Date: S. Di. 24/06/21 Checked By IPQA sign/Date: V. 24/06/21

14.1 COMPRESSED TABLETS RELEASED FOR INSPECTION:

Reconciliation checked and compression tablets are released for Inspection.

Production sign/Date: S. Di. 24/06/21 IPQA sign/Date: V. 24/06/21

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

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	54 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

15.0 TABLET INSPECTION

15.1 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: S. Pi 28/06/21

Verified by (IPQA) sign/date: [Signature] 28/06/21

15.2 ENVIRONMENTAL CONDITIONS	Date: <u>28/06/2021</u>		Date:	
	Observation	Production Sign	Observation	Production Sign
Temperature: 23°C to 27°C	<u>24°C</u>	<u>S. Pi</u>		
Relative Humidity: 45% to 55 %	<u>52%</u>	<u>S. Pi</u>		

15.3 APPROVAL FOR INSPECTION:

Production Sign/Date: S. Pi 28/06/2021

Line clearance IPQA Sign./Date: [Signature] 28/06/21

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.

15.4 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	Tablets Inspection Done by/Date	Checked by/Date
	From	To	Started	Completed			
<u>28/06/21</u>	<u>01</u>	<u>28</u>	<u>08:15</u>	<u>20:28</u>	<u>0.40 kg</u>	<u>Mundhira, Kanyathur 28/06/21</u>	<u>S. Pi 28/06/2021</u>
						<u>Mayoralhi, Senthil, Vallu</u>	<u>[Signature] 28/06/21</u>

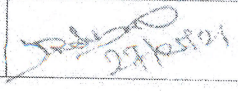
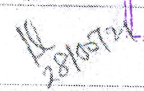
Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	<u>[Signature] 28/06/21</u>	<u>[Signature] 28/06/21</u>	<u>[Signature] 28/06/21</u>

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	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	55 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg. Date:	06/2021	Exp. Date:	05/2024

15.5 WEIGHING RECORD OF INSPECTED TABLETS: Date: 28/06/21

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	30.02	2.50	27.52	Cropi	(H) 28/06/21	31					
2	30.10	2.50	27.60	Cropi	(H) 28/06/21	32					
3	30.38	2.50	27.88	Cropi	(H) 28/06/21	33					
4	29.62	2.50	27.12	Cropi	(H) 28/06/21	34					
5	29.38	2.50	26.88	Cropi	(H) 28/06/21	35					
6	28.67	2.50	26.17	Cropi	(H) 28/06/21	36					
7	31.37	2.50	28.87	Cropi	(H) 28/06/21	37					
8	33.02	2.50	30.52	Cropi	(H) 28/06/21	38					
9	30.98	2.50	28.48	Cropi	(H) 28/06/21	39					
10	27.95	2.50	25.45	Cropi	(H) 28/06/21	40					
11	28.36	2.50	25.86	Cropi	(H) 28/06/21	41					
12	29.80	2.50	27.30	Cropi	(H) 28/06/21	42					
13	28.75	2.50	26.25	Cropi	(H) 28/06/21	43					
14	25.97	2.50	23.47	Cropi	(H) 28/06/21	44					
15	31.71	2.50	29.21	Cropi	(H) 28/06/21	45					
16	32.47	2.50	29.97	Cropi	(H) 28/06/21	46					
17	35.70	2.50	33.20	Cropi	(H) 28/06/21	47					
18	32.47	2.50	29.97	Cropi	(H) 28/06/21	48					
19	34.92	2.50	32.42	Cropi	(H) 28/06/21	49					
20	33.25	2.50	30.75	Cropi	(H) 28/06/21	50					
21	33.84	2.50	31.34	Cropi	(H) 28/06/21	51					
22	36.15	2.50	33.65	Cropi	(H) 28/06/21	52					
23	35.48	2.50	32.98	Cropi	(H) 28/06/21	53					
24	31.50	2.50	29.00	Cropi	(H) 28/06/21	54					
25	28.75	2.50	26.25	Cropi	(H) 28/06/21	55					
26	36.24	2.50	33.74	Cropi	(H) 28/06/21	56					
27	25.36	2.50	22.86	Cropi	(H) 28/06/21	57					
28	42.79	2.50	40.29	Cropi	(H) 28/06/21	58					
29						59					
30						60					
Total weight of inspected tablets:						814.60	kg				

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date			

CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	56 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

15.6 RECONCILIATION: (INSPECTION OF TABLETS)

1.0	Theoretical weight of tablets	:	832.00 kg	800000 No's
2.0	Tablets transferred to inspection	:	815.00 kg	783653 No's
3.0	Rejected tablets	:	0.40 kg	384 No's
4.0	Total weight of good tablets	:	814.60 kg	783269 No's
5.0	% Yield = $\frac{4.0}{1.0} \times 100$ (Limit- NLT 97.00%)*	:	97.91 %	

*Tentative limit

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: 0.40 Kg.

Rejected materials shall be destroyed in the presence of QA

Done by Packing sign/Date: *[Signature]* 28/06/21

Checked by IPQA sign/Date: *[Signature]* 28/06/21

Reconciliation Done by Production sign/Date: *[Signature]* 28/06/21

Checked By IPQA sign/Date: *[Signature]* 28/06/21

15.7 RELEASE FOR PACKING

Compressed tablets report checked and released for packing

Checked by Competent Staff Sign/Date: *[Signature]* 28/06/21

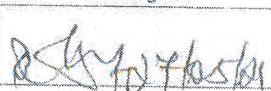
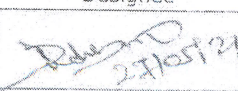
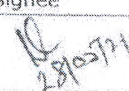
IPQA Sign/Date : *[Signature]* 28/06/21

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<i>[Signature]</i> 27/05/21	<i>[Signature]</i> 27/05/21	<i>[Signature]</i> 28/05/21	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	57 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	NII
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

16.0 PROCESS HISTORY


 06/07/24

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 27/05/24	 27/05/24	 28/05/24	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	58 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

17.0 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	✓	✓
3	Compression stage analytical report	✓	✓
4	Blend container label	✓	✓
5	Compressed tablets container label	✓	✓

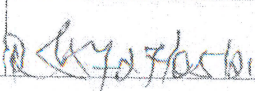
Note: Tick mark (✓) if Complies and (X) if Does not comply.

This Batch Manufacturing reviewed on date...28/06/21...

Production Head sign/date... 28/06/21...

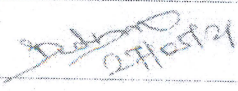
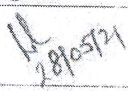
This Batch Manufacturing Record received, reviewed and batch is released for packing on date...28/06/21...

Reviewed by QA Head... 28/06/21...

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u> 28/06/21</u>	<u> 28/06/21</u>	<u> 28/06/21</u>	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	59 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

18.0 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

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

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	60 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

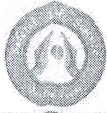
BMR COPY/QUALITY CONTROL COPY

19.0 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.: 06/2021 Date of Exp.: 05/2024		Quantity Sampled: 50gms	
Test Request for: Content		Sampled by: [Signature] on date: 06/06/2021	
TRF raised by: [Signature] on date: 05/06/21		No. of containers: 20	
		Sample received by: [Signature] on date: 05/06/21	
To be filled by QC			
TRF received on: 05/06/21			
Sample tested on: 08/06/2021			
Test Results		Limits	
Each 1040mg of granules contains: <u>Assay:</u> Paracetamol - 500.22mg (100.0%) Ibuprofen - 400.41mg (100.1%)			
Analytical Reference no.: GTF/00570/2021		Space for QC Approval (Stamping and Signing)	
Analysed By: [Signature] on: 14/06/2021		APPROVED [Signature] Date: 14/6/21	

	Prepared by:	Checked by:	Approved By:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	[Signature] 27/05/21	[Signature] 27/05/21	[Signature] 28/05/21

CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	61 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

BMR COPY/QUALITY CONTROL COPY

20.0 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.: 06/2021 Date of Exp.: 05/2024		Quantity Sampled: 100 tablets	
Test Request for: content		Sampled by: [Signature] on date: 24/06/2021	
TRF raised by: [Signature] on date: 24/06/21		No. of containers: 20	
TRF received on: 24/06/21		Sample received by: [Signature] on date: 24/06/21	
Sample tested on: 27/06/21			
Test Results			
Each tablet contains:- Paracetamol:- 500.3mg (100.06%), ORSD:- Avg:- 101.6%, Min:- 100.4%, Max:- 102.2%. Ibuprofen:- 391.3mg (97.8%), ORSD:- Avg:- 101.6%, Min:- 100.7%, Max:- 102.6%. Relatg substances:- ① Org. matter:- 0.04%, ② Total Imp:- 0.07%.			
Analytical Reference no.: SPP/F1007AD/2021		Space for QC Approval (Stamping and Signing)	
Reported by: [Signature] Analysed By: [Signature] on: 06/07/2021		APPROVED [Signature] 20/07/21 Sign: Date:	

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	[Signature] 24/06/21	[Signature] 24/06/21	[Signature] 20/07/21	CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	62 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

21.0 BATCH MANUFACTURING RECORD REVIEW CHECK LIST		
S.No. No.	CHECK POINTS	Status
1	The entire Page no: <u>1</u> to <u>63</u> are available, verified and found correct.	<u>Yes</u> / No
2	Batch numbers available in all pages verified and are correct.	<u>Yes</u> / No
3	Manufacturing and expiry is correctly allotted verified.	<u>Yes</u> / No
4	Dispensing carried out on calibrated balance verified.	<u>Yes</u> / No
5	Dispensing Cards attached.	<u>Yes</u> / No
6	Line clearance is taken prior to all dispensing and manufacturing activities.	<u>Yes</u> / No
7	Dispensing is carried out as per indent of raw materials are correct.	<u>Yes</u> / No
8	Environmental conditions comply during all the manufacturing steps.	<u>Yes</u> / No
9	All wrong entries if any have been strike out and signed and verified.	<u>Yes</u> / No
10	Actual equipment used is as specified and verified.	<u>Yes</u> / No
11	Blend, Compressed Tablet container labels are attached.	<u>Yes</u> / No
12	Lubrication, Compression and Inspection reconciliation is filled and variance is within acceptance limit.	<u>Yes</u> / No
13	If any deviation and change control raised related to this batch attached with Batch record.	Yes / <u>No</u> / 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: 28/06/24

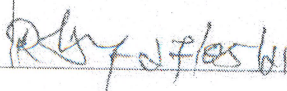
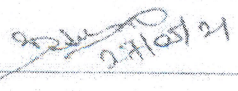
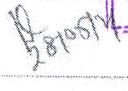
QA Head Sign/Date: 28/06/24

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>[Signature]</u> 28/06/24	<u>[Signature]</u> 28/06/24	<u>[Signature]</u> 28/06/24	CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
BATCH MANUFACTURING RECORD				Page No.:	63 of 63
Brand Name	GENFORTE TABLETS	Product ID No.:	977	Batch Size	800000 Tablets
Generic Name:	Ibuprofen (400mg) and Paracetamol (500mg) Tablets	MFC NO:	ST/MFC/118/R0	Supersedes MFC No:	Nil
Batch No.:	GD210601	Mfg.Date:	06/2021	Exp.Date:	05/2024

22.0 REVISION HISTORY:

Revision No.	Date of Revision	Changes Made	Effective Date
00	--	1. New product introduced refer change control No: ST/CC/20/004.	04.03.2020
01	27/05/2021	1. New granulation area and equipment used refer change control No: ST/CC/21/75.	01/06/2021

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 27/05/21	 27/05/21	 28/05/21	