Safetab Life Science

Plot No. A-67&68,
PIPDIC Electronic Park,
Thirubuvanai,
Puducherry-605107

Tel: 0413 – 2641099
2641199
3535656
Fax: 0413 - 2641666
info@safetab.net
www.safetab.net

Certificate of Analysis

(As per Drugs and Cosmetics Act. 1940 and the rules made there under)

Name of the product	: LITACOLD FLU	Date of receipt	: 31/03/2020
Batch No	: GD200301	Quantity sampled	: 100 Tablets
Batch size	: 10.0 Lac Tablets	Date of Commencement	: 07/04/2020
Date of Mfg	: MAR' 2020	Date of Completion	: 13/05/2020
Date of Exp	: FEB' 2023	A.R. Number	: SFP/C/00345/2020
Condition	: Finished product	Date of Report	: 13/05/2020

S.No:	Test	Specification	Results
1	Description	Light yellow coloured, flat, round beveled edged uncoated tablet with break line on one side and plain on another side.	Light yellow coloured, flat, round beveled edged uncoated tablet with break line on one side and plain on another side.
2	Identification a) Chlorphenamine Maleate (By HPLC)	The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Chlorphenamine Maleate in the standard preparation as obtained in assay.	Complies
	b) Phenylephrine Hydrochloride (By HPLC)	The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Phenylephrine Hydrochloride in the standard preparation as obtained in assay.	Complies
	c) Caffeine (By HPLC)	The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Caffeine in the standard preparation as obtained in assay.	Complies
	d) Paracetamol (By HPLC)	The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Paracetamol in the standard preparation as obtained in assay.	Complies
3	Average weight of tablet	635.0 mg ± 3 % (615.9 mg to 654.0 mg)	635.7mg
4	Uniformity of Weight	Not more than 2 of the individual weights deviate from the average weight by more than ±5% and none deviate by more than ±10.0%.	(-) 0.87% (+) 1.06%
5	Diameter	12.70±0.20mm (12.50 - 12.90mm)	12.71mm
6	Thickness	4.30mm±0.2mm (4.10mm to 4.50mm)	4.31mm
7	Hardness	100 N – 250 N	214.84 N
8	Disintegration Time	Not more than 15 minutes	05 Minutes 49 Seconds
9	Friability	Not more than 1.0%	0.22%
10	**Dissolution:** a) Chlorphenamine Maleate BP	Not less than 80% of the stated amount of Chlorphenamine Maleate dissolved in 45 Minutes.	Min: 87.9%; Max: 95.0%; Avg: 92.6%
	b) Phenylephrine Hydrochloride BP	Not less than 80% of the stated amount of Phenylephrine Hydrochloride dissolved in 45 Minutes.	Min: 95.1%; Max: 97.0%; Avg: 96.0%
	c) Caffeine BP	Not less than 80% of the stated amount of Caffeine Anhydrous dissolved in 45 Minutes.	Min: 98.6%; Max: 110.1%; Avg: 101.1%
	d) Paracetamol BP	Not less than 80% of the stated amount of Paracetamol dissolved in 45 Minutes.	Min: 97.4%; Max: 109.2%; Avg: 100.3%

In this opinion of the undersigned the sample refered to above is of standard Quality / ~~is not of standard Quality~~ as defined in the Act and the Rules made thereunder for the reason given below:

Observation : The Product complies as per Inhouse Specification with respect to above test.

Prepared by	Checked by	Approved by
13/05/2020	13/05/2020	13/05/20
Executive-QC	Assistant Manager-QC	AGM-QC

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Certificate of Analysis

(As per Drugs and Cosmetics Act. 1940 and the rules made there under)

Name of the product	: LITACOLD FLU	Date of receipt	: 31/03/2020
Batch No	: GD200301	Quantity sampled	: 100 Tablets
Batch size	: 10.0 Lac Tablets	Date of Commencement	: 07/04/2020
Date of Mfg	: MAR' 2020	Date of Completion	: 13/05/2020
Date of Exp	: FEB' 2023	A.R. Number	: SFP/C/00345/2020
Condition	: Finished product	Date of Report	: 13/05/2020

S.No:	Test	Specification	Results
11	**Uniformity of content:** a) For Chlorphenamine Maleate BP	Not less than 85.0% and not more than 115.0% of the average value.	Min: 96.0%; Max: 100.3%; Avg: 97.2%
	b) For Phenylephrine Hydrochloride BP	Not less than 85.0% and not more than 115.0% of the average value.	Min: 94.1%; Max: 99.2%; Avg: 95.2%
12	**Related substances:** i) Single maximum unknown impurity ii) Total impurities	Not more than 0.20% Not more than 0.50%	0.02% 0.03%
13	**Assay: Each Uncoated tablet contains:**		
	Chlorphenamine Maleate BP 2mg	90.0% to 110.0% of the labeled claim I.e. 1.8mg to 2.2mg	1.90mg (95.2%)
	Phenylephrine Hydrochloride BP 5mg	90.0% to 110.0% of the labeled claim I.e. 4.5mg to 5.5mg	4.87mg (97.5%)
	Caffeine (anhydrous) BP 30mg	90.0% to 110.0% of the labeled claim I.e. 27.0mg to 33.0mg	29.60mg (98.7%)
	Paracetamol BP 500mg	90.0% to 110.0% of the labeled claim I.e. 450.0mg to 550.0mg	491.09mg (98.2%)
14	**Microbiological parameters:**		
	i) Total Viable aerobic count a) Total aerobic microbial count	Not more than 1000 cfu/g	80cfu/g
	b) Total yeast and mould count	Not more than 100 cfu/g	Found absent
	ii) Pseudomonas aeruginosa	Should be absent/g	Found absent
	iii) Salmonella Species	Should be absent/10g	Found absent
	iv) Esherichia Coli	Should be absent/g	Found absent
	v) Staphylococcus aureus	Should be absent/g	Found absent

In this opinion of the undersigned the sample refered to above is of standard Quality / ~~is not of standard Quality~~ as defined in the Act and the Rules made thereunder for the reason given below:

Observation : The Product complies as per Inhouse Specification with respect to above test.

Note: For Microbiological Parameters test refer Ideal Lab Report No: AR/20/05/05/025

Prepared by	Checked by	Approved by
13/05/2020	13/05/2020	13/05/20
Executive-QC	Assistant Manager-QC	AGM-QC

	Safetab Life Science Puducherry	
	RECORD OF ANALYSIS	

Name of Product: LITACOLD FLU
(Chlorphenamine Maleate 2mg, Phenylephrine Hydrochloride 5mg, Caffeine 30mg and Paracetamol 500mg)- Finished Product

Specification No	ROA No	Revision No.	Effective date	Page No:
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Batch No.	GD200301	Sample Quantity	13 STRIPS
Batch Size	10 Lac	Sampled By /Date	Ramkumar / 05/05/2020
Mfg. Date	Mar-2020	Test started on	05/05/2020
Exp. Date	Feb-2023	Test completed on	13/05/2020
Stage	Finished Product	A.R.No	FGE/00306/2020

PRODUCT TEST REPORT

S.NO	TEST	RESULT	SPECIFICATION
1.0	Description	Light yellow coloured, flat, round beveled edged uncoated tablet, with break line on one side and plain on another side.	Light yellow coloured, flat, round beveled edged uncoated tablet with break line on one side and plain on another side.
2.0	***Identification**		
	a) Chlorphenamine Maleate (By HPLC)	Complies	The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Chlorphenamine Maleate in the standard preparation as obtained in assay.
	b) Phenylephrine Hydrochloride (By HPLC)	Complies	The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Phenylephrine Hydrochloride in the standard preparation as obtained in assay.
	c) Caffeine (By HPLC) (anhydrous)	Complies	The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Caffeine in the standard preparation as obtained in assay.

Remarks: The product Complies / ~~Doesn't comply~~ as per IP Specification.

ANALYSED BY	CHECKED BY	APPROVED BY
Sign: RV Date: 13/05/2020	Sign: Date: 13/05/2020	Sign: Date: 13/5/20

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Sign:	Date: 02/03/2020	Sign:	Date: 11/03/20

	Safetab Life Science Puducherry	
	RECORD OF ANALYSIS	

Name of Product: LITACOLD FLU
(Chlorphenamine Maleate 2mg, Phenylephrine Hydrochloride 5mg, Caffeine 30mg and Paracetamol 500mg)- Finished Product

Specification No	ROA No	Revision No.	Effective date	Page No:
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PRODUCT TEST REPORT

S.NO	TEST	RESULT	SPECIFICATION
	d) Paracetamol (By HPLC)	Complies	The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Paracetamol in the standard preparation as obtained in assay.
3.0	Average weight of tablet	638.1 mg	635.0 mg ± 3 % (615.9 mg to 654.0 mg)
4.0	Uniformity of weight	Min (-) : 1.62%. Max(+) : 1.34%.	Not more than 2 of the individual weights deviate from the average weight by more than ±5% and none deviate by more than ±10.0%.
5.0	*Diameter	12.71 mm	12.70 ± 0.20mm (12.50 – 12.90)
6.0	#*Thickness	4.31 mm	4.30±0.2mm (4.10 – 4.50mm)
7.0	#*Hardness	214.84N	100 N – 250 N
8.0	Disintegration time	08 Mins 58 Seconds	Not more than 15 minutes
9.0	Friability	0.22%	Not more than 1.0%
10.0	**Dissolution** Chlorphenamine Maleate BP	Min: 87.9% ; Max: 95.0%. Avg: 92.6%.	Not less than 80% of the stated amount of Chlorphenamine Maleate dissolved in 45 Minutes.

Remarks: The product Complies / ~~Doesn't comply as~~ per DH Specification.

ANALYSED BY	CHECKED BY	APPROVED BY
Sign: R.D Date: 13/05/2020	Sign: Date: 13/05/2020	Sign: Date: 13/05/20

MASTER COPY APPROVAL:	USAGE COPY APPROVAL:
Sign: Date: 02/03/2020	Sign: Date: 11/03/20

	Safetab Life Science Puducherry	
	RECORD OF ANALYSIS	

Name of Product: LITACOLD FLU
(Chlorphenamine Maleate 2mg, Phenylephrine Hydrochloride 5mg, Caffeine 30mg and Paracetamol 500mg)- Finished Product

Specification No	ROA No	Revision No.	Effective date	Page No:
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PRODUCT TEST REPORT

S.NO	TEST	RESULT	SPECIFICATION
	b) Phenylephrine Hydrochloride BP	Min: 95.1% ; Max: 97.0% Avg: 96.0%	Not less than 80% of the stated amount of Phenylephrine Hydrochloride dissolved in 45 Minutes.
	c) Caffeine BP	Min: 98.6% ; Max: 110.1% Avg: 101.1%	Not less than 80% of the stated amount of Caffeine Anhydrous dissolved in 45 Minutes.
	d) Paracetamol BP	Min: 97.4% ; Max: 104.2% Avg: 100.3%	Not less than 80% of the stated amount of Paracetamol dissolved in 45 Minutes.
11.0	***Uniformity of content**		
	a) Chlorphenamine Maleate BP	Min: 96.0% ; Max: 100.3% Avg: 97.2%	Not less than 85.0% and not more than 115.0% of the average value.
	b) Phenylephrine Hydrochloride BP	Min: 94.1% ; Max: 99.2% Avg: 95.2%	Not less than 85.0% and not more than 115.0% of the average value.
12.0	***Related substances**		
	i) Single maximum unknown impurity	0.02%	Not more than 0.20%
	ii) Total impurities	0.03%	Not more than 0.50%
13.0	***Assay: Each Uncoated tablet contains:**		
	Chlorphenamine Maleate BP 2mg	1.90mg (95.2%)	90.0% to 110.0% of the labeled claim I.e. 1.8mg to 2.2mg
	Phenylephrine Hydrochloride BP 5mg	4.87mg (97.5%)	90.0% to 110.0% of the labeled claim I.e. 4.5mg to 5.5mg

Remarks: The product Complies / ~~Doesn't comply~~ as per IH Specification.

ANALYSED BY	CHECKED BY	APPROVED BY
Sign: R.L Date: 13/05/2020	Sign: Date: 13/05/2020	Sign: Date: 13/05/20

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Sign:	Date: 02/03/2020	Sign:	Date: 11/09/20

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	Safetab Life Science Puducherry	
	RECORD OF ANALYSIS	

Name of Product: LITACOLD FLU
(Chlorphenamine Maleate 2mg, Phenylephrine Hydrochloride 5mg, Caffeine 30mg and Paracetamol 500mg)- Finished Product

Specification No	ROA No	Revision No.	Effective date	Page No:
FGSTSL022-00	ROA/ FGTSL022-00	00	03-03-2020	4 of 4

PRODUCT TEST REPORT

S.NO	TEST		RESULT	SPECIFICATION
	Caffeine BP (anhydrous)	30mg	29.60mg (98.7%)	90.0% to 110.0% of the labeled claim I.e. 27.0mg to 33.0mg
	Paracetamol BP	500mg	491.09mg (98.2%)	90.0% to 110.0% of the labeled claim I.e. 450.0mg to 550.0mg
14.0	**Microbial Contamination**			
	i) Total Viable aerobic count			
	a) Total aerobic microbial count		80 cfu/gm	Not more than 1000 cfu/g
	b) Total yeast and mould count		Absent	Not more than 100 cfu/g
	ii) Pseudomonas aeruginosa		Absent	Should be absent/g
	iii) Salmonella Species		Absent	Should be absent/10g
	iv) Esherichia Coli		Absent	Should be absent/g
	v) Staphylococcus aureus		Absent	Should be absent/g

Remarks: The product Complies / ~~Doesn't comply~~ as per IH Specification.

ANALYSED BY	CHECKED BY	APPROVED BY
Sign: RV Date: 13/05/2020	Sign: Date: 13/05/2020	Sign: Date: 13/5/20

Remarks: The above * marked test results shall be documented as based on Compressed stage report.

The # Marked parameters shall be monitored up to five batch, after five batch the limit will be fixed.

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Sign:	Date: 02/03/2020	Sign:	Date: 17/03/20

	Safetab Life Science **Puducherry**	
	RECORD OF ANALYSIS	

Name of Product: LITACOLD FLU
(Chlorphenamine Maleate 2mg, Phenylephrine Hydrochloride 5mg, Caffeine 30mg and Paracetamol 500mg)- **Finished Product**

Batch No/Lot No.	GD200301	A.R.No.	FGE/06306/2020	
STP No	**ROA No**	**Revision No.**	**Effective date**	**Page No:**
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S.No	TEST / OBSERVATION / LIMIT
1.0	**Description:** Light yellow coloured, flat, round beveled edged uncoated tablet with break line on one side and plain on another side. **Observation:** Conforms: ☑ Does not conform: ☐ **Analyst:** R.V **Date :** 13/05/2020
2.0	**Identification:** **Refer:** Compressed tablet report. **Observation:** Conforms: ☑ Does not conform: ☐ **Analyst:** C.K. Saravanan **Date:** 13/05/2020
3.0	**Average weight:** **Balance ID: ST/QC/EQ/** 041 **Calibration due date:** 06/05/2020

Number of tablets	Total weight (g)	Average weight of a tablet(g)	Limit (g)
20	12.7625 gm	0.6381 gm	0.6159 – 0.6540

Observation: Conforms: ☑ Does not conform: ☐	
Analyst: R.V	**Date:** 13/05/2020
4.0	**Uniformity of weight:** **Balance ID: ST/QC/EQ/** 041 **Calibration due date:** 06/05/2020

Checked by : Date : 13/05/2020

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Sign:	Date: 02/03/2020	Sign:	Date: 11/03/20

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	Safetab Life Science Puducherry	
	RECORD OF ANALYSIS	

Name of Product: LITACOLD FLU
(Chlorphenamine Maleate 2mg, Phenylephrine Hydrochloride 5mg, Caffeine 30mg and Paracetamol 500mg)- **Finished Product**

Batch No/Lot No.	GD200301	A.R.No.	FGB/00306/2020	
STP No	ROA No	Revision No.	Effective date	Page No:
FGTTSL022-00	ROA/ FGTSL022-00	00	03-03-2020	2 of 5

S.No	Weight(g)	S.No	Weight(g)	S.No	Weight(g)	S.No	Weight(g)
1	0.6301	6	0.6343	11	0.6334	16	0.6424
2	0.6247	7	0.6468	12	0.6424	17	0.6361
3	0.6376	8	0.6406	13	0.6392	18	0.6385
4	0.6353	9	0.6413	14	0.6427	19	0.6485
5	0.6390	10	0.6427	15	0.6407	20	0.6372

Deviation (Mini): { Lowest weight X100} -100
Average weight

= { 0.6247 / 0.635 x 100} – 100

= - 1.62 %

Deviation (Max): { Highest weight X100} -100
Average weight

= { 0.6435 / 0.635 x 100} – 100

= + 1.34 %

Limit: ± 7.5% deviation from the average weight of a tablet

Observation: Conforms: ☑ Does not conform: ☐

Analyst: R.V **Date:** 13/05/2020

5.0 Diameter:

Refer: Compressed tablet report.

6.0 Thickness:

Refer: Compressed tablet report.

7.0 Hardness:

Refer: Compressed tablet report.

Checked by : [signature] Date : 13/05/2020

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Sign: [signature]	Date: 02/03/2020	Sign: [signature]	Date: 11/03/20

	Safetab Life Science Puducherry	
	RECORD OF ANALYSIS	

Name of Product: LITACOLD FLU
(Chlorphenamine Maleate 2mg, Phenylephrine Hydrochloride 5mg, Caffeine 30mg and Paracetamol 500mg)- **Finished Product**

Batch No/Lot No.	GTD200301	A.R.No.	FGE/00306/2020	
STP No	**ROA No**	**Revision No.**	**Effective date**	**Page No:**
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8.0 Disintegration time:

DT Apparatus ID: ST/QC/EQ/ 004	Calibration due date: 16/07/2020

Introduce one tablet into each tube of the disintegration testing apparatus. Add a disc to each tube suspend the assembly in the beaker containing water maintained at 37°C ± 2°C and operate the apparatus for 30 minutes. Observe all the tablets, if all the tablets are disintegrated completely within 30 minutes, lift the basket from the fluid and note down the time required. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets. The requirement is met if not fewer than 16 of the total of 18 tablets tested are disintegrated.

Result: 08 Mins 52 Secs	**Limit:** Not more than 15 minutes
Observation: Conforms: ☑ Does not conform: ☐	
Analyst: R.N	**Date:** 13/05/2020

9.0 Friability:

Refer: Compressed tablet report.

10.0 Dissolution:

Refer: Compressed tablet report.

11.0 Uniformity of content:

Refer: Compressed tablet report.

12.0 Related substances:

Refer: Compressed tablet report.

13.0 Assay:

Refer: Compressed tablet report.

Checked by : [signature] Date : 13/05/2020

MASTER COPY APPROVAL:		USAGE COPY APPROVAL:	
Sign: [signature]	Date: 02/03/2020	Sign: [signature]	Date: 17/03/20

14.0 Microbial contamination:

a. Total aerobic microbial count:

Procedure: Proceed as per the current General Analytical Method GAM-035.

b. Total Moulds and yeast count:

Procedure: Proceed as per the current General Analytical Method GAM-036.

Pathogens:

C. Esherichia Coli:

Procedure: Proceed as per the current General Analytical Method GAM-037.

d. Salmonella Species:

Procedure: Proceed as per the current General Analytical Method GAM-038.

e. Pseudomonas aeruginosa:

Procedure: Proceed as per the current General Analytical Method GAM-039.

f. Staphylococcus aureus:

Procedure: Proceed as per the current General Analytical Method GAM-040.

Result:	**Limit:**
i)Total Viable aerobic count:	i)Total Viable aerobic count:
a) Total aerobic microbial count: 80 cfu/g	a) Total aerobic microbial count: Not more than 1000 cfu/g
b) Total yeast and mould count: Absent	b) Total yeast and mould count: Not more than 100 cfu/g
ii) Pseudomonas aeruginosa: Absent	ii) Pseudomonas aeruginosa: Should be absent/g
iii) Salmonella Species: Absent	iii) Salmonella Species: Should be absent/10g
iv) Esherichia Coli: Absent	iv) Esherichia Coli: Should be absent/g
v) Staphylococcus aureus: Absent	v) Staphylococcus aureus: Should be absent/g

Note: For Microbiological Parameters test refer Commercial Lab Report No: AR/20/05/05/025

Observation: Conforms: ☑ Does not conform: ☐

Analyst: Ideal Lab. **Date:** 11/05/2020

Checked by : Date : 13/05/2020

MASTER COPY APPROVAL:		USAGE COPY APPROVAL:	
Sign:	Date: 02/03/2020	Sign:	Date: 11/03/20

	Safetab Life Science **Puducherry**	
	RECORD OF ANALYSIS	

Name of Product: LITACOLD FLU
(Chlorphenamine Maleate 2mg, Phenylephrine Hydrochloride 5mg, Caffeine 30mg and Paracetamol 500mg)- **Finished Product**

Batch No/Lot No.	FLB GD 200301	A.R.No.	FAB/00306/2020	
STP No	**ROA No**	**Revision No.**	**Effective date**	**Page No:**
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15.0 ANALYTICAL REPORT VERIFICATION CHECK LIST:

Check the following details and enclosures in the report. If the details are available then put '✓' mark on the remarks column and put '×' mark if the details are not available

S.No:	DETAILS	Remarks:
1	TRF is enclosed with the protocol	✓
2	Product name, B.No, Mfg date, Exp date, A.R.No matches with TRF	✓
3	All the tests are performed as per standard specification	✓
4	All the sheets are page numbered, signed and dated by analyst	✓
5	The protocol is duly filled, no blank place, calculations and entries are ok	✓
6	The printouts of UV-VIS spectrophotometer readings are enclosed	✓
7	The spectrum of IR spectrophotometer is enclosed	✓
8	All HPLC chromatograms are enclosed	✓
9	Other instruments sheets (if applicable, then specify in comments column)	✓
10	Public laboratory reports (if applicable, then specify the reasons below)	✓
11	Comments (if any): Weigh Balance printed Sheet is enclosed "y" means is not applicable in this product	

Remarks: The report is found to be satisfactory ☑ not satisfactory ☐

Verifying authority (Sign & date): _____ 13/05/2020

Checked by : _____ Date : 13/05/2020

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Sign:	Date: 02/03/2020		Sign:	Date: 11/03/20	

Format No: ST/QC/058(R1):A1

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	Safetab Life Science Puducherry	
	RECORD OF ANALYSIS	

Name of Product: LITACOLD FLU
(Chlorphenamine Maleate 2mg, Phenylephrine Hydrochloride 5mg, Caffeine 30mg and Paracetamol 500mg)- Compressed Tablets

Specification No	ROA No	Revision No.	Effective date	Page No:
IMSL00117-00	ROA/ IML00117-00	00	03-03-2020	1 of 4

Batch No.	GD200301	Sample Quantity	100 tablets
Batch Size	10.01 Lac	Sampled By /Date	Nirmalraj / 31/03/2020
Mfg. Date	Mar-2020	Test started on	07/04/2020
Exp. Date	Feb-2023	Test completed on	15/04/2020
Stage	Compressed Tablets	A.R.No	SFPL/00345/2020

PRODUCT TEST REPORT

S.NO	TEST	RESULT	SPECIFICATION
1.0	Description	Light yellow coloured, flat, round beveled edged, uncoated tablet with break line on one side and plain on another side.	Light yellow coloured, flat, round beveled edged uncoated tablet with break line on one side and plain on another side.
2.0	**Identification**		
	a) Chlorphenamine Maleate (By HPLC)	Complies	The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Chlorphenamine Maleate in the standard preparation as obtained in assay.
	b) Phenylephrine Hydrochloride (By HPLC)	Complies	The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Phenylephrine Hydrochloride in the standard preparation as obtained in assay.
	c) Caffeine (By HPLC)	Complies	The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Caffeine in the standard preparation as obtained in assay.

Remarks: The product Complies / ~~Doesn't comply~~ as per IP Specification.

ANALYSED BY	CHECKED BY	APPROVED BY
Sign: Date: 15/04/2020	Sign: Date: 15/04/2020	Sign: Date: 15-4-20

MASTER COPY APPROVAL:		USAGE COPY APPROVAL:	
Sign:	Date: 02/03/2020	Sign:	Date: 11/03/20

PRODUCT TEST REPORT

S.NO	TEST	RESULT	SPECIFICATION
	d) Paracetamol (By HPLC)	Complies	The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Paracetamol in the standard preparation as obtained in assay.
3.0	Average weight of tablet	635.7mg	635.0 mg ± 3 % (615.9 mg to 654.0 mg)
4.0	Uniformity of weight	Min (-) : 0.87 % Max(+) : 1.06%	Not more than 2 of the individual weights deviate from the average weight by more than ±5% and none deviate by more than ±10.0%.
5.0	*Diameter	12.71 mm	12.70 ± 0.20mm (12.50 – 12.90)
6.0	*Thickness	4.31 mm	4.30±0.2mm (4.10 – 4.50mm)
7.0	*Hardness	214.84 N	100 N – 250 N
8.0	Disintegration time	05 Minutes 49 seconds	Not more than 15 minutes
9.0	Friability	0.22%	Not more than 1.0%
10.0	**Dissolution** Chlorphenamine Maleate BP	Min: 87.9%. ; Max: 95.0%. Avg: 92.6%	Not less than 80% of the stated amount of Chlorphenamine Maleate dissolved in 45 Minutes.

Remarks: The product Complies / ~~Doesn't comply~~ as per IH Specification.

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PRODUCT TEST REPORT

S.NO	TEST	RESULT	SPECIFICATION
	Phenylephrine Hydrochloride BP	Min: 95.1%. ; Max: 97.0%. Avg: 96.0%.	Not less than 80% of the stated amount of Phenylephrine Hydrochloride dissolved in 45 Minutes.
	Caffeine BP	Min: 98.6%. ; Max: 110.1%. Avg: 101.1%.	Not less than 80% of the stated amount of Caffeine Anhydrous dissolved in 45 Minutes.
	Paracetamol BP	Min: 97.4%. ; Max: 109.2%. Avg: 100.3%.	Not less than 80% of the stated amount of Paracetamol dissolved in 45 Minutes.
11.0	**Uniformity of content**		
	Chlorphenamine Maleate BP	Min: 96.0%. ; Max: 100.3%. Avg: 97.2%.	Not less than 85.0% and not more than 115.0% of the average value.
	Phenylephrine Hydrochloride BP	Min: 94.1%. ; Max: 99.2%. Avg: 95.2%.	Not less than 85.0% and not more than 115.0% of the average value.
12.0	**Related substances**		
	i) Single maximum unknown impurity	0.02%	Not more than 0.20%
	ii) Total impurities	0.03%.	Not more than 0.50%
13.0	**Assay: Each Uncoated tablet contains:**		
	Chlorphenamine Maleate BP 2mg	1.90mg (95.2%)	90.0% to 110.0% of the labeled claim I.e. 1.8mg to 2.2mg
	Phenylephrine Hydrochloride BP 5mg	4.87mg (97.5%)	90.0% to 110.0% of the labeled claim I.e. 4.5mg to 5.5mg

Remarks: The product Complies / ~~Doesn't comply~~ as per IP Specification.

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	RECORD OF ANALYSIS	

Name of Product: LITACOLD FLU
(Chlorphenamine Maleate 2mg, Phenylephrine Hydrochloride 5mg, Caffeine 30mg and Paracetamol 500mg)- Compressed Tablets

Specification No	ROA No	Revision No.	Effective date	Page No:
IMSL00117-00	ROA/ IML00117-00	00	03-03-2020	4 of 4

PRODUCT TEST REPORT

S.NO	TEST	RESULT	SPECIFICATION
	Caffeine (anhydrous) BP 30mg	29.60mg (98.7%)	90.0% to 110.0% of the labeled claim I.e. 27.0mg to 33.0mg
	Paracetamol BP 500mg	491.09mg (98.2%)	90.0% to 110.0% of the labeled claim I.e. 450.0mg to 550.0mg

Remarks: The product Complies / ~~Doesn't comply~~ as per DH Specification.

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Remarks: The *Marked parameters shall be monitored up to five batch, after five batch the limit will be fixed.

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	Safetab Life Science Puducherry	
	RECORD OF ANALYSIS	

Name of Product: LITACOLD FLU
(Chlorphenamine Maleate 2mg, Phenylephrine Hydrochloride 5mg, Caffeine 30mg and Paracetamol 500mg)- Compressed Tablets

Batch No/Lot No.	GD200301	A.R.No.	SFP/C/00345/2020	
STP No	**ROA No**	**Revision No.**	**Effective date**	**Page No:**
IMTL00117-00	ROA/ IML00117-00	00	03-03-2020	1 of 25

S.No	TEST / OBSERVATION / LIMIT
1.0	**Description:** Light yellow coloured, flat, round beveled edged uncoated tablet with break line on one side and plain on another side. **Observation:** Conforms: ☑ Does not conform: ☐ **Analyst:** K. Sawant **Date :** 08/04/2020
2.0	**Identification:** **a) Chlorphenamine Maleate:** The RT of Chlorphenamine Maleate peak in standard 14.749 min, the RT of principal peak in assay 14.730 min. **b) Phenylephrine Hydrochloride:** The RT of Phenylephrine Hydrochloride peak in standard 4.452 min, the RT of principal peak in assay 4.442 min. **c) Caffeine:** The RT of Caffeine peak in standard 12.389 min, the RT of principal peak in assay 12.385 min. **D) Paracetamol:** The RT of Paracetamol peak in standard 10.237 min, the RT of principal peak in assay 10.238 min. **Observation:** Conforms: ☑ Does not conform: ☐ **Analyst:** **Date:** 13/04/2020
3.0	**Average weight of tablet:** **Balance ID: ST/QC/EQ/** 30 **Calibration due date:** 06/05/2020

Number of tablets	Total weight (g)	Average weight of a tablet(g)	Limit (g)
20	12.7135 g	0.6357 gm	0.6159 – 0.6540

Observation: Conforms: ☑ Does not conform: ☐
Analyst: K. Sawant **Date:** 08/04/2020

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4.0 Uniformity of weight:

Balance ID: ST/QC/EQ/ 030	Calibration due date: 06/05/2020

S.No	Weight(g)	S.No	Weight(g)	S.No	Weight(g)	S.No	Weight(g)
1	0.6347	6	0.6357	11	0.6372	16	0.6370
2	0.6379	7	0.6354	12	0.6340	17	0.6417
3	0.6377	8	0.6381	13	0.6295	18	0.6337
4	0.6388	9	0.6337	14	0.6309	19	0.6305
5	0.6332	10	0.6408	15	0.6393	20	0.6337

Deviation (Mini): { Lowest weight X100} -100 / Average weight

$= \{\frac{0.6295}{0.635} \times 100\} - 100$

$= -0.87$ %

Deviation (Max): { Highest weight X100} -100 / Average weight

$= \{\frac{0.6417}{0.635} \times 100\} - 100$

$= +1.06$ %

Limit: Not more than 2 of the individual weights deviate from the average weight by more than ±5% and none deviate by more than ±10.0%.

Observation: Conforms: ☑ Does not conform: ☐

Analyst: K. Saravanan **Date:** 08/04/2020

5.0 Diameter:

Vernier caliper ID: ST/QC/EQ/ 008	Calibration due date: 11/02/2020

1. 12.69	2. 12.73	3. 12.71	4. 12.75	5. 12.71
6. 12.72	7. 12.70	8. 12.70	9. 12.70	10. 12.70

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	Result: 12.71mm	**Limit:** 12.70 ± 0.20mm (12.50 – 12.90)
	Observation: Conforms: ☑ Does not conform: ☐	
	Analyst: K. Saravanan	**Date:** 08/04/2020

6.0 Thickness:

Vernier caliper ID: ST/QC/EQ/ 008	Calibration due date: 11/02/2021

1. 4.29	2. 4.30	3. 4.30	4. 4.32	5. 4.32
6. 4.30	7. 4.36	8. 4.30	9. 4.32	10. 4.32

Result: 4.31mm	**Limit:** 4.30±0.2mm (4.10 – 4.50mm)
Observation: Conforms: ☑ Does not conform: ☐	
Analyst: K. Saravanan	**Date:** 08/04/2020

7.0 Hardness:

Hardness Test ID: ST/QC/EQ/ 035	Calibration due date: 07/10/2020

1. 231.69	2. 202.21	3. 214.38	4. 237.83	5. 194.64
6. 211.62	7. 208.32	8. 207.21	9. 226.97	10. 213.49

Result: 214.84 N	**Limit:** 100 N – 250 N
Observation: Conforms: ☑ Does not conform: ☐	
Analyst: K. Saravanan	**Date:** 08/04/2020

8.0 Disintegration time:

DT apparatus ID: ST/QC/EQ/ 004	Calibration due date: 16/07/2020

Introduce one tablet into each tube of the disintegration testing apparatus. Add a disc to each tube suspend the assembly in the beaker containing water maintained at 37°C ± 2°C and operate the apparatus for 30 minutes.

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Observe all the tablets, if all the tablets are disintegrated completely within 30 minutes, lift the basket from the fluid and note down the time required. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets. The requirement is met if not fewer than 16 of the total of 18 tablets tested are disintegrated.

Result: 05 Mins 49 Seconds	**Limit:** Not more than 15 minutes
Observation: Conforms: ☑ Does not conform: ☐	
Analyst: K. Saloni.	**Date:** 08/04/2020

9.0 Friability:

Balance ID: ST/QC/EQ/ 030	**Calibration due date:** 06/05/2020
Friability ID: ST/QC/EQ/ 010	**Calibration due date:** 07/07/2020

Weigh 11 tablets and note down the mass in gram up to four decimals (a). Placed weighed tablets in friability test apparatus and operate the friability test apparatus for 100 rotations. After completion of the test collect the tablets from sample collector carefully. Remove broken particles, chipped pieces (if any) by means of gentle brushing. Weigh the tablet and record the mass in gram up to four decimals (b).

Initial weight (Before friability)	Final weight (After friability)
7.0021	6.9866

$$\% \text{ of Friability} = \frac{7.0021 - 6.9866}{7.0021} \times 100 = 0.22\ \%$$

Result: 0.22%	**Limit:** Not more than 1.0% w/w
Observation: Conforms: ☑ Does not conform: ☐	
Analyst: K. Saloni	**Date:** 08/04/2020

10.0 DISSOLUTION:

Balance ID: ST/QC/EQ/ 021	**Calibration due date:** 06/05/2020
HPLC ID : ST/QC/EQ/ 045	**Calibration due date:** 12/09/2020
Dissolution apparatus ID: ST/QC/EQ/ 027	**Calibration due date:** 08/07/2020
pH meter ID: ST/QC/EQ/ 036	**Calibration due date:** 26/04/2020

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Column ID : QC/CL/ 19/009

Reference: In House
Procedure: By HPLC

Chemicals/Reagents/Standards:

Chlorphenamine Maleate	:	Working standard
Phenylephrine Hydrochloride	:	Working standard
Caffeine	:	Working standard
Paracetamol	:	Working standard
Potassium Dihydrogen orthophosphate	:	AR grade
Orthophosphoric acid	:	AR grade
Methanol	:	HPLC grade
Acetonitrile	:	HPLC grade
Purified Water	:	Milli-Q water (or) equivalent

Dissolution parameters:

Apparatus	:	Paddle (USP Apparatus 2)
Medium	:	900ml of PH 6.8 Phosphate buffer
Time	:	45 minutes
Speed	:	75 RPM
Temperature	:	37° C ± 0.5° C

Preparation of Dissolution medium:

Dissolve 68g of Potassium dihydrogen phosphate and 9.8g of Sodium hydroxide pellets in 10 liters of purified water and mix well. Adjust pH to 6.83 (6.8±0.05) with dilute Sodium hydroxide or dilute Orthophosphoric acid and mix well.

Preparation of Buffer:

Weigh accurately about 6.8 g of potassium Di-hydrogen orthophosphate in 1000 mL of milli-Q water, sonicate to dissolve. Adjust pH to 3.00 (3.0±0.05) with Orthophosphoric acid. Filter through 0.45µ membrane filter.

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Chromatographic Conditions:

Column	:	Inertsil ODS-3V, 250 mm X 4.6 mm, 5µm (or) Equivalent
Wave length	:	220 nm
Column Temperature	:	40°C
Flow Rate	:	1.2 mL/min
Injection Volume	:	20 µL
Run time	:	30.01 Minutes
Retention time	:	About 4.6 minutes for Phenylephrine Hydrochloride, about 10.5 minutes for Paracetamol, about 12.7 minutes for Caffeine and about 14.8 minutes for Chlorphenamine maleate,

Preparation of Mobile phase-A:

Prepare a degassed mixture of buffer and acetonitrile in the ratio 95:5 *v/v*.

Preparation of Mobile phase-B:

100% Methanol

Preparation of Blank solution:

Use Dissolution medium as a blank.

Preparation of Diluent:

Prepare a degassed mixture of Buffer and methanol in the ratio 50:50 *v/v*.

Gradient Program:

Time	Mobile phase A %	Mobile phase B%
0.01	100	0
6.0	100	0
7.0	70	30
9.0	70	30
10.0	45	55
25.0	45	55
27.0	100	0
30.01	100	0

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Preparation of Standard stock solution:

Weigh accurately and transfer about 27.92mg (28mg) of Chlorphenamine maleate working standard (W.S.No. / Valid upto WS/A/09/01 / 14/09/2020), 67.97mg (68mg) of Phenylephrine Hydrochloride working standard (W.S.No. / Valid upto WS/A/11/01 / 13/11/2020) and 82.99mg (83mg) of Caffeine working standard (W.S.No. / Valid upto WS/A/09/04 / 09/09/2020) into a 250 mL volumetric flask, add 20 mL of diluent and sonicate to dissolve and make up to volume with dissolution medium and mix.

Preparation of Standard solution:

Weigh accurately and transfer about 21.69mg (22mg) of Paracetamol working standard (W.S.No. / Valid upto WS/A/07/01 / 20/07/2020) into a 200 mL volumetric flask. Add 20 mL of diluent and sonicate to dissolve and add 4 mL of Standard stock solution and make up to volume with dissolution medium and mix.

Test Preparation :

Preparation of sample solution(A) (For Chlorphenamine maleate and Phenylephrine Hydrochloride)

Set the dissolution parameters and place one tablet into each vessel individually containing 900 mL of dissolution medium, immediately start the apparatus. At the end of specified time withdraw the sample and filter through 0.45µ PVDF filter.

Preparation of Sample Solution-B:(For Paracetamol and Caffeine)

Further dilute 10 mL of above filtered solution to 50 mL with Dissolution medium and mix.

Procedure:

Inject the solutions as mentioned below and measure the responses of the peaks due to Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine maleate, Caffeine.

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Injection sequence:

S. No	Sample Name	No. of injections
1	Dissolution medium (blank)	1
2	Standard preparation	5
3	Sample solution A (1 injection each)	6
4	Sample solution B (1 injection each)	6
5	Bracketing standard	1 (After every 6 injections)

System suitability:

Theoretical plate count	:	NLT 2000 for Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine maleate, Caffeine peak.
Tailing factor	:	NMT 2.0 for Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine maleate, Caffeine peak.
Relative standard deviation	:	NMT 2.0% for five replicate injections of Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine maleate, Caffeine peak.

Calculations:

Calculate % drug release of Chlorphenamine maleate as follows:

$$= \frac{AT}{AS} \times \frac{WS}{250} \times \frac{4}{200} \times \frac{900}{1} \times \frac{P}{100} \times \frac{100}{LC}$$

Where,

AT	=	Area of peak due to Chlorphenamine maleate in Sample solution A.
AS	=	Average area of peak due to Chlorphenamine maleate in standard preparation.
WS	=	Weight of Chlorphenamine maleate working standard in mg.
P	=	Potency of Chlorphenamine maleate working standard in % on as such basis.
LC	=	Label claim of Chlorphenamine maleate in mg/tablet.

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Calculate % drug release of Phenylephrine Hydrochloride, as follows:

$$= \frac{AT}{AS} \times \frac{WS}{250} \times \frac{4}{200} \times \frac{900}{1} \times \frac{P}{100} \times \frac{100}{LC}$$

Where,

AT = Area of peak due to Phenylephrine hydrochloride in Sample solution A.

AS = Average area of peak due to Phenylephrine hydrochloride in standard preparation.

WS = Weight of Phenylephrine hydrochloride working standard in mg.

P = Potency of Phenylephrine hydrochloride working standard in % on as such basis.

LC = Label claim of Phenylephrine hydrochloride in mg/tablet.

Calculate % drug release of Caffeine as follows:

$$= \frac{AT}{AS} \times \frac{WS}{250} \times \frac{4}{200} \times \frac{900}{1} \times \frac{50}{10} \times \frac{P}{100} \times \frac{100}{LC}$$

Where,

AT = Area of peak due to Caffeine in Sample solution B.

AS = Average area of peak due to Caffeine in standard preparation.

WS = Weight of Caffeine working standard in mg.

P = Potency of Caffeine working standard in % on as such basis.

LC = Label claim of Caffeine in mg/tablet.

Calculate % drug release of Paracetamol as follows:

$$= \frac{AT}{AS} \times \frac{WS}{200} \times \frac{900}{1} \times \frac{50}{10} \times \frac{P}{100} \times \frac{100}{LC}$$

Where,

AT = Area of peak due to Paracetamol in Sample solution B.

AS = Average area of peak due to Paracetamol in standard preparation.

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	WS = Weight of Paracetamol working standard in mg. P = Potency of Paracetamol working standard in % on as such basis. LC = Label claim of Paracetamol in mg/tablet.
	Limit: Not less than 80% of the stated amount of Chlorphenamine Maleate dissolved in 45 Minutes. Not less than 80% of the stated amount of Phenylephrine Hydrochloride dissolved in 45 Minutes. Not less than 80% of the stated amount of Caffeine dissolved in 45 Minutes. Not less than 80% of the stated amount of Paracetamol dissolved in 45 Minutes.
	Result: HPLC Graph and validated XL sheet attached.
	Observation: Conforms: ☑ Does not conform: ☐
	Analyst: **Date:** 11/04/2020
11.0	**Uniformity of content:** **(Chlorphenamine maleate and Phenylephrine Hydrochloride)**

Balance ID: ST/QC/EQ/ 041	**Calibration due date:** 06/05/2020
HPLC ID : ST/QC/EQ/ 039	**Calibration due date:** 26/07/2020

Column ID : QC/CL/ 19/009

Reference: In-house
Procedure: By HPLC

Note 1: Buffer preparation, Diluent, Mobile phase A, Mobile phase B, Chromatographic condition and gradient program proceed as directed under dissolution test.

Note 2: Standard preparation use under assay test.

Test preparation:

Take 1 tablet into 100 ml volumetric flask. Add about 10 ml of purified water and shake gently to disperse the tablet completely. Add about 60 ml of diluent, sonicate for 20 minutes with intermediate shaking, cool and dilute up to the volume with diluent and Centrifuge this solution at 3000rpm for 10 Minutes. Further dilute 10 ml of this solution to 25ml with diluent. Repeat the same procedure for another 9 tablets.

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Procedure:

Equilibrate the chromatographic system with mobile phase till a stable baseline is obtained. Separately inject equal volumes (20 µl) of solutions as per Sequence of injections into the chromatograph and record the peak area responses for the major peaks and check for the System suitability requirements.

Injection sequence:

S. No	Sample Name	No. of injections
1	Diluent (blank)	1
2	Standard preparation	5
3	Test preparation	10
4	Bracketing standard	1 (After every 10 injections)

System suitability:

Theoretical plate count	:	NLT 2000 for Chlorphenamine maleate and Phenylephrine Hydrochloride peak.
Tailing factor	:	NMT 2.0 for Chlorphenamine maleate and Phenylephrine Hydrochloride peak.
Relative standard deviation	:	NMT 2.0% for five replicate injections of Chlorphenamine maleate and Phenylephrine Hydrochloride peak.

Calculation:

Calculate the % content of Chlorphenamine maleate by using following formula:

$$= \frac{AT}{AS} \times \frac{WS}{200} \times \frac{10}{200} \times \frac{100}{1} \times \frac{25}{10} \times \frac{P}{100} \times \frac{100}{LC}$$

Where,

AT	=	Area of peak response of Chlorphenamine maleate obtained with Test preparation
AS	=	Average area peak response of Chlorphenamine maleate obtained with replicate injections of standard preparation
WS	=	Weight of Chlorphenamine maleate working standard in mg.
P	=	Potency of Chlorphenamine maleate working standard in % on as such basis.

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LC = Label claim of Chlorphenamine maleate in mg.

Calculate the % content of Phenylephrine Hydrochloride by using following formula:

$$= \frac{AT}{AS} \times \frac{WS}{200} \times \frac{10}{200} \times \frac{100}{1} \times \frac{25}{10} \times \frac{P}{100} \times \frac{100}{LC}$$

Where,

AT = Area of peak response of Phenylephrine hydrochloride obtained with Test preparation.

AS = Average area of peak response of Phenylephrine hydrochloride obtained with replicate injections of standard preparation.

WS = Weight of Phenylephrine Hydrochloride working standard in mg.

P = Potency of Phenylephrine Hydrochloride working standard in % on as such basis.

LC = Label claim of Phenylephrine Hydrochloride in mg.

Limit: Chlorphenamine Maleate: Not less than 85.0% and not more than 115.0% of the average value.
Phenylephrine Hydrochloride: Not less than 85.0% and not more than 115.0% of the average value.

Result: HPLC Graph and validated XL sheet attached.

Observation: Conforms: ☑ Does not conform: ☐

Analyst: | **Date:** 13/04/2020

12.0 Related substances:

Balance ID: ST/QC/EQ/041	Calibration due date: 06/05/2020
HPLC ID : ST/QC/EQ/ 023	Calibration due date: 26/07/2020

Column ID : QC/CL/ 20/013

Reference: In-house

Procedure: By HPLC

Chemicals/Reagents/Standards:

Chlorphenamine maleate : Working standard

Phenylephrine hydrochloride : Working standard

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Caffeine	:	Working standard
Paracetamol	:	Working standard
Potassium Di-hydrogen orthophosphate	:	HPLC grade
Acetonitrile	:	HPLC grade
Orthophosphoric acid	:	AR grade
Methanol	:	HPLC grade
Purified water	:	Milli-Q water or equivalent

Chromatographic Conditions:

Column	:	Kromasil C8 (250 mm X 4.6 mm), 5µm (or) equivalent
Wave length	:	220 nm
Column Temperature	:	30°C
Flow Rate	:	1.0 mL/min
Injection Volume	:	20 µl
Run time	:	15 minutes for Standard solution 40 minutes for Blank, System suitability solution, placebo solution and Sample solution
Retention time	:	About 3.5 minutes for Chlorphenamine maleate, about 4.1 minutes for Phenylephrine Hydrochloride, about 8.4 minutes for Paracetamol and about 20.5 minutes for Caffeine

Preparation of Buffer:

Weigh accurately about 6.8g of potassium Di-hydrogen orthophosphate in 1000 mL of purified water, sonicate to dissolve. Adjust pH 3.07 (3.0±0.05) with Orthophosphoric acid. Filter through 0.45µ membrane filter.

Preparation of Mobile phase:

Prepare a degassed mixture of buffer and methanol in the ratio 85:15 *v/v*.

Preparation of Diluent:

Prepare a degassed mixture of water and methanol in the ratio 80:20 *v/v*.

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Preparation of Placebo solution:

Weigh accurately and transfer about 57.70 (55 mg) of Plain placebo into 100 (100mL) volumetric flask. Add 50 mL of diluent and sonicate for 10 minutes with intermittent shaking. Cool and make up to volume with diluent and mix. Further dilute 5 (5 mL) of above solution into 50 (50 mL) with diluent. Filter through 0.45µ PVDF filter.

Preparation of Standard solution:

Weigh accurately and transfer about 60.28mg (60 mg) of Paracetamol working standard (W.S.No. / Valid upto WS/A/07/01 / 20/07/2020) into a 100 (100 mL) volumetric flask. Add 50 mL of diluent and sonicate to dissolve. Make up to volume with diluent and mix. Dilute 1 (1mL) of this solution to 100 (100 mL) with diluent and mix. Further dilute to 5 (5mL) of above solution into 50 (50 mL) with diluent and mix.

Preparation of system suitability stock solution:

Weigh accurately and transfer about 179.95mg (180mg) of Caffeine working standard (W.S.No. / Valid upto WS/A/09/04 / 09/09/2020) and 12.03mg (12mg) of Chlororphenamine maleate working standard (W.S.No. / Valid upto WS/A/09/01 / 14/09/2020) and 30.53mg (30mg) of Phenylepheine hydrochloride working standard (W.S.No. / Valid upto WS/A/11/01 / 13/11/2020) into a 100 (100 mL) volumetric flask. Add 50 mL of diluent and sonicate to dissolve. Make up to volume with diluent and mix.

Preparation of system suitability solution:

Weigh accurately and transfer about 30 mg of Paracetamol working standard into a 100 mL volumetric flask. Add 1 mL of system suitability standard stock solution and 50 mL of diluent and sonicate to dissolve. Make up to volume with diluent and mix.

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Test preparation:

Weigh accurately 20 tablets and make powder by using mortar and pestle. Weigh and transfer sample powder equivalent to 300 mg of Paracetamol 381.0mg (381mg) of sample, into a 100 (100 mL) volumetric flask. Add about 50 mL of diluent and sonicate for 10 minutes with intermittent shaking dilute up to the volume with diluent and mix. Further dilute 10 (10 mL) of above solution into 100 (100 mL) with diluent. Filter through 0.45µ PVDF filter.

Inject 20 µL of the above solution (blank, system suitability solution, standard, placebo and sample) as per following sequence and measure the area due to any unknown impurity peak.

Injection sequence:

S. No	Sample Name	No. of injections
1	Diluent (blank)	1
2	System suitability solution	1
3	Standard solution	5
4	Placebo Preparation	1
5	Test preparation	1
6	Bracketing standard	1

Calculation:

Single maximum unknown impurity:

$$= \frac{AT_I}{AS_T} \times \frac{WS}{100} \times \frac{1^*}{100} \times \frac{5}{50} \times \frac{100}{WT} \times \frac{100}{10} \times AW \times \frac{P}{100} \times \frac{100}{500}$$

Where,

AT_I = Area of peak due to Single maximum unknown impurity in test preparation.

AS_T = Average area of peak due to Paracetamol in standard preparation.

WS = Weight of Paracetamol working standard in mg.

WT = Weight of sample taken in mg.

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AW = Average weight of tablet in mg.

P = Potency of Paracetamol working standard in % on as such basis.

Total impurities:

$$= \frac{AT_T}{AS_T} \times \frac{WS}{100} \times \frac{1}{100} \times \frac{5}{50} \times \frac{100}{WT} \times \frac{100}{10} \times AW \times \frac{P}{100} \times \frac{100}{500}$$

Where,

AT_T = Area of peak due to Total impurities in test preparation.

AS_T = Average area of peak due to Paracetamol in standard preparation.

WS = Weight of Paracetamol working standard in mg.

WT = Weight of sample taken in mg.

AW = Average weight of tablet in mg.

P = Potency of Paracetamol working standard in % on as such basis.

Single maximum unknown impurity: (NMT 0.20%)

$$= \frac{2128}{25278} \times \frac{60.28}{100} \times \frac{1}{100} \times \frac{5}{50} \times \frac{100}{381.0} \times \frac{100}{10} \times \frac{99.7}{100} \times \frac{100}{500} \times \frac{635.7}{\text{------}} = 0.02\ \%$$

Total impurities: (NMT 0.50%)

$$= \frac{3550}{25278} \times \frac{60.28}{100} \times \frac{1}{100} \times \frac{5}{50} \times \frac{100}{381.0} \times \frac{100}{10} \times \frac{99.7}{100} \times \frac{100}{500} \times \frac{635.7}{\text{------}} = 0.03\ \%$$

Result:	**Limit:**
Single maximum unknown impurity: 0.02%	**Single maximum unknown impurity:** Not more than 0.2%
Total impurities: 0.03%,	**Total impurities:** Not more than 0.5%
Observation: Conforms: ☑ Does not conform: ☐	
Analyst:	**Date:** 15/04/2020

Checked by : Date : 15/04/2020

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13.0 Assay :

Balance ID: ST/QC/EQ/ 041	Calibration due date: 06/05/2020
HPLC ID : ST/QC/EQ/ 039	Calibration due date: 26/07/2020

Column ID : QC/CL/ 20/008

Reference: In-House

Procedure: By HPLC

Note: For reagents, buffer preparation, Diluent, Mobile phase-A, Mobile phase-B, Chromatographic conditions and Gradient program proceed as directed in dissolution Test.

Preparation of Standard stock solution:

Weigh accurately and transfer about 31.92mg (32mg) of Chlorphenamine maleate Working standard (W.S.No. / Valid upto WS/A/069/01 / 14/09/2020), 79.73mg (80mg) of Phenylephrine Hydrochloride working standard (W.S.No. / Valid upto WS/A/117/01 / 13/11/2020) and 24.43mg (24mg) of Caffeine working standard (W.S.No. / Valid upto WS/A/069/04 / 09/09/2020) into a 200 (200 mL) volumetric flask. Add 120 mL of diluent and sonicate to dissolve. Make up to volume with diluent and mix.

Preparation of Standard solution:

Weigh accurately and transfer about 19.92mg (20mg) of Paracetamol working standard (W.S.No. / Valid upto WS/A/078/01 / 20/07/2020) into a 200 (200 mL) volumetric flask. Add 120 mL of diluent and sonicate to dissolve. Add 10 mL of standard stock solution (Chlorphenamine, Phenylephrine and Caffeine) and make up to volume with diluent and mix.

Test preparation:

Preparation of Sample Solution-A: (For Chlorphenamine maleate and Phenylephrine Hydrochloride)

Weigh accurately 20 tablets and make powder by using morter and pestle. Weigh and transfer sample powder equivalent to 500 mg of Paracetamol 635.0 (635mg), into a 250 (250 mL) volumetric flask. Add about 170 mL of diluent and sonicate for 30 minutes with intermittent shaking. Make up to the volume with diluent and mix and Centrifuge this solution at 3000rpm for 10minutes.

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Preparation of Sample Solution-B: (For Paracetamol and Caffeine)

Further dilute 5 (5mL) of above solution to 100 (100mL) with diluent and mix.

Procedure:

Inject the solutions as mentioned below and measure the responses of the peaks due to Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine maleate, Caffeine.

Injection sequence:

S. No	Sample Name	No. of injections
1	Diluent (blank)	1
2	Standard preparation	5
3	Sample solution-A	2
4	Sample solution-B	2
5	Bracketing standard	1

System suitability:

Theoretical plate count	:	NLT 2000 for Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine maleate, Caffeine peak.
Tailing factor	:	NMT 2.0 for Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine maleate, Caffeine peak.
Relative standard deviation	:	NMT 2.0% for five replicate injections of Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine maleate, Caffeine peak.

Calculations:

Calculate the assay of Chlorphenamine maleate in mg/tablet as follows:

$$= \frac{AT}{AS} \times \frac{WS}{200} \times \frac{10}{200} \times \frac{250}{WT} \times \frac{P}{100} \times AW$$

Where,

AT = Average area of peak due to Chlorphenamine maleate in Sample solution A.

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AS = Average area of peak due to Chlorphenamine maleate in standard preparation.

WS = Weight of Chlorphenamine maleate working standard in mg.

WT = Weight of sample taken in mg.

AW = Average weight of tablet in mg.

P = Potency of Chlorphenamine maleate working standard in % on as such basis.

Calculate the assay of Chlorphenamine maleate in % as follows:

$$= \frac{\text{mg/tablet}}{\text{LC}} \times 100$$

LC = Label claim of Chlorphenamine maleate in mg/tablet.

System suitability:

Theoretical Plates : 87889 (Not less than 2000)

Tailing factor : 1.141 (Not more than 2.0%)

Relative standard deviation : 1.082 (Not more than 2.0%)

Standard and Sample Chromatogram value :

Average peak area of Chlorphenamine maleate standard preparation: 215368

Sample Chromatogram value:

1. 205732, 2. 206286 Avg.value 206009

Calculate the assay of Chlorphenamine maleate in mg/tablet as follows:

$$\frac{206009}{215368} \times \frac{31.92}{200} \times \frac{10}{200} \times \frac{250}{635.0} \times \frac{99.70}{100} \times \frac{635.7}{} = 1.90 \text{ mg}$$

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Calculate the assay of Chlorphenamine maleate in % as follows:

$$= \frac{1.90}{2} \times 100 = 95.2\ \%$$

Calculate the assay of Phenylephrine Hydrochloride in mg/tablet as follows:

$$= \frac{AT}{AS} \times \frac{WS}{200} \times \frac{10}{200} \times \frac{250}{WT} \times \frac{P}{100} \times AW$$

Where,

AT	=	Average area of peak due to Phenylephrine Hydrochloride in Sample solution A.
AS	=	Average area of peak due to Phenylephrine Hydrochloride in standard preparation.
WS	=	Weight of Phenylephrine Hydrochloride working standard in mg.
WT	=	Weight of sample taken in mg.
AW	=	Average weight of tablet in mg.
P	=	Potency of Phenylephrine Hydrochloride working standard in % on as such basis.

Calculate the assay of Phenylephrine Hydrochloride in % as follows:

$$= \frac{\text{mg/tablet}}{LC} \times 100$$

LC = Label claim of Phenylephrine Hydrochloride in mg/tablet.

System suitability:

Theoretical Plates	:	6634 (Not less than 2000)
Tailing factor	:	1.103 (Not more than 2.0%)
Relative standard deviation	:	0.285 (Not more than 2.0%)

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Standard and Sample Chromatogram value :

Average peak area of Phenylephrine Hydrochloride standard preparation: 268886

Sample Chromatogram value:

1. 264853 , 2. 264172 Avg.value 264513

Calculate the assay of Phenylephrine Hydrochloride in mg/tablet as follows:

$$\frac{264513}{268886} \times \frac{7973}{200} \times \frac{10}{200} \times \frac{250}{6350} \times \frac{9930}{100} \times \frac{6357}{} = 4.87 \text{ mg}$$

Calculate the assay of Phenylephrine Hydrochloride in % as follows:

$$= \frac{4.87}{5} \times 100 = 97.5\ \%$$

Calculate the assay of Caffeine in mg/tablet as follows:

$$= \frac{AT}{AS} \times \frac{WS}{200} \times \frac{10}{200} \times \frac{250}{WT} \times \frac{100}{5} \times \frac{P}{100} \times AW$$

Where,

AT	=	Average area of peak due to Caffeine in Sample solution B.
AS	=	Average area of peak due to Caffeine in standard preparation.
WS	=	Weight of Caffeine working standard in mg.
WT	=	Weight of sample taken in mg.
AW	=	Average weight of tablet in mg.
P	=	Potency of Caffeine working standard in % on as such basis.

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Calculate the assay of Caffeine in % as follows:

$$= \frac{\text{mg/tablet}}{\text{LC}} \times 100$$

LC = Label claim of Caffeine in mg/tablet.

System suitability:

Theoretical Plates : 93861 (Not less than (2000)

Tailing factor : 1.166 (Not more than 2.0%)

Relative standard deviation : 0.289% (Not more than 2.0%)

Standard and Sample Chromatogram value :

Average peak area of Caffeine standard preparation: 265077

Sample Chromatogram value:

1. 259013 , 2. 258993 Avg.value 259003

Calculate the assay of Caffeine in mg/tablet as follows:

$$\frac{259003}{265077} \times \frac{24.43}{200} \times \frac{10}{200} \times \frac{250}{635.0} \times \frac{100}{5} \times \frac{99.10}{100} \times \frac{635.7}{1} = 29.60 \text{ mg}$$

Calculate the assay of Caffeine in % as follows:

$$= \frac{29.60}{30} \times 100 = 98.7\ \%$$

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Calculate the assay of Paracetamol in mg/tablet as follows:

$$= \frac{AT}{AS} \times \frac{WS}{200} \times \frac{250}{WT} \times \frac{100}{5} \times \frac{P}{100} \times AW$$

Where,

AT = Average area of peak due to Paracetamol in Sample solution B.

AS = Average area of peak due to Paracetamol in standard preparation.

WS = Weight of Paracetamol working standard in mg.

WT = Weight of sample taken in mg.

AW = Average weight of tablet in mg.

P = Potency of Paracetamol working standard in % on as such basis.

Calculate the assay of Paracetamol in % as follows:

$$= \frac{\text{mg/tablet}}{LC} \times 100$$

LC = Label claim of Paracetamol in mg/tablet

System suitability:

Theoretical Plates : 12658 (Not less than (2000)

Tailing factor : 1.430 (Not more than 2.0%)

Relative standard deviation : 0.079 (Not more than 2.0%)

Standard and Sample Chromatogram value :

Average peak area of Paracetamol standard preparation: 3017628

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Sign:	Date: 02/03/2020	Sign:	Date: 11/03/20

	Safetab Life Science Puducherry	
	RECORD OF ANALYSIS	

Name of Product: LITACOLD FLU
(Chlorphenamine Maleate 2mg, Phenylephrine Hydrochloride 5mg, Caffeine 30mg and Paracetamol 500mg)- Compressed Tablets

Batch No/Lot No.	GD200301	A.R.No.	SFP/L/00345/2020	
STP No	**ROA No**	**Revision No.**	**Effective date**	**Page No:**
IMTL00117-00	ROA/ IML00117-00	00	03-03-2020	24 of 25

Sample Chromatogram value:

1. 2982013, 2. 2980841 Avg.value 2981427

Calculate the assay of Paracetamol in mg/tablet as follows:

$$\frac{2981427}{3017628} \times \frac{19.92}{200} \times \frac{250}{635} \times \frac{100}{5} \times \frac{99.70}{100} \times 635.7 = 491.09 \text{ mg}$$

Calculate the assay of Paracetamol in % as follows:

$$= \frac{491.09}{500} \times 100 = 98.2\ \%$$

Limit: Chlorphenamine Maleate: 90.0% to 110.0% of the labeled claim I.e. 1.8mg to 2.2mg

Phenylephrine Hydrochloride: 90.0% to 110.0% of the labeled claim I.e. 4.5mg to 5.5mg

Caffeine: 90.0% to 110.0% of the labeled claim I.e. 27.0mg to 33.0mg

Paracetamol: 90.0% to 110.0% of the labeled claim I.e. 450.0mg to 550.0mg

Observation: Conforms: ☑ Does not conform: ☐

Analyst: **Date:** 13/04/2020

Checked by : Date : 15/04/2020

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Sign:	Date: 02/03/2020	Sign:	Date: 11/03/20

14.0 ANALYTICAL REPORT VERIFICATION CHECK LIST:

Check the following details and enclosures in the report. If the details are available then put '✓' mark on the remarks column and put '*' mark if the details are not available

S.No:	DETAILS	Remarks:
1	TRF is enclosed with the protocol	☑
2	Product name, B.No, Mfg date, Exp date, A.R.No matches with TRF	☑
3	All the tests are performed as per standard specification	☑
4	All the sheets are page numbered, signed and dated by analyst	☑
5	The protocol is duly filled, no blank place, calculations and entries are ok	☑
6	The printouts of UV-VIS spectrophotometer readings are enclosed	☒
7	The spectrum of IR spectrophotometer is enclosed	☒
8	All HPLC chromatograms are enclosed	☑
9	Other instruments sheets (if applicable, then specify in comments column)	☑
10	Public laboratory reports (if applicable, then specify the reasons below)	☒
11	Comments (if any): Weigh Balance printout sheet is enclosed "X" mark is not applicable for this product.	

Remarks: The report is found to be satisfactory ☑ not satisfactory ☐

Verifying authority (Sign & date): _____ 15/04/2020

Checked by : _____ Date : 15/04/2020

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Sign:	Date: 02/03/2020	Sign:	Date: 11/03/20

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Safetab Life Science,
Puducherry - 605 107

QUALITY CONTROL ANALYSIS CALCULATION SHEET

Product Name :	LITACOLD FLU	Batch size :	10.0 LAC
Batch Number :	GD200301	Mfg.Date :	Mar-20
Stage :	UNCOATED TABLET	Exp.Date :	Feb-23

Each Uncoated tablet contains:
Chlorphenamine Maleate BP ---------- 2mg
Phenylephrine Hydrochloride BP ---------- 5mg
Caffeine (anhydrous) BP ---------- 30mg
Paracetamol BP ---------- 500mg

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QC/EQ/023	Balance ID:	ST/QC/EQ/041	WS No.:	WS/A/07/01	% Purity (aib)	99.7

Standard dilution.:	60.28	mg to --->	100	ml to --->	1	ml to --->	100
Std.conc (in ppm)-0.6028	5	ml to --->	50	ml to --->	1	ml to --->	1

Test dilution .:	381.00	mg to --->	100	ml to --->	10	ml to --->	100
Test.conc (in ppm)-299.665	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labelled content :	500	mg
Average weight :	635.7	mg

System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %
Paracetamol	25166	25326	25256	25289	25306	25326	25278	60.9	0.241
With Bracketing std.							25278	60.9	0.241

Name of the Peaks	RT	RRT	Individual Impurity Peak areas	Maximum Impurity Area
UNKNOWN Imp.	2.853		2128	2128
UNKNOWN Imp.	4.536		910	
UNKNOWN Imp.	15.844		512	
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
Total Impurity Area			3550	

SINGLE MAXIMUM UNKNOWN IMPURTIY

Limit: NMT 0.20%

Calculation formula :

Any individual impurity in% = Max.impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100 / Standard area x sample dilution X Label claim x 100

= 2128 / 25278

= 0.02

TOTAL IMPURITIES

Limit: NMT 0.50%

Calculation formula :

Total impurities in% = Total impurity area x Std.dilution X Purity % (aib)x conversion factor x avg.weight x100 / Standard area x sample dilution X Label claim x 100

= 3550 / 25278

= 0.03

Analysed by : C.K.SARAVANAN 15/04/2020
Date : 15.04.2020

Checked by : 15/04/2020
Date :

Safetab Life Science

Plot No. A-68,PIPDIC Electronic Park, Thirubuvanai,Puducherry- 605 107

Quality control Department

< Sample Information >

Acquired by	: Admin
Sample Name	: LITACOLD FLU
Sample ID	: BLANK-RS
Tray#	: 2
Vail#	: 1
Injection Volume	: 20 uL
Data Filename	: 08042020 LITACOLD FLU-TAB-301-304-RS-SPL-01.lcd
Method Filename	: LITACOLD FLU-TAB-RS_SPL.lcm
Batch Filename	: 08042020 LITACOLD FLU-TAB-301-304-RS.lcb
Report Filename	: Default.lcr
Date Acquired	: 08/04/2020 2:57:19
Data Processed	: 13/04/2020 11:25:44

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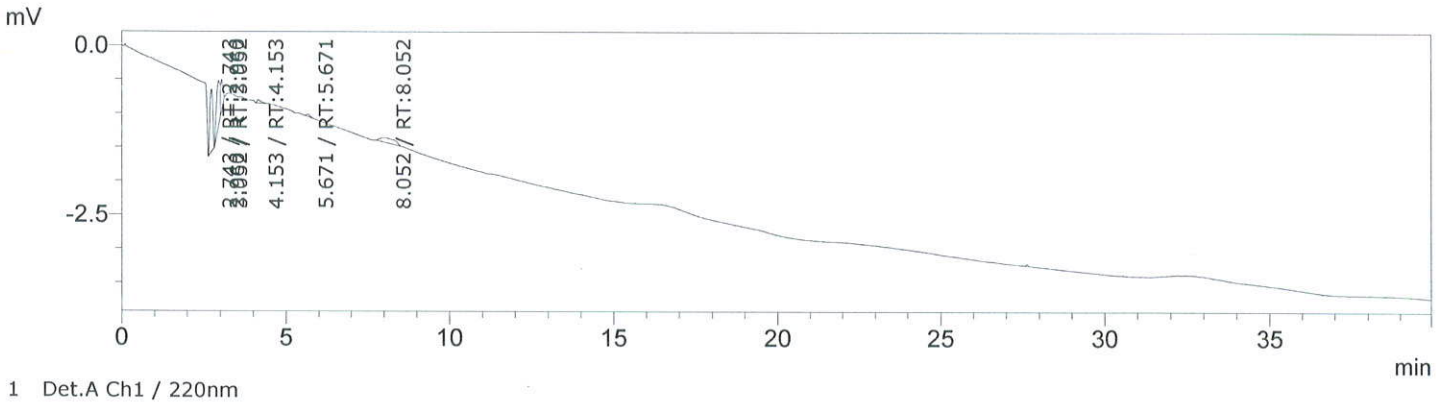

1 Det.A Ch1 / 220nm

< Peak Table >

PeakTable

Detector A Ch1 220nm

Ret. Time	Area	Area %	Resolution	ive Retention	Tailing Factor	heoretical Plate	Name
2.743	5764	35.619	0.000	0.000	0.978	4189.472	RT:2.743
2.960	5398	33.354	0.949	0.000	0.000	1689.333	RT:2.960
3.052	2114	13.063	0.193	0.000	0.000	326.446	RT:3.052
4.153	467	2.887	2.464	0.000	3.133	5841.226	RT:4.153
5.671	255	1.573	7.250	0.000	1.427	12676.733	RT:5.671
8.052	2185	13.503	5.077	0.000	1.305	1911.771	RT:8.052
	16183	100.000					

Analysed by

Date 13/04/2020

Checked by

Date

Safetab Life Science

Plot No. A-68,PIPDIC Electronic Park, Thirubuvanai,Puducherry- 605 107

Quality control Department

< Sample Information >

Acquired by	: Admin
Sample Name	: LITACOLD FLU
Sample ID	: BLANK-RS
Tray#	: 2
Vail#	: 1
Injection Volume	: 20 uL
Data Filename	: 08042020 LITACOLD FLU-TAB-301-304-RS-SPL-02.lcd
Method Filename	: LITACOLD FLU-TAB-RS_SPL.lcm
Batch Filename	: 08042020 LITACOLD FLU-TAB-301-304-RS.lcb
Report Filename	: Default.lcr
Date Acquired	: 08/04/2020 3:38:09
Data Processed	: 13/04/2020 11:28:21

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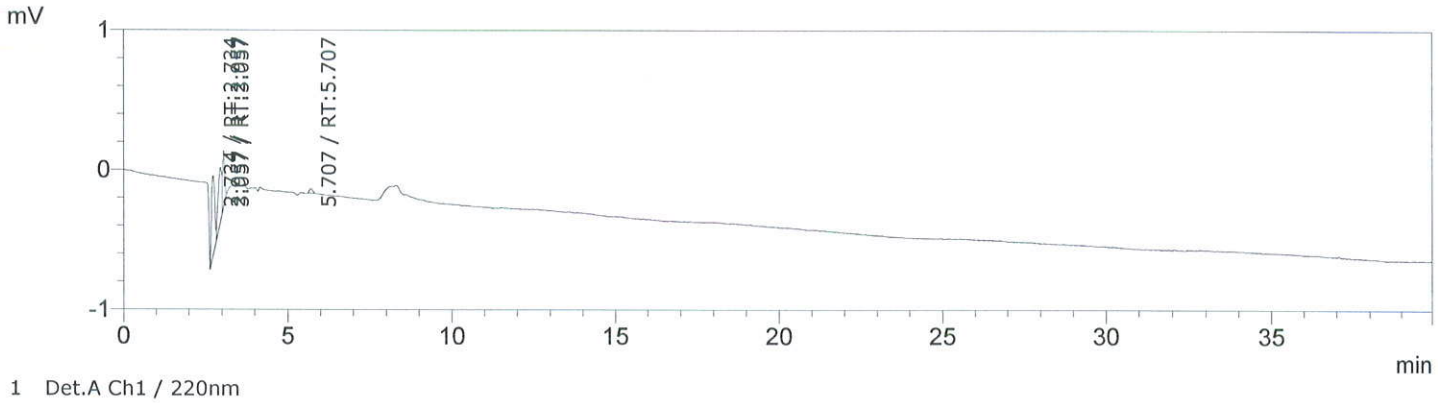

1 Det.A Ch1 / 220nm

< Peak Table >

PeakTable

Detector A Ch1 220nm

Ret. Time	Area	Area %	Resolution	ive Retention	Tailing Factor	heoretical Plate	Name
2.734	3948	43.502	0.000	0.000	0.000	3577.025	RT:2.734
2.957	3034	33.431	0.919	0.000	0.000	1529.518	RT:2.957
3.057	1864	20.544	0.393	0.000	0.000	3565.468	RT:3.057
5.707	229	2.522	13.264	0.000	1.623	13735.054	RT:5.707
	9074	100.000					

Analysed by

Date 13/04/2020

Checked by

Date 13/04/2020

Safetab Life Science

Plot No. A-68,PIPDIC Electronic Park, Thirubuvanai,Puducherry- 605 107

Quality control Department

< Sample Information >

Acquired by	: Admin
Sample Name	: LITACOLD FLU
Sample ID	: SYSTEM SUITABILITY SOLUTION
Tray#	: 2
Vail#	: 2
Injection Volume	: 20 uL
Data Filename	: 08042020 LITACOLD FLU-TAB-301-304-RS-SPL-03.lcd
Method Filename	: LITACOLD FLU-TAB-RS_SPL.lcm
Batch Filename	: 08042020 LITACOLD FLU-TAB-301-304-RS.lcb
Report Filename	: Default.lcr
Date Acquired	: 08/04/2020 4:18:59
Data Processed	: 13/04/2020 11:30:34

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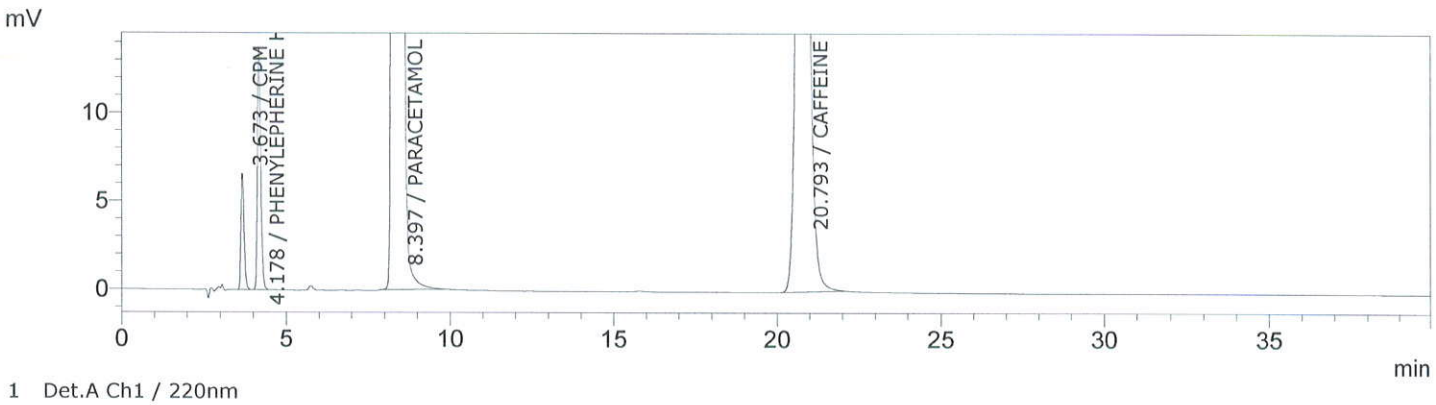


1 Det.A Ch1 / 220nm

< Peak Table >

PeakTable

Detector A Ch1 220nm

Ret. Time	Area	Area %	Resolution	ive Retention	Tailing Factor	heoretical Plate	Name
3.673	42541	0.324	0.000	0.000	1.345	6569.865	CPM
4.178	97387	0.743	2.673	0.000	1.269	7240.342	PHENYLEPHERINE HCL
8.397	11852580	90.406	17.134	0.000	1.103	12874.615	PARACETAMOL
20.793	1117820	8.526	26.635	0.000	1.095	17167.130	CAFFEINE
	13110328	100.000					

Analysed by

Date 15/04/2020

Checked by

Date 15/04/2020

Safetab Life Science

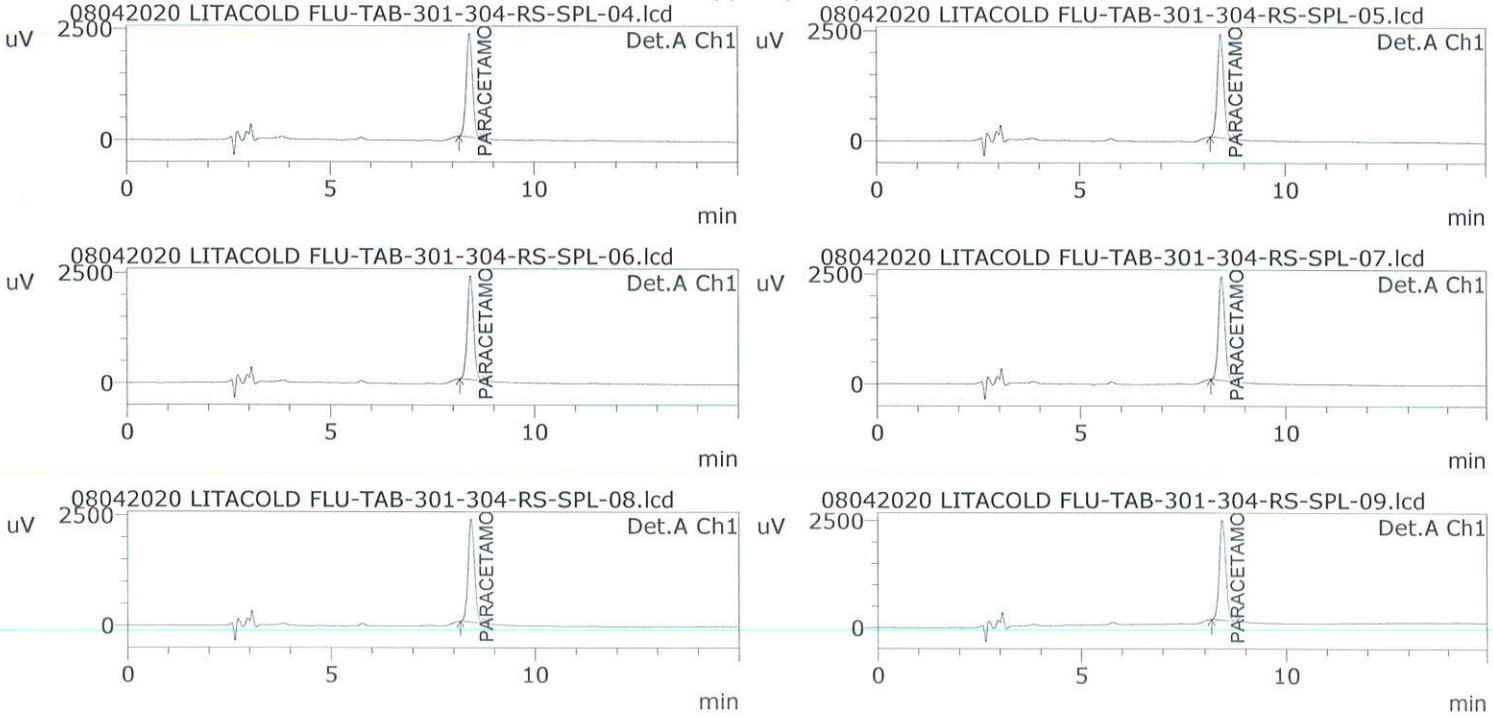
Plot No. A-68,PIPDIC Electronic Park, Thirubuvanai,Puducherry- 605 107

Quality control Department

Sample Information

Acquired by	: Admin
Sample Name	: LITACOLD FLU
Sample ID	: PARACETAMOL-RS-STD-01
Tray#	: 2
Vail#	: 3
Injection Volume	: 20 uL
Data Filename	: 08042020 LITACOLD FLU-TAB-301-304-RS-SPL-04.lcd
Method Filename	: LITACOLD FLU-TAB-RS_STD.lcm
Batch Filename	: 08042020 LITACOLD FLU-TAB-301-304-RS.lcb
Report Filename	: Default.lcr
Date Acquired	: 08/04/2020 4:59:47
Data Processed	: 13/04/2020 11:41:14

Summary(Compound)



<< Detector A >>

ID#1 Compound Name: PARACETAMOL

Vial#	Title	Sample ID	Ret. Time	Area	T. Plate	T.Factor
3	301-304-RS-SPL-04.lcd	PARACETAMOL-RS-STD-01	8.424	25166	13296.32	1.057
3	301-304-RS-SPL-05.lcd	PARACETAMOL-RS-STD-02	8.427	25326	13356.39	1.055
3	301-304-RS-SPL-06.lcd	PARACETAMOL-RS-STD-03	8.431	25256	13390.65	1.058
3	301-304-RS-SPL-07.lcd	PARACETAMOL-RS-STD-04	8.432	25289	13356.03	1.059
3	301-304-RS-SPL-08.lcd	PARACETAMOL-RS-STD-05	8.435	25306	13328.81	1.053
3	301-304-RS-SPL-09.lcd	PARACETAMOL-RS-STD-06	8.435	25326	13358.69	1.055
	Average		8.431	25278	13347.81	1.056
	%RSD		0.051	0.241	0.239	0.208

Analysed by

Date : 13/04/2020

Checked by

Date : 13/04/2020

Safetab Life Science

Plot No. A-68,PIPDIC Electronic Park, Thirubuvanai,Puducherry- 605 107

Quality control Department

< Sample Information >

Acquired by	: Admin
Sample Name	: LITACOLD FLU
Sample ID	: PLIAN PLACEBO
Tray#	: 2
Vail#	: 4
Injection Volume	: 20 uL
Data Filename	: 08042020 LITACOLD FLU-TAB-301-304-RS-SPL-10.lcd
Method Filename	: LITACOLD FLU-TAB-RS_SPL.lcm
Batch Filename	: 08042020 LITACOLD FLU-TAB-301-304-RS.lcb
Report Filename	: Default.lcr
Date Acquired	: 08/04/2020 6:34:35
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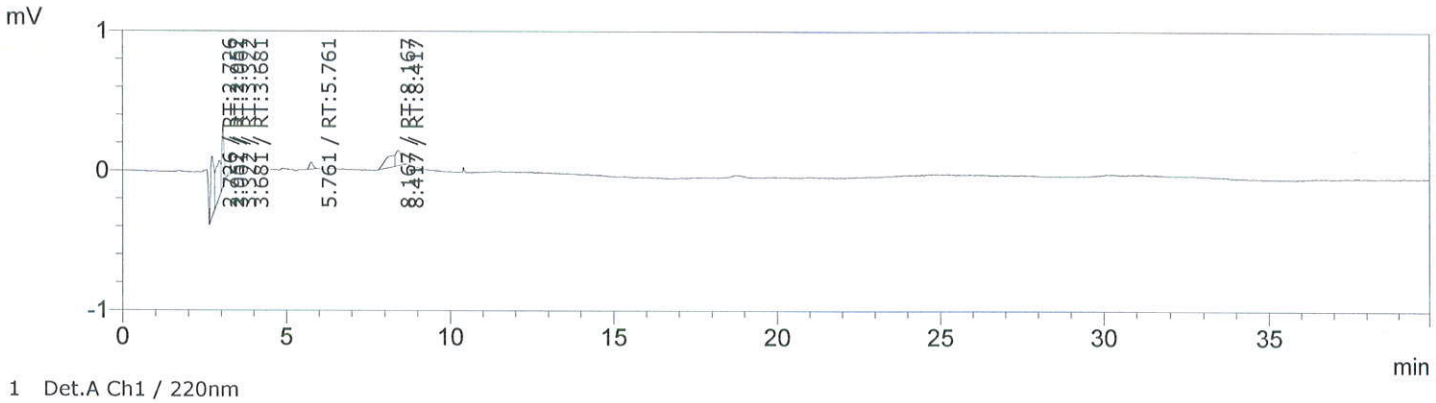

1 Det.A Ch1 / 220nm

< Peak Table >

PeakTable

Detector A Ch1 220nm

Ret. Time	Area	Area %	Resolution	ive Retention	Tailing Factor	heoretical Plate	Name
2.726	3074	24.137	0.000	0.000	0.000	1761.995	RT:2.726
2.952	2982	23.420	0.297	0.000	0.000	86.890	RT:2.952
3.061	2206	17.324	0.154	0.000	0.000	6490.079	RT:3.061
3.322	781	6.130	1.290	0.000	1.068	2770.316	RT:3.322
3.681	323	2.539	1.683	0.000	1.381	7160.477	RT:3.681
5.761	392	3.079	10.714	0.000	1.310	11559.954	RT:5.761
8.167	1730	13.585	0.225	0.000	0.000	2.376	RT:8.167
8.417	1246	9.786	0.023	0.000	0.000	5201.247	RT:8.417
	12734	100.000					

Analysed by

Date 13/04/2020

Checked by

Date 13/04/2020

Safetab Life Science

Plot No. A-68,PIPDIC Electronic Park, Thirubuvanai,Puducherry- 605 107

Quality control Department

< Sample Information >

Acquired by	: Admin
Sample Name	: LITACOLD FLU
Sample ID	: LITACOLD FLU-TAB-301-RS-SPL
Tray#	: 2
Vail#	: 5
Injection Volume	: 20 uL
Data Filename	: 08042020 LITACOLD FLU-TAB-301-304-RS-SPL-11.lcd
Method Filename	: LITACOLD FLU-TAB-RS_SPL.lcm
Batch Filename	: 08042020 LITACOLD FLU-TAB-301-304-RS.lcb
Report Filename	: Default.lcr
Date Acquired	: 08/04/2020 7:23:22
Data Processed	: 13/04/2020 12:28:17

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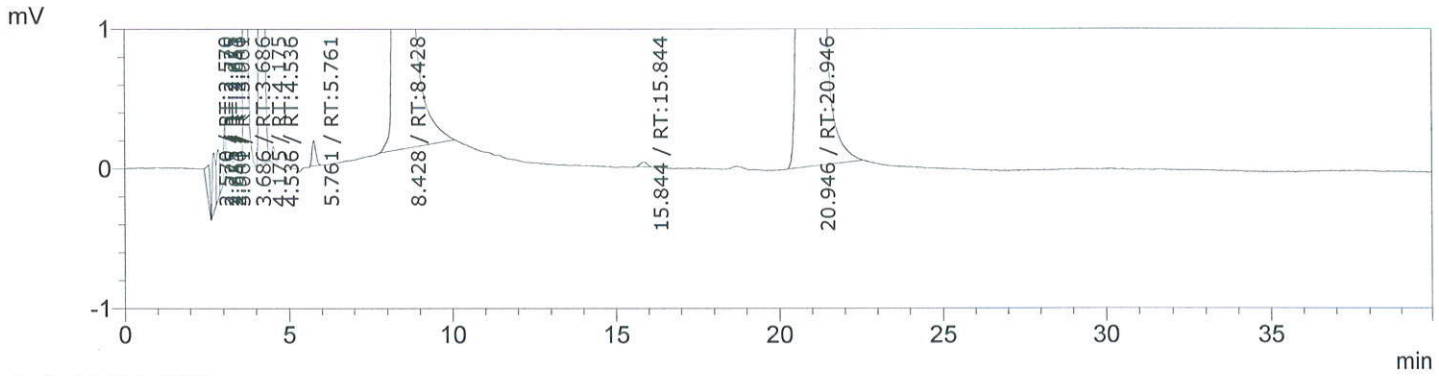

1 Det.A Ch1 / 220nm

< Peak Table >

PeakTable

Detector A Ch1 220nm

Ret. Time	Area	Area %	Resolution	ive Retention	Tailing Factor	heoretical Plate	Name
2.570	1830	0.014	0.000	0.000	0.764	2551.553	RT:2.570
2.725	2882	0.023	0.652	0.000	0.000	1585.867	RT:2.725
2.853	2128	0.017	0.372	0.000	0.000	756.281	RT:2.853
2.946	468	0.012	0.000	0.000	0.000	0.000	RT:2.946
3.061	1852	0.015	0.000	0.000	0.000	6599.029	RT:3.061
3.686	38830	0.305	3.764	0.000	1.371	6614.952	RT:3.686
4.175	83985	0.659	2.580	0.000	1.260	7127.576	RT:4.175
4.536	910	0.007	1.737	0.000	1.270	6940.364	RT:4.536
5.761	1493	0.012	5.479	0.000	1.312	10110.090	RT:5.761
8.428	11498387	90.267	10.155	0.000	1.103	12954.313	RT:8.428
15.844	512	0.004	20.113	0.000	1.276	20632.518	RT:15.844
20.946	1103881	8.666	9.455	0.000	1.100	17251.268	RT:20.946
	12738157	100.000					

cpm → phenylephrine HCl

paracetamol

caffeine

Analysed by

Date 15/04/2020

Checked by

Date 15/04/2020

~ → Unknown impurity peak

d → Blank peak

Safetab Life Science,

Puducherry - 605 107

QUALITY CONTROL ANALYSIS CALCULATION SHEET

Product Name :	LITACOLD-FLU	Batch size :	10.0 LAC
Batch Number :	GD200301	Mfg.Date :	Mar-20
Stage :	UNCOATED TABLET	Exp.Date :	Feb-23

Each Uncoated tablet contains:
Chlorphenamine Maleate BP ---------- 2mg
Phenylephrine Hydrochloride BP ---------- 5mg
Caffeine (anhydrous) BP ---------- 30mg
Paracetamol BP ---------- 500mg

DISSOLUTION OF PHENYLEPHRINE HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/045	Balance ID:	ST/QC/EQ/041	WS No.:	WS/A/11/01	% Purity (aib)	99.30

Dissolution medium :	pH 6.8 Phosphate buffer
Volume (ml)	900
Time & Speed	45 minutes & 75RPM
Limit	Not less than 80.0%

Standard dilution.:	67.97	mg to --->	250	ml to --->	4	ml to --->	200
Std.conc (in ppm)-5.4376	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	One tablet	mg to --->	900	ml to --->	1	ml to --->	1
Test.conc (in ppm)-5.55555	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labelled claim ;	5 mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Phenylephrine Hcl	135468	135514	135134	135257	135053	135285	202.1	0.149
With Bracketing std.	134526	133554				134929	689.3	0.511

Stage - S1				Stage - S2			
Tablets	Sample area	Drug release in mg/tablet	Drug Release in %	Tablets	Sample area	Drug release in mg/tablet	Drug Release in %
Unit-1	134502	4.83	96.63	Unit-1		0.00	0.00
Unit-2	133219	4.79	95.71	Unit-2		0.00	0.00
Unit-3	135030	4.85	97.01	Unit-3		0.00	0.00
Unit-4	133926	4.81	96.22	Unit-4		0.00	0.00
Unit-5	132413	4.76	95.13	Unit-5		0.00	0.00
Unit-6	132708	4.77	95.34	Unit-6		0.00	0.00
Average			96.0	Average			0.0
Std.Dev			0.74	Std.Dev			0.00
% RSD			0.77	% RSD			#DIV/0!
Minimum			95.1	Minimum			0.0
			97.0	Maximum			0.0

Calculation formula :

Drug release in mg /tablet	Sample area x Std.dilution X Purity %(aib) x conversion factor / Standard area x sample dilution X 100

Drug release in %	Drug release in mg /tablet x 100 / Labeled claim

Analysed by : C.K.SARAVANAN 11/04/2020

Date : 11.04.2020

Checked by :

Date : 13/04/2020

Safetab Life Science,

Puducherry - 605 107

QUALITY CONTROL ANALYSIS CALCULATION SHEET

Product Name :	LITACOLD-FLU	Batch size :	10.0 LAC
Batch Number :	GD200301	Mfg.Date :	Mar-20
Stage :	UNCOATED TABLET	Exp.Date :	Feb-23

Each Uncoated tablet contains:
Chlorphenamine Maleate BP ---------- 2mg
Phenylephrine Hydrochloride BP ---------- 5mg
Caffeine (anhydrous) BP ---------- 30mg
Paracetamol BP ---------- 500mg

DISSOLUTION OF CHLORPHENAMINE MALEATE

Instrument ID:	ST/QC/EQ/045	Balance ID:	ST/QC/EQ/041	WS No.:	WS/A/09/01	% Purity (aib)	99.70

Dissolution medium :	pH 6.8 Phosphate buffer
Volume (ml)	900
Time & Speed	45 minutes & 75RPM
Limit	Not less than 80.0%

Standard dilution.:	27.92	mg to --->	250	ml to --->	4	ml to --->	200
Std.conc (in ppm)-2.2336	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	One tablet	mg to --->	900	ml to --->	1	ml to --->	1
Test.conc (in ppm)-2.22222	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labelled claim ;	2 mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Chlorphenamine maleate	67669	66728	67259	67313	67111	67216	341.2	0.508
With Bracketing std.	67238	67342				67237	282.5	0.420

Stage - S1				Stage - S2			
Tablets	Sample area	Drug release in mg/tablet	Drug Release in %	Tablets	Sample area	Drug release in mg/tablet	Drug Release in %
Unit-1	63700	1.90	94.97	Unit-1		0.00	0.00
Unit-2	63682	1.90	94.94	Unit-2		0.00	0.00
Unit-3	61137	1.82	91.15	Unit-3		0.00	0.00
Unit-4	62738	1.87	93.53	Unit-4		0.00	0.00
Unit-5	58948	1.76	87.88	Unit-5		0.00	0.00
Unit-6	62439	1.86	93.09	Unit-6		0.00	0.00
Average			92.6	Average			0.0
Std.Dev			2.70	Std.Dev			0.00
% RSD			2.92	% RSD			#DIV/0!
Minimum			87.9	Minimum			0.0
			95.0	Maximum			0.0

Calculation formula :

Drug release in mg /tablet	Sample area x Std.dilution X Purity %(aib) x conversion factor / Standard area x sample dilution X 100

Drug release in %	Drug release in mg /tablet x 100 / Labeled claim

Analysed by : C.K.SARAVANAN
Date : 11.04.2020

Checked by :
Date : 15/04/2020

Safetab Life Science,

Puducherry - 605 107

QUALITY CONTROL ANALYSIS CALCULATION SHEET

Product Name :	LITACOLD-FLU	Batch size :	10.0 LAC
Batch Number :	GD200301	Mfg.Date :	Mar-20
Stage :	UNCOATED TABLET	Exp.Date :	Feb-23

Each Uncoated tablet contains:
Chlorphenamine Maleate BP ---------- 2mg
Phenylephrine Hydrochloride BP ---------- 5mg
Caffeine (anhydrous) BP ---------- 30mg
Paracetamol BP ---------- 500mg

DISSOLUTION OF PARACETAMOL

Instrument ID:	ST/QC/EQ/045	Balance ID:	ST/QC/EQ/041	WS No.:	WS/A/07/01	% Purity (aib)	99.70

Dissolution medium :	pH6.8 Phosphate buffer
Volume (ml)	900
Time & Speed	45 minutes & 75RPM
Limit	Not less than 80.0%

Standard dilution.:	21.69	mg to --->	200	ml to --->	1	ml to --->	1
Std.conc (in ppm)-108.45	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	One tablet	mg to --->	900	ml to --->	10	ml to --->	50
Test.conc (in ppm)-111.1111	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labelled claim ;	500 mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Paracetamol	3409313	3410373	3412346	3411601	3410388	3410804	1182.7	0.035
With Bracketing std.	3404459	3397472				3407993	5296.1	0.155

Stage - S1				Stage - S2			
Tablets	Sample area	Drug release in mg/tablet	Drug Release in %	Tablets	Sample area	Drug release in mg/tablet	Drug Release in %
Unit-1	3826157	545.81	109.16	Unit-1		0.00	0.00
Unit-2	3467869	494.70	98.94	Unit-2		0.00	0.00
Unit-3	3489426	497.78	99.56	Unit-3		0.00	0.00
Unit-4	3459332	493.48	98.70	Unit-4		0.00	0.00
Unit-5	3413343	486.92	97.38	Unit-5		0.00	0.00
Unit-6	3439862	490.71	98.14	Unit-6		0.00	0.00
Average			100.3	Average			0.0
Std.Dev			4.40	Std.Dev			0.00
% RSD			4.38	% RSD			#DIV/0!
Minimum			97.4	Minimum			0.0
			109.2	Maximum			0.0

Calculation formula :

Drug release in mg /tablet	Sample area x Std.dilution X Purity %(aib) x conversion factor / Standard area x sample dilution X 100

Drug release in %	Drug release in mg /tablet x 100 / Labeled claim

Analysed by : C.K.SARAVANAN
Date : 11.04.2020

Checked by :
Date : 11/04/2020

Safetab Life Science,

Puducherry - 605 107

QUALITY CONTROL ANALYSIS CALCULATION SHEET

Product Name :	LITACOLD-FLU	Batch size :	10.0 LAC
Batch Number :	GD200301	Mfg.Date :	Mar-20
Stage :	UNCOATED TABLET	Exp.Date :	Feb-23

Each Uncoated tablet contains:
Chlorphenamine Maleate BP ---------- 2mg
Phenylephrine Hydrochloride BP ---------- 5mg
Caffeine (anhydrous) BP ---------- 30mg
Paracetamol BP ---------- 500mg

DISSOLUTION OF CAFFEINE

Instrument ID:	ST/QC/EQ/045	Balance ID:	ST/QC/EQ/041	WS No.:	WS/A/09/04	% Purity (aib)	99.10

Dissolution medium :	pH6.8 Phosphate buffer
Volume (ml)	900
Time & Speed	45 minutes & 75RPM
Limit	Not less than 80.0%

Standard dilution.:	82.99	mg to --->	250	ml to --->	4	ml to --->	200
Std.conc (in ppm)-6.6392	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	One tablet	mg to --->	900	ml to --->	10	ml to --->	50
Test.conc (in ppm)-6.66666	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labelled claim ;	30 mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Caffeine	311848	311704	312357	311725	311617	311850	295.1	0.095
With Bracketing std.	312249	310420				311703	632.6	0.203

Stage - S1				Stage - S2			
Tablets	Sample area	Drug release in mg/tablet	Drug Release in %	Tablets	Sample area	Drug release in mg/tablet	Drug Release in %
Unit-1	348050	33.04	110.15	Unit-1		0.00	0.00
Unit-2	311555	29.58	98.60	Unit-2		0.00	0.00
Unit-3	315666	29.97	99.90	Unit-3		0.00	0.00
Unit-4	312305	29.65	98.84	Unit-4		0.00	0.00
Unit-5	316844	30.08	100.27	Unit-5		0.00	0.00
Unit-6	312588	29.68	98.93	Unit-6		0.00	0.00
Average			101.1	Average			33.7
Std.Dev			4.47	Std.Dev			0.00
% RSD			4.43	% RSD			0.00
Minimum			98.6	Minimum			0.0
Maximum			110.1	Maximum			0.0

Calculation formula :

$$\text{Drug release in mg /tablet} = \frac{\text{Sample area x Std.dilution X Purity \%(aib) x conversion factor}}{\text{Standard area x sample dilution X 100}}$$

$$\text{Drug release in \%} = \frac{\text{Drug release in mg /tablet x 100}}{\text{Labeled claim}}$$

Analysed by : C.K.SARAVANAN
Date : 11.04.2020

Checked by :
Date : 15/04/2020

Safetab Life Science

Puducherry- 605 107

Quality control Department

<Sample Information>

Acquired by	: C.K.Saravanan
Sample Name	: LITACOLD FLU
Sample ID	: DILUENT-DS
Data Filename	: 08042020 LITACOLD FLU-TAB-301-304-DS-SPL-01.lcd
Method Filename	: PARA+CPM+CAFFEINE+PHENYL_AHPL_DS_STD_P.lcm
Batch Filename	: 08042020 LITACOLD FLU-TAB-301-304-DS.lcb
Vial #	: 1-1
Injection Volume	: 20 uL
Date Acquired	: 4/8/2020 1:42:09 AM
Date Processed	: 4/10/2020 4:39:08 PM

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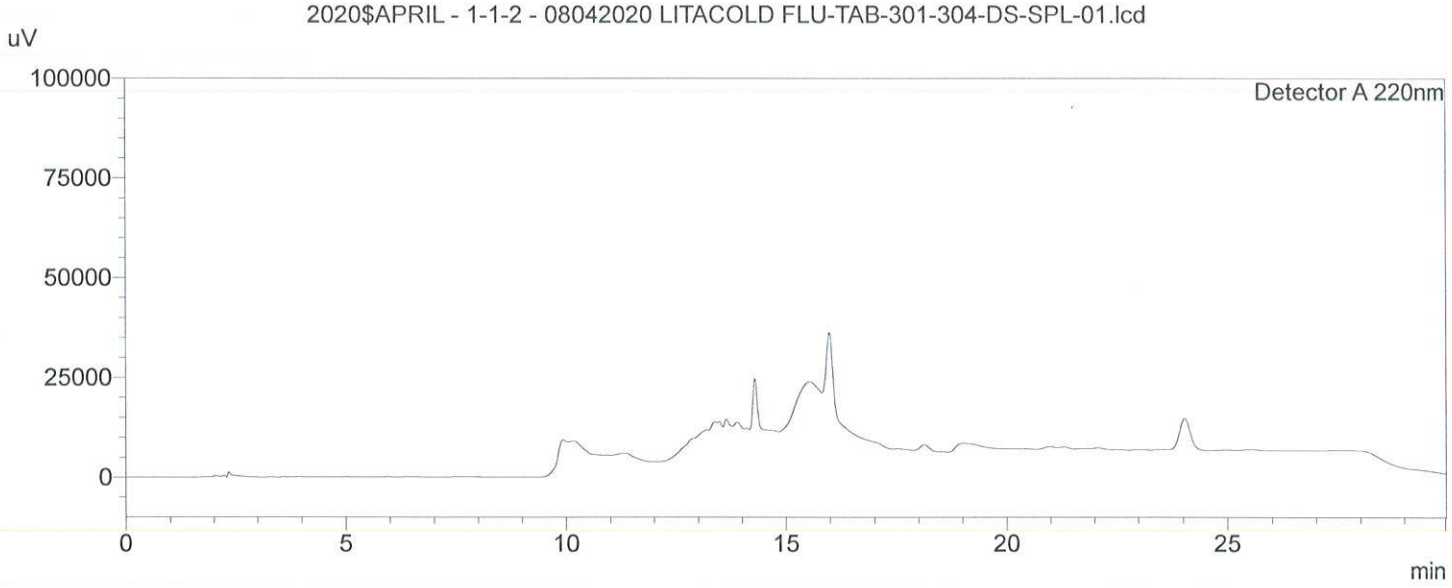

<Peak Table>

Detector A 220nm

Peak#	Ret. Time	Area	Area%	T.Plate	T.Factor	Resolution	R.R.Time	Name
Total								

Analysed By

Date : 11/04/2020

Checked By

Date : 15/04/2020

Safetab Life Science

Puducherry- 605 107

Quality control Department

Sample Information

Acquired by	: C.K.Saravanan
Sample Name	: LITACOLD FLU
Sample ID	: PHEN+PARA+CAFF+CPM-DS-STD-01
Tray#	: 1
Vial#	: 2
Injection Volume	: 20
Data File	: 08042020 LITACOLD FLU-TAB-301-304-DS-SPL-02.lcd
Method File	: PARA+CPM+CAFFEINE+PHENYL_AHPL_DS_STD_P.lcm
Batch File	: 08042020 LITACOLD FLU-TAB-301-304-DS.lcb
Report Format File	: DEFAULT.lsr
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Date Processed	: 4/10/2020 4:39:08 PM

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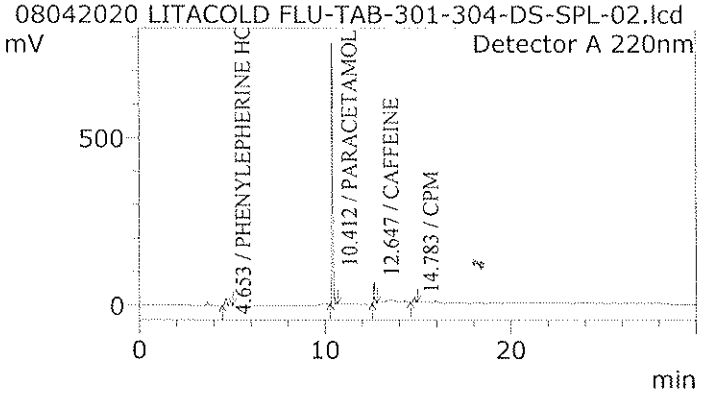

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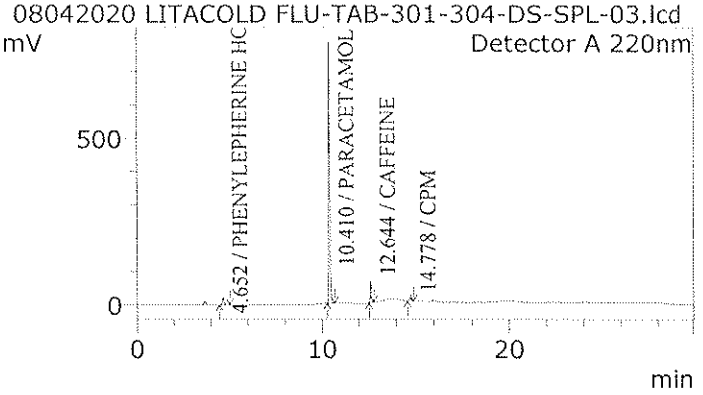

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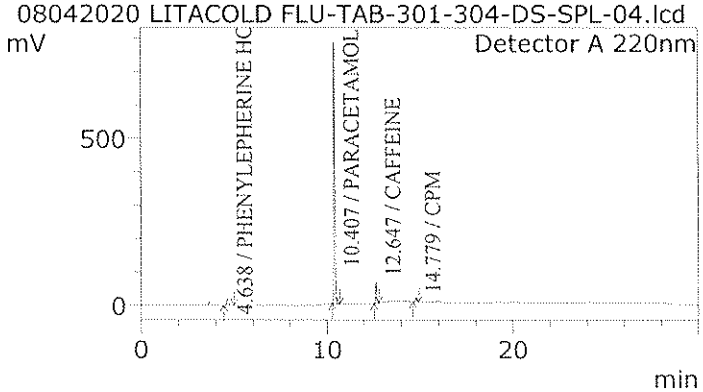

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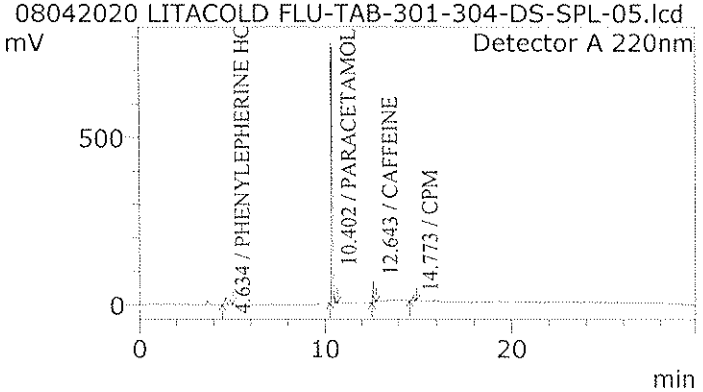

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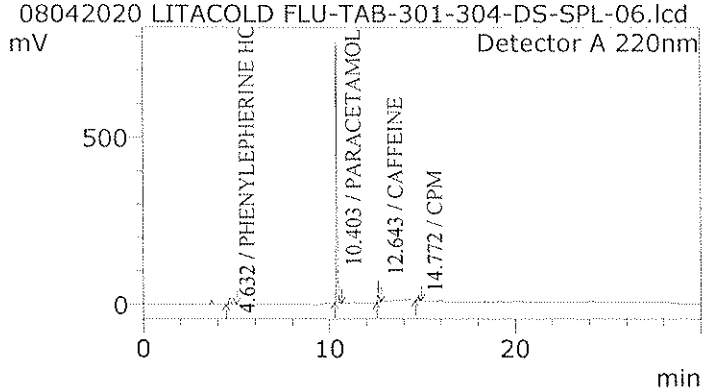


<< Detector A >>

ID#1 Compound Name: PHENYLEPHERINE HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
2	DS-SPL-02.lcd	PHEN+PARA+CAFF+CPM-DS-STD-01	4.653	135468	9646	1.179
2	DS-SPL-03.lcd	PHEN+PARA+CAFF+CPM-DS-STD-02	4.652	135514	9673	1.178
2	DS-SPL-04.lcd	PHEN+PARA+CAFF+CPM-DS-STD-03	4.638	135134	9599	1.180
2	DS-SPL-05.lcd	PHEN+PARA+CAFF+CPM-DS-STD-04	4.634	135257	9639	1.179
2	DS-SPL-06.lcd	PHEN+PARA+CAFF+CPM-DS-STD-05	4.632	135053	9625	1.181
	Average		4.642	135285	9636	1.180
	%RSD		0.214	0.149	0.282	0.093

ID#2 Compound Name: PARACETAMOL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
2	DS-SPL-02.lcd	PHEN+PARA+CAFF+CPM-DS-STD-01	10.412	3409313	103081	1.249
2	DS-SPL-03.lcd	PHEN+PARA+CAFF+CPM-DS-STD-02	10.410	3410373	100670	1.254
2	DS-SPL-04.lcd	PHEN+PARA+CAFF+CPM-DS-STD-03	10.407	3412346	100467	1.248
2	DS-SPL-05.lcd	PHEN+PARA+CAFF+CPM-DS-STD-04	10.402	3411601	102314	1.250
2	DS-SPL-06.lcd	PHEN+PARA+CAFF+CPM-DS-STD-05	10.403	3410388	102374	1.250
	Average		10.407	3410804	101781	1.250
	%RSD		0.040	0.035	1.130	0.158

ID#3 Compound Name: CAFFEINE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
2	DS-SPL-02.lcd	PHEN+PARA+CAFF+CPM-DS-STD-01	12.647	311848	127245	1.173
2	DS-SPL-03.lcd	PHEN+PARA+CAFF+CPM-DS-STD-02	12.644	311704	126980	1.181
2	DS-SPL-04.lcd	PHEN+PARA+CAFF+CPM-DS-STD-03	12.647	312357	126908	1.174
2	DS-SPL-05.lcd	PHEN+PARA+CAFF+CPM-DS-STD-04	12.643	311725	125919	1.180
2	DS-SPL-06.lcd	PHEN+PARA+CAFF+CPM-DS-STD-05	12.643	311617	125866	1.180
	Average		12.645	311850	126584	1.178
	%RSD		0.015	0.095	0.508	0.324

ID#4 Compound Name: CPM

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
2	DS-SPL-02.lcd	PHEN+PARA+CAFF+CPM-DS-STD-01	14.783	67669	98594	1.082
2	DS-SPL-03.lcd	PHEN+PARA+CAFF+CPM-DS-STD-02	14.778	66728	99212	1.089
2	DS-SPL-04.lcd	PHEN+PARA+CAFF+CPM-DS-STD-03	14.779	67259	98177	1.093
2	DS-SPL-05.lcd	PHEN+PARA+CAFF+CPM-DS-STD-04	14.773	67313	98536	1.091
2	DS-SPL-06.lcd	PHEN+PARA+CAFF+CPM-DS-STD-05	14.772	67111	98625	1.095
	Average		14.777	67216	98629	1.090
	%RSD		0.030	0.507	0.378	0.450

Analysed By

Date : 11/04/2022

Checked By

Date : 12/04/2022

Safetab Life Science

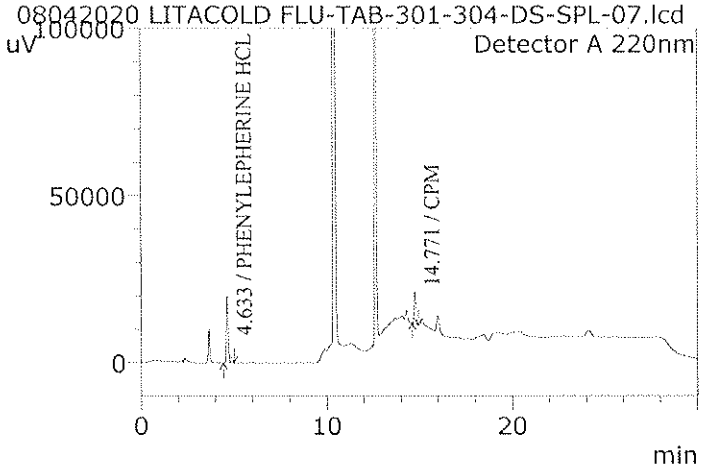
Puducherry- 605 107

Quality control Department

Sample Information

Acquired by	: C.K.Saravanan
Sample Name	: LITACOLD FLU
Sample ID	: LITACOLD FLU-T-01-PH+C-DS-SPL-1
Tray#	: 1
Vial#	: 3
Injection Volume	: 20
Data File	: 08042020 LITACOLD FLU-TAB-301-304-DS-SPL-07.lcd
Method File	: PARA+CPM+CAFFEINE+PHENYL_AHPL_DS_PHENYL+CPM_P.lcm
Batch File	: 08042020 LITACOLD FLU-TAB-301-304-DS.lcb
Report Format File	: DEFAULT.lsr
Date Acquired	: 4/8/2020 4:45:57 AM
Date Processed	: 4/10/2020 4:48:10 PM

08042020 LITACOLD FLU-TAB-301-304-DS-SPL-07.lcd



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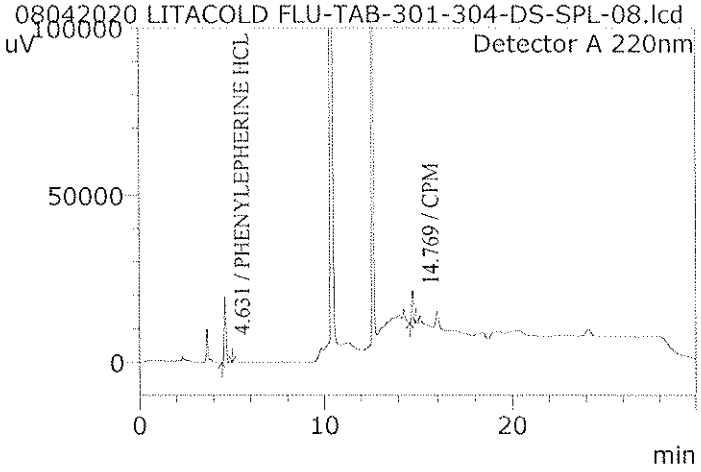

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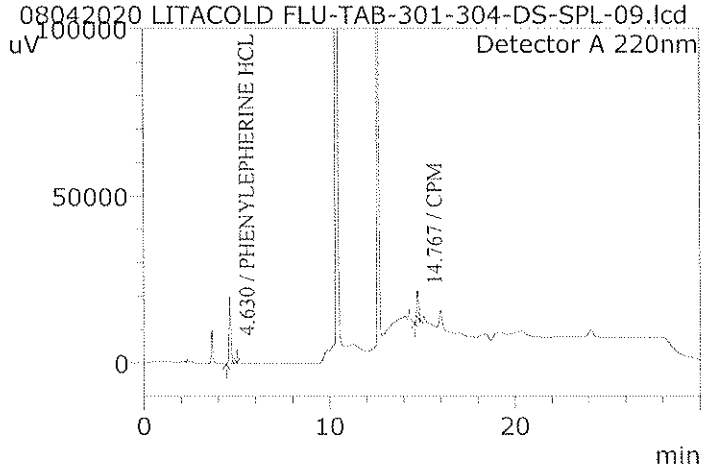

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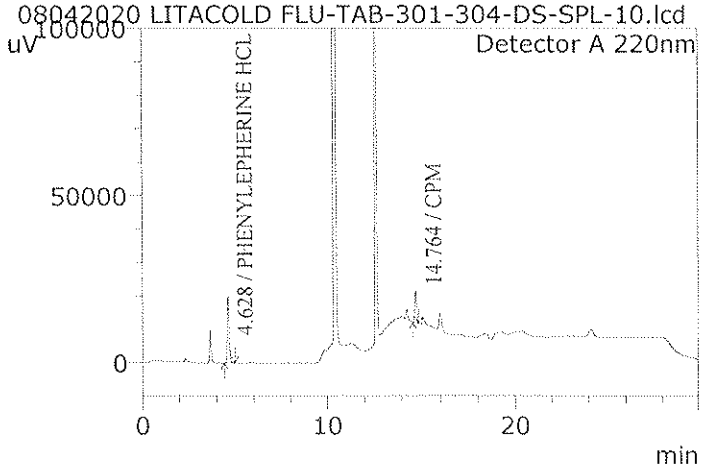

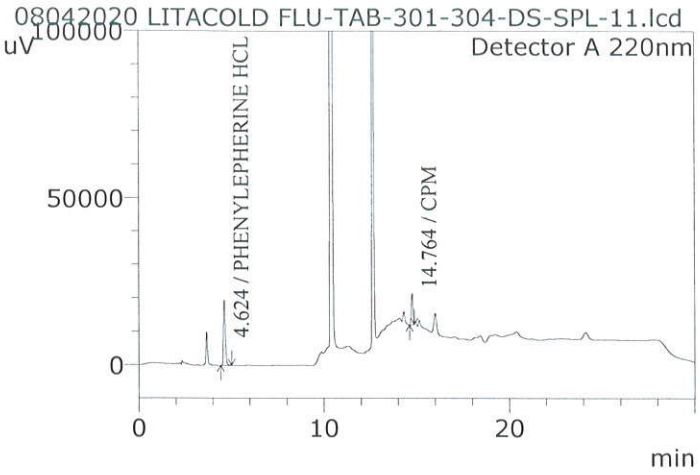

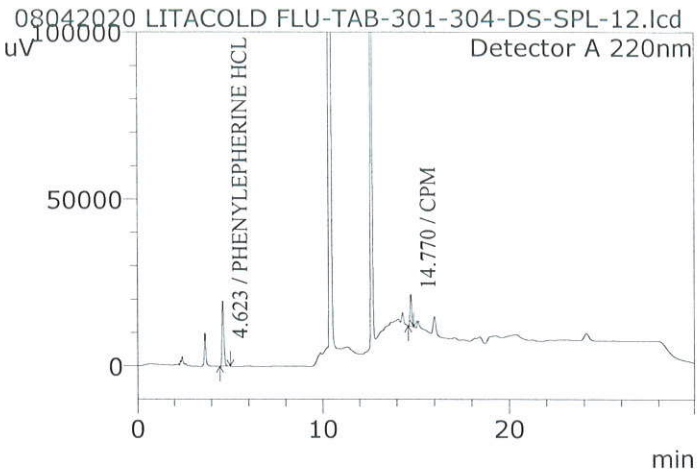

<< Detector A >>

ID#1 Compound Name: PHENYLEPHERINE HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	DS-SPL-07.lcd	LITACOLD FLU-T-01-PH+C-DS-SPL-1	4.633	134502	9732	1.178
4	DS-SPL-08.lcd	LITACOLD FLU-T-01-PH+C-DS-SPL-2	4.631	133219	9716	1.180
5	DS-SPL-09.lcd	LITACOLD FLU-T-01-PH+C-DS-SPL-3	4.630	135030	9675	1.181
6	DS-SPL-10.lcd	LITACOLD FLU-T-01-PH+C-DS-SPL-4	4.628	133926	9701	1.177
7	DS-SPL-11.lcd	LITACOLD FLU-T-01-PH+C-DS-SPL-5	4.624	132413	9695	1.178
8	DS-SPL-12.lcd	LITACOLD FLU-T-01-PH+C-DS-SPL-6	4.623	132708	9705	1.180
	Average		4.628	133633	9704	1.179
	%RSD		0.084	0.771	0.199	0.126

ID#2 Compound Name: CPM

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	DS-SPL-07.lcd	LITACOLD FLU-T-01-PH+C-DS-SPL-1	14.771	63700	99901	1.080
4	DS-SPL-08.lcd	LITACOLD FLU-T-01-PH+C-DS-SPL-2	14.769	63682	100255	1.071
5	DS-SPL-09.lcd	LITACOLD FLU-T-01-PH+C-DS-SPL-3	14.767	61137	103732	1.046
6	DS-SPL-10.lcd	LITACOLD FLU-T-01-PH+C-DS-SPL-4	14.764	62738	101519	1.069
7	DS-SPL-11.lcd	LITACOLD FLU-T-01-PH+C-DS-SPL-5	14.764	58948	106844	1.025
8	DS-SPL-12.lcd	LITACOLD FLU-T-01-PH+C-DS-SPL-6	14.770	62439	101088	1.069
	Average		14.768	62107	102223	1.060
	%RSD		0.021	2.921	2.576	1.917

Analysed By

Date : 1/04/2020

Checked By

Date : 15/04/2020

Safetab Life Science

Puducherry- 605 107

Quality control Department

Sample Information

Acquired by	: C.K.Saravanan
Sample Name	: LITACOLD FLU
Sample ID	: LITACOLD FLU-T-01-P+CA-DS-SPL-1
Tray#	: 1
Vial#	: 9
Injection Volume	: 20
Data File	: 08042020 LITACOLD FLU-TAB-301-304-DS-SPL-14.lcd
Method File	: PARA+CPM+CAFFEINE+PHENYL_AHPL_DS_PARA+CAFFEINE_P.lcm
Batch File	: 08042020 LITACOLD FLU-TAB-301-304-DS.lcb
Report Format File	: DEFAULT.lsr
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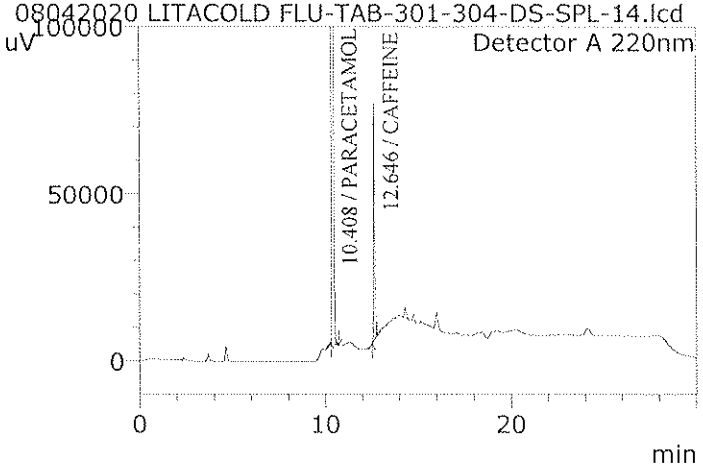
Date Processed	: 4/10/2020 4:56:20 PM

08042020 LITACOLD FLU-TAB-301-304-DS-SPL-14.lcd



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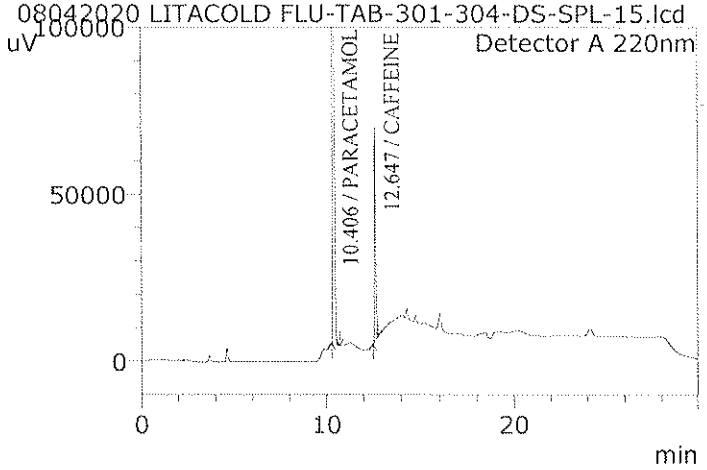

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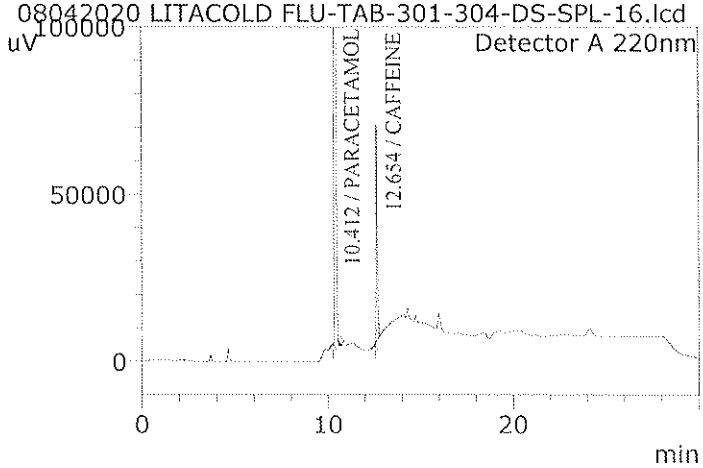

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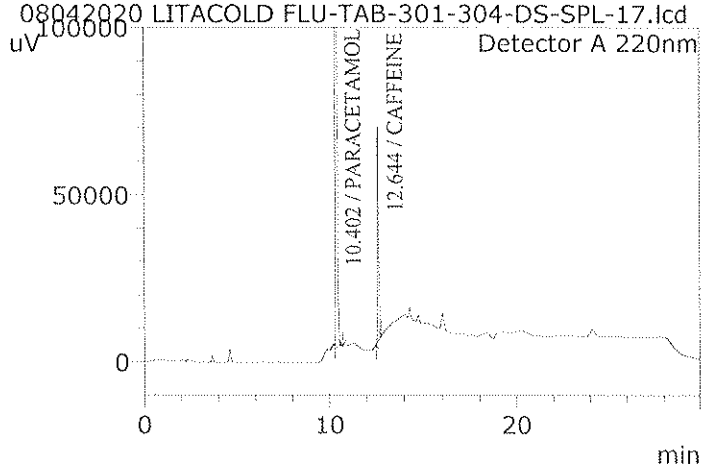

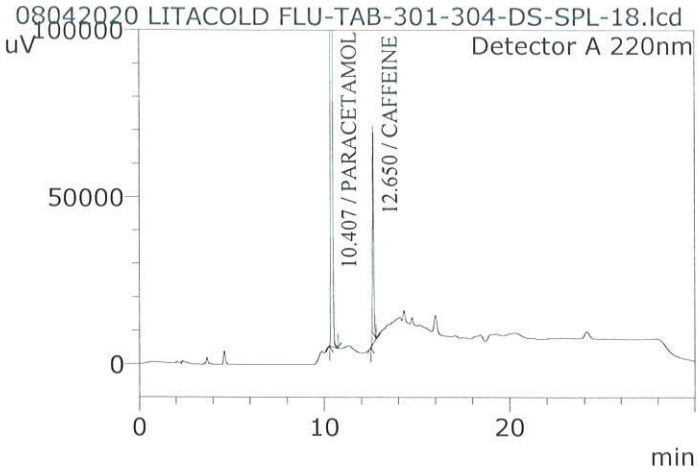

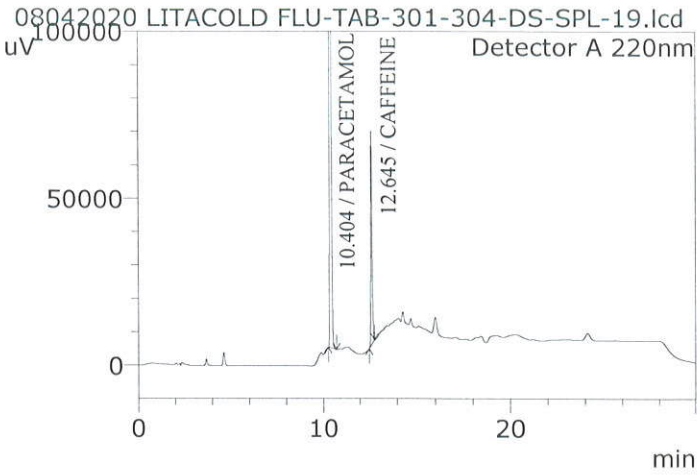

<< Detector A >>

ID#1 Compound Name: PARACETAMOL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
9	DS-SPL-14.lcd	LITACOLD FLU-T-01-P+CA-DS-SPL-1	10.408	3826157	100177	1.251
10	DS-SPL-15.lcd	LITACOLD FLU-T-01-P+CA-DS-SPL-2	10.406	3467869	99532	1.248
11	DS-SPL-16.lcd	LITACOLD FLU-T-01-P+CA-DS-SPL-3	10.412	3489426	105135	1.250
12	DS-SPL-17.lcd	LITACOLD FLU-T-01-P+CA-DS-SPL-4	10.402	3459332	101977	1.249
13	DS-SPL-18.lcd	LITACOLD FLU-T-01-P+CA-DS-SPL-5	10.407	3413343	99935	1.248
14	DS-SPL-19.lcd	LITACOLD FLU-T-01-P+CA-DS-SPL-6	10.404	3439862	102210	1.250
	Average		10.407	3515998	101494	1.249
	%RSD		0.034	4.383	2.068	0.091

ID#2 Compound Name: CAFFEINE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
9	DS-SPL-14.lcd	LITACOLD FLU-T-01-P+CA-DS-SPL-1	12.646	348050	126164	1.174
10	DS-SPL-15.lcd	LITACOLD FLU-T-01-P+CA-DS-SPL-2	12.647	311555	126167	1.173
11	DS-SPL-16.lcd	LITACOLD FLU-T-01-P+CA-DS-SPL-3	12.654	315666	126795	1.176
12	DS-SPL-17.lcd	LITACOLD FLU-T-01-P+CA-DS-SPL-4	12.644	312305	126088	1.178
13	DS-SPL-18.lcd	LITACOLD FLU-T-01-P+CA-DS-SPL-5	12.650	316844	126829	1.173
14	DS-SPL-19.lcd	LITACOLD FLU-T-01-P+CA-DS-SPL-6	12.645	312588	125845	1.178
	Average		12.648	319501	126315	1.175
	%RSD		0.030	4.425	0.319	0.208

Analysed By

Date : 11/04/2020

Checked By

Date : 13/04/2020

Safetab Life Science

Puducherry- 605 107

Quality control Department

<Sample Information>

Acquired by	: C.K.Saravanan
Sample Name	: LITACOLD FLU
Sample ID	: PHEN+PARA+CAFF+CPM-DS-BKT-01
Data Filename	: 08042020 LITACOLD FLU-TAB-301-304-DS-SPL-13.lcd
Method Filename	: PARA+CPM+CAFFEINE+PHENYL_AHPL_DS_STD_P.lcm
Batch Filename	: 08042020 LITACOLD FLU-TAB-301-304-DS.lcb
Vial #	: 1-2
Injection Volume	: 20 uL
Date Acquired	: 4/8/2020 7:49:49 AM
Date Processed	: 4/10/2020 4:41:25 PM

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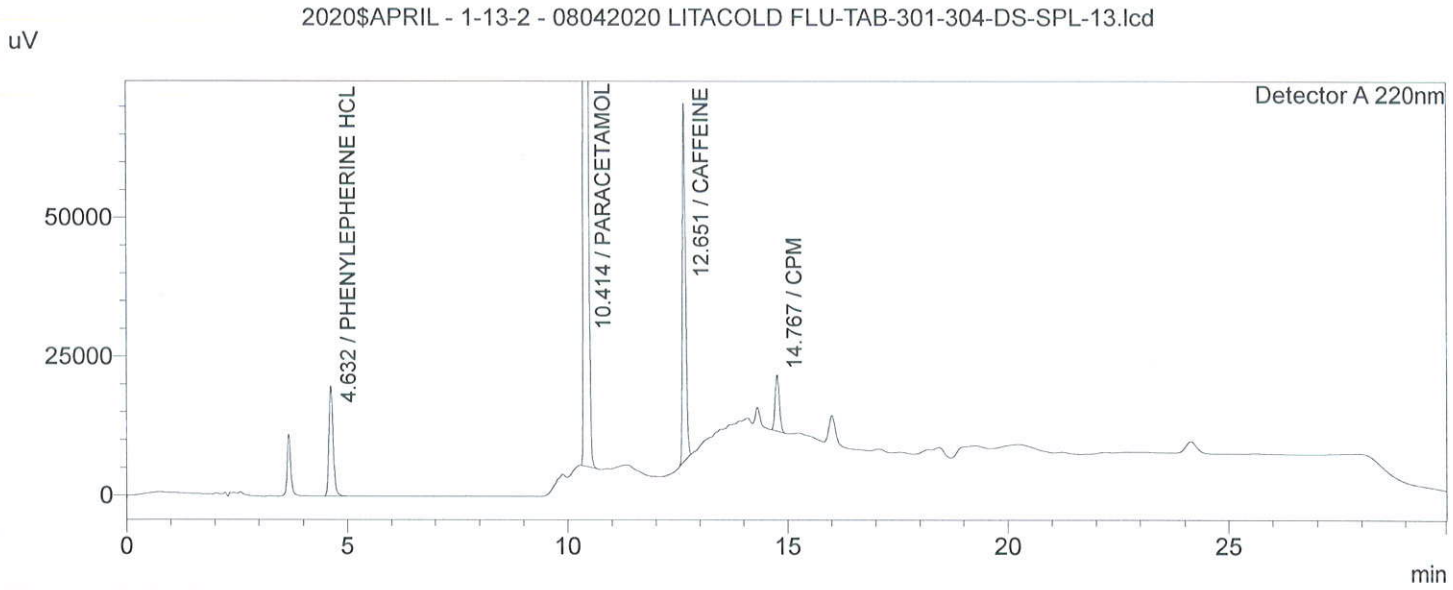

<Peak Table>

Detector A 220nm

Peak#	Ret. Time	Area	Area%	T.Plate	T.Factor	Resolution	R.R.Time	Name
1	4.632	134526	3.433	9627	1.181	--	--	PHENYLEPHERINE HCL
2	10.414	3404459	86.882	99457	1.248	36.03	--	PARACETAMOL
3	12.651	312249	7.969	125351	1.176	16.27	--	CAFFEINE
4	14.767	67238	1.716	99197	1.100	12.81	--	CPM
Total		3918472	100.000					

Analysed By **Checked By**

Date : 9/04/2020 **Date :** 10/04/2020

Safetab Life Science

Puducherry- 605 107

Quality control Department

<Sample Information>

Acquired by	: C.K.Saravanan
Sample Name	: LITACOLD FLU
Sample ID	: PHEN+PARA+CAFF+CPM-DS-BKT-02
Data Filename	: 08042020 LITACOLD FLU-TAB-301-304-DS-SPL-20.lcd
Method Filename	: PARA+CPM+CAFFEINE+PHENYL_AHPL_DS_STD_P.lcm
Batch Filename	: 08042020 LITACOLD FLU-TAB-301-304-DS.lcb
Vial #	: 1-2
Injection Volume	: 20 uL
Date Acquired	: 4/8/2020 11:24:16 AM
Date Processed	: 4/10/2020 4:41:26 PM

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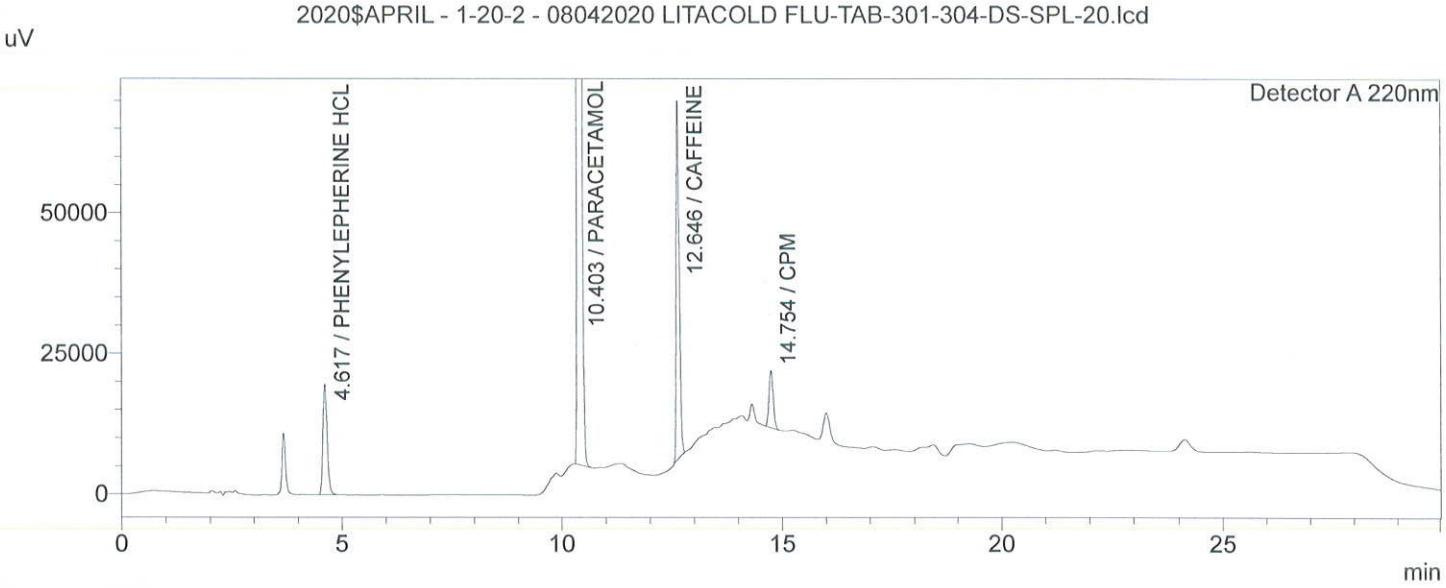


<Peak Table>

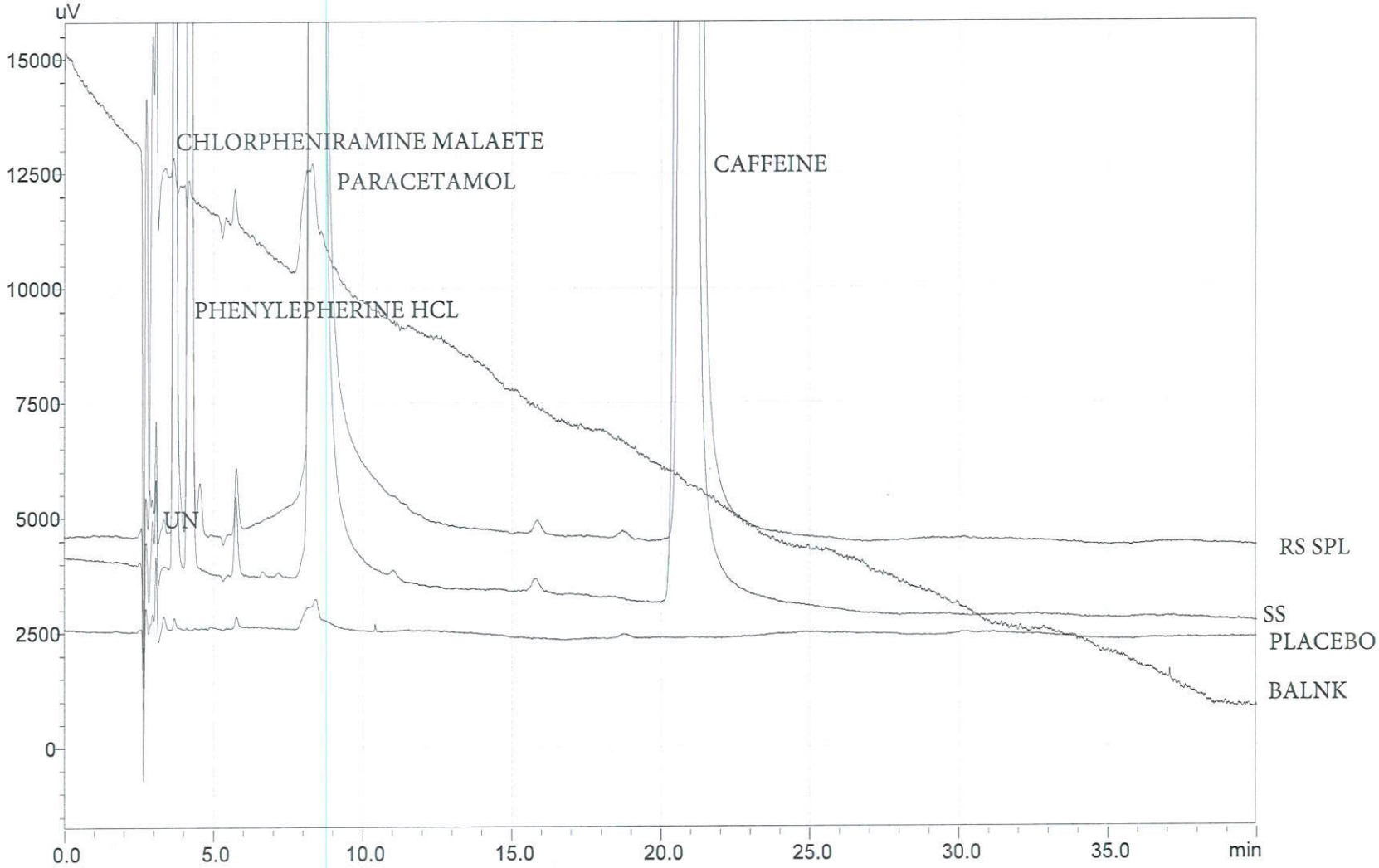
Detector A 220nm

Peak#	Ret. Time	Area	Area%	T.Plate	T.Factor	Resolution	R.R.Time	Name
1	4.617	133554	3.417	9603	1.178	--	--	PHENYLEPHERINE HCL
2	10.403	3397472	86.919	101993	1.250	36.30	--	PARACETAMOL
3	12.646	310420	7.942	126470	1.179	16.45	--	CAFFEINE
4	14.754	67342	1.723	98627	1.102	12.77	--	CPM
Total		3908789	100.000					

Analysed By **Checked By**

Date : 11/04/2020 **Date :** 13/04/2020

LITACOLD FLU-TABLETS-GD200301-RELATED SUBSTANCES COMPARISION-REPORT



ANALYSED BY

CHECKED BY

Safetab Life Science
Puducherry - 605 107

QUALITY CONTROL ANALYSIS CALCULATION SHEET

Product Name	LITACOLD FLU	Batch size	10.0LAC
Batch Number	GD200301	Mfg.Date	Mar-20
Stage	COMPRESSED TABLETS	Exp.Date	Feb-23

Each uncoated tablets contains;

Chlorphenamine Maleate BP ---------- 2mg
Phenylephrine Hydrochloride BP ---------- 5mg
Caffeine (anhydrous) BP ---------- 30mg
Paracetamol BP ---------- 500mg

ASSAY OF PHENYLEPHRINE HYDROCHLORIDE

Instrument ID:	ST/QC/EQ/039	Balance ID:	ST/QC/EQ/041	WS No.:	WS/A/11/01	% Purity (aib)	99.30

Standard dilution.:	79.73	mg to --->	200	ml to --->	10	ml to --->	200
Std.conc (in ppm)-19.9325	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution .:	Tablets/Pow.	mg to --->	250	ml to --->	1	ml to --->	1
Test conc(in ppm)-19.9779770	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labeled claim :	5	mg
Average weight :	635.7	mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Phenylephrine Hcl	269902	269060	268983	268716	267769	268886	766	0.285
With Bracketing std.	263680					268018	2233	0.833

Sample preparation	Sample Weight taken in mg	Sample Area	Content in mg/tablet	Content in %	Assay limit :90.0% to 110.0%
1	635.00	264513	4.87	97.5	

ASSAY OF PARACETAMOL

						WS No.:	WS/A/07/01	% Purity (aib)	99.70
Standard dilution.:	19.92	mg to --->	200	ml to --->	1	ml to --->	1		
Std.conc (in ppm)-99.6	1	ml to --->	1	ml to --->	1	ml to --->	1		
Test dilution .:	Tablets/Pow.	mg to --->	250	ml to --->	5	ml to --->	100		
Test.conc (in ppm)-99.8898851	1	ml to --->	1	ml to --->	1	ml to --->	1		

Conversion factor :	1.0000	
Labeled claim :	500	mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Paracetamol	3016347	3021721	3016844	3017550	3015677	3017628	2389	0.079
With Bracketing std.	3004856					3015499	5634.8	0.187

Sample preparation	Sample Weight taken in mg	Sample Area	Content in mg/tablet	Content in %	Assay limit :90.0% to 110.0%
1	635.00	2981427	491.09	98.2	

ASSAY OF CAFFEINE

						WS No.:	WS/A/09/04	% Purity (aib)	99.10
Standard dilution.:	24.43	mg to --->	200	ml to --->	10	ml to --->	200		
Std.conc (in ppm)-6.1075	1	ml to --->	1	ml to --->	1	ml to --->	1		
Test dilution .:	Tablets/Pow.	mg to --->	250	ml to --->	5	ml to --->	100		
Test conc(in ppm)-5.99339310	1	ml to --->	1	ml to --->	1	ml to --->	1		

Conversion factor :	1.0000	
Labeled claim :	30	mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Caffeine	264694	265871	264616	265924	264278	265077	766	0.289
With Bracketing std.	263056					264740	1072	0.405

Sample preparation	Sample Weight taken in mg	Sample Area	Content in mg/tablet	Content in %	Assay limit :90.0% to 110.0%
1	635.00	259003	29.60	98.7	

ASSAY OF CHLORPHENAMINE MALEATE

						WS No.:	WS/A/09/01	% Purity (aib)	99.70
Standard dilution.:	31.92	mg to --->	200	ml to --->	10	ml to --->	200		
Std.conc (in ppm)-7.98	1	ml to --->	1	ml to --->	1	ml to --->	1		
Test dilution .:	Granule/Pow.	mg to --->	250	ml to --->	1	ml to --->	1		
Test conc(in ppm)-7.991190813	1	ml to --->	1	ml to --->	1	ml to --->	1		

Conversion factor :	1.0000	
Labeled claim :	2	mg

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Chlorphenamine maleate	212078	214229	216540	215791	218205	215369	2330	1.082
With Bracketing std.	218141					215831	2372	1.099

Sample preparation	Sample Weight taken in mg	Sample Area	Content in mg/635mg of granule	Content in %	Assay limit :90.0% to 110.0%
1	635.00	206009	1.90	95.2	

Calculation fomula :

Assay in mg /tablet	Sample area x Std.dilution x Avg.wt x Purity %(aib) x conversion factor x 1000 / Standard area x sample dilution x 100	Assay in %	Assay in mg/tablet x 100 / Labeled claim

Analysed by : C.K.SARAVANAN
Date : 13.04.2020

Checked by :
Date: 13/04/2020

Safetab Life Science,

Puducherry - 605 107

QUALITY CONTROL ANALYSIS CALCULATION SHEET

Product Name :	**LITACOLD FLU**	**Batch size :**	**10.0LAC**
Batch Number :	**GD200301**	**Mfg.Date :**	**Mar-20**
Stage :	**COMPRESSED TABLETS**	**Exp.Date :**	**Feb-23**

Each uncoated tablets contains;

Chlorphenamine Maleate BP ---------- 2mg
Phenylephrine Hydrochloride BP ---------- 5mg
Caffeine (anhydrous) BP ---------- 30mg
Paracetamol BP ---------- 500mg

UNIFORMITY CONTENT OF PHEYLEPHRINE HCL

Instrument ID:	ST/QC/EQ/039	Balance ID:	ST/QC/EQ/41	WS No.:	WS/A/11/01	% Purity (aib)	99.30

Standard dilution.:	79.73	mg to --->	200	ml to --->	10	ml to --->	200
Std.conc (in ppm)-19.9325	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	One tablet	to --->	100	ml to --->	10	ml to --->	25
Test.conc (in ppm)-20	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labelled claim :	5

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Phenylephrine Hydrochloride	269902	269060	268983	268716	267769	268886	766	0.28
With Bracketing std.	260817					267541	3365	1.26

Tablets	Sample Area	Uniformity Content in mg/tablet	Uniformity content in %	Tablets	Sample Area	Uniformity Content in mg/tablet	Uniformity content in %
1	258594	4.76	95.18	6	255592	4.70	94.07
2	259278	4.77	95.43	7	269426	4.96	99.16
3	256673	4.72	94.47	8	256802	4.73	94.52
4	259838	4.78	95.63	9	257751	4.74	94.87
5	256279	4.72	94.32	10	256442	4.72	94.38
Average							95.2
Minimum							94.1
Maximum							99.2
					Uniformity content Limit : 85.0% to 115.0%		

Calculation formula :

Uniformity Content in mg /tablet	Sample area x Std.dilution x Purity %(aib) x conversion factor / Standard area x sample dilution X 100

Uniformity content in %	Uniformity content in mg /tablets x 100 / Labeled claim

Analysed by : C.K.SARAVANAN
Date : 13.04.2020

13/04/2020

Checked by :
Date : 13/04/2020

Safetab Life Science,

Puducherry - 605 107

QUALITY CONTROL ANALYSIS CALCULATION SHEET

Product Name :	LITACOLD FLU	Batch size :	10.0LAC
Batch Number :	GD200301	Mfg.Date :	Mar-20
Stage :	COMPRESSED TABLETS	Exp.Date :	Feb-23

Each uncoated tablets contains;

Chlorphenamine Maleate BP ---------- 2mg
Phenylephrine Hydrochloride BP ---------- 5mg
Caffeine (anhydrous) BP ---------- 30mg
Paracetamol BP ---------- 500mg

UNIFORMITY CONTENT OF CHLORPHENAMINE MALEATE

Instrument ID:	ST/QC/EQ/039	Balance ID:	ST/QC/EQ/41	WS No.:	WS/A/09/01	% Purity (aib)	99.70

Standard dilution.:	31.92	mg to --->	200	ml to --->	10	ml to --->	200
Std.conc (in ppm)-7.98	1	ml to --->	1	ml to --->	1	ml to --->	1

Test dilution .:	One tablet	to --->	100	ml to --->	10	ml to --->	25
Test.conc (in ppm)-8	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labelled claim :	2

System suitability	1	2	3	4	5	MEAN	S.D	RSD in %
Chlorphenamine Maleate	212078	214229	216540	215791	218205	215369	2330	1.08
With Bracketing std.	219470					216052	2674	1.24

Tablets	Sample Area	Uniformity Content in mg/tablet	Uniformity content in %	Tablets	Sample Area	Uniformity Content in mg/tablet	Uniformity content in %
1	210808	1.95	97.34	6	208825	1.93	96.43
2	209923	1.94	96.94	7	217229	2.01	100.31
3	207977	1.92	96.04	8	210635	1.95	97.26
4	210345	1.94	97.13	9	209846	1.94	96.90
5	209746	1.94	96.85	10	210548	1.94	97.22
Average							97.2
Minimum							96.0
Maximum							100.3
					Uniformity content Limit : 85.0% to 115.0%		

Calculation formula :

Uniformity Content in mg /tablet	Sample area x Std.dilution x Purity %(aib) x conversion factor / Standard area x sample dilution X 100

Uniformity content in %	Uniformity content in mg /tablets x 100 / Labeled claim

Analysed by : C.K.SARAVANAN
Date : 13.04.2020

Checked by
Date : 15/04/2020

Safetab Life Science

Puducherry- 605 107

Quality control Department

<Sample Information>

Acquired by	: C.K.Saravanan
Sample Name	: LITACOLD FLU
Sample ID	: BLANK-AS
Data Filename	: 07042020 LITACOLD FLU-TAB-301-304-AS&CU-SPL-01.lcd
Method Filename	: LITACOLD FLU-AHPL-METHOD -AS_STD_P.lcm
Batch Filename	: 07042020 LITA COLD FLU-TAB-301-304-AS&CU.lcb
Vial #	: 1-1
Injection Volume	: 20 uL
Date Acquired	: 07/04/2020 23:26:26
Date Processed	: 11/04/2020 15:03:58

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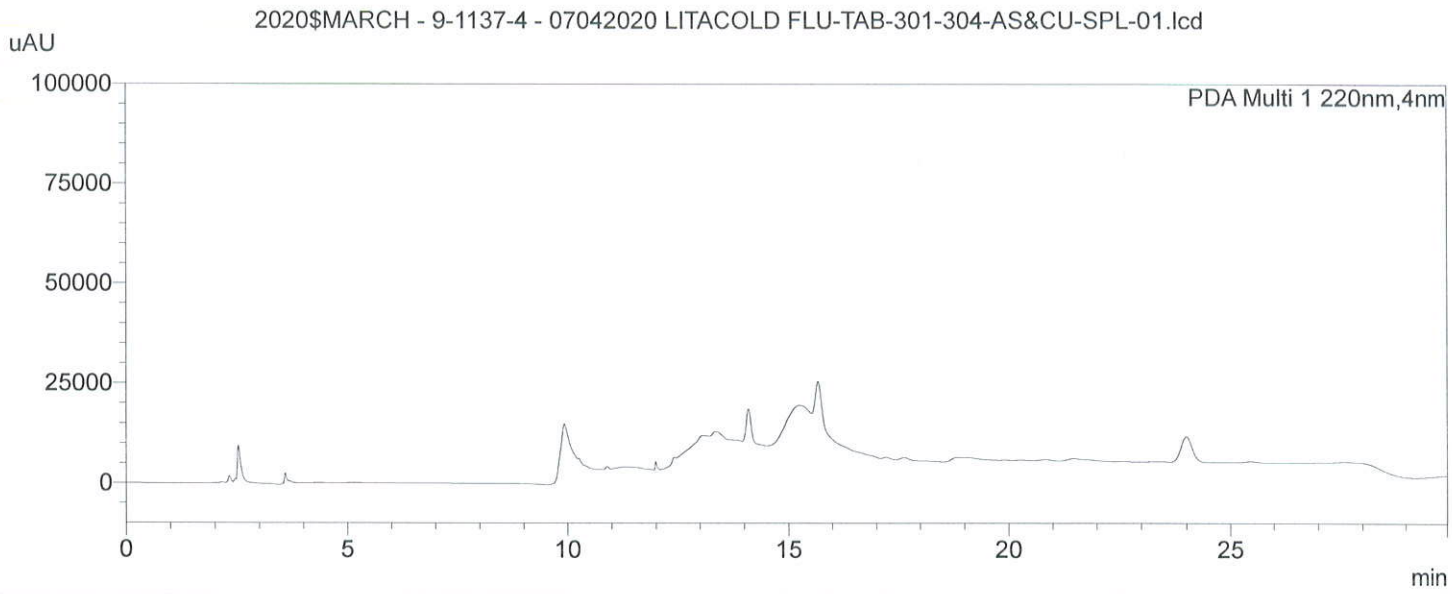

<Peak Table>

PDA Ch1 220nm

Peak#	Ret. Time	Area	Area%	T.Plate	T.Factor	Resolution	R.R.Time	Name
Total								

Analysed By

Date : 11/04/2020

Checked By

Date : 11/04/2020

Safetab Life Science

Puducherry- 605 107

Quality control Department

Sample Information

Acquired by	: C.K.Saravanan
Sample Name	: LITACOLD FLU
Sample ID	: PHE+PARA+CAFF+CPM-AS-STD-01
Tray#	: 1
Vial#	: 2
Injection Volume	: 20
Data File	: 07042020 LITACOLD FLU-TAB-301-304-AS&CU-SPL-02.lcd
Method File	: LITACOLD FLU-AHPL-METHOD -AS_STD_P.lcm
Batch File	: 07042020 LITA COLD FLU-TAB-301-304-AS&CU.lcb
Report Format File	: DEFAULT.lsr
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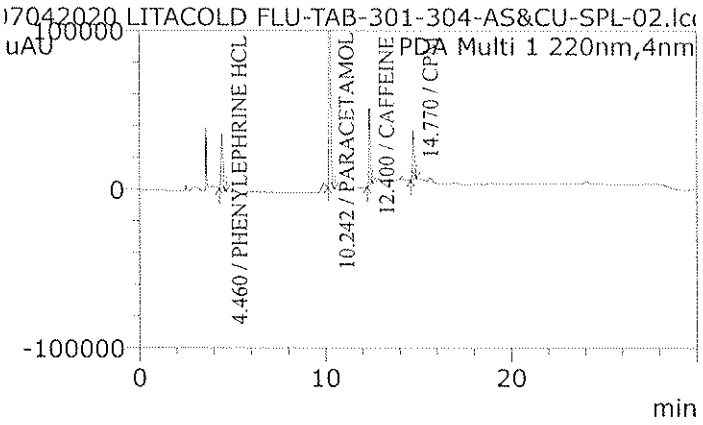
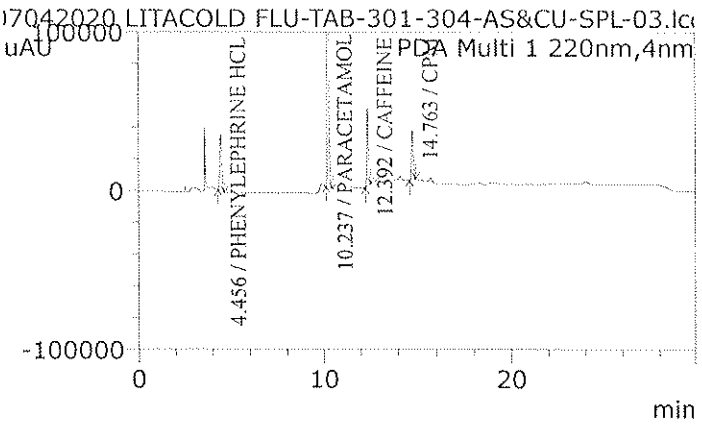
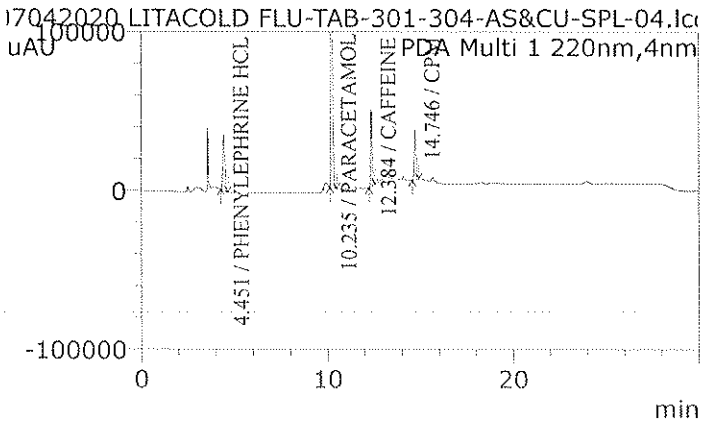
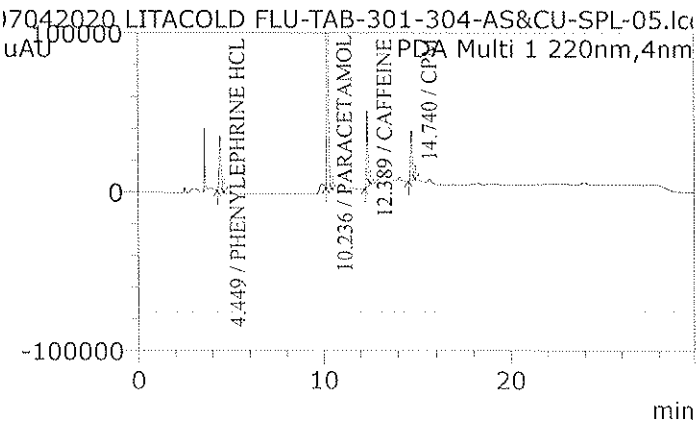
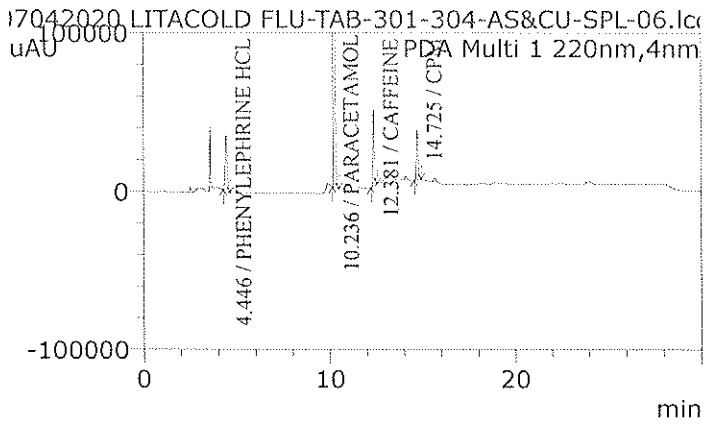
Date Processed	: 11/04/2020 15:03:46











<< PDA >>

ID#1 Compound Name: PHENYLEPHRINE HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
2	CU-SPL-02.lcd	PHE+PARA+CAFF+CPM-AS-STD-01	4.460	269902	6626	1.101
2	CU-SPL-03.lcd	PHE+PARA+CAFF+CPM-AS-STD-02	4.456	269060	6640	1.105
2	CU-SPL-04.lcd	PHE+PARA+CAFF+CPM-AS-STD-03	4.451	268983	6643	1.103
2	CU-SPL-05.lcd	PHE+PARA+CAFF+CPM-AS-STD-04	4.449	268716	6621	1.102
2	CU-SPL-06.lcd	PHE+PARA+CAFF+CPM-AS-STD-05	4.446	267769	6640	1.105
	Average		4.452	268886	6634	1.103
	%RSD		0.126	0.285	0.148	0.164

ID#2 Compound Name: PARACETAMOL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
2	CU-SPL-02.lcd	PHE+PARA+CAFF+CPM-AS-STD-01	10.242	3016347	123374	1.407
2	CU-SPL-03.lcd	PHE+PARA+CAFF+CPM-AS-STD-02	10.237	3021721	122044	1.426
2	CU-SPL-04.lcd	PHE+PARA+CAFF+CPM-AS-STD-03	10.235	3016844	128551	1.436
2	CU-SPL-05.lcd	PHE+PARA+CAFF+CPM-AS-STD-04	10.236	3017550	129295	1.440
2	CU-SPL-06.lcd	PHE+PARA+CAFF+CPM-AS-STD-05	10.236	3015677	129327	1.441
	Average		10.237	3017628	126518	1.430
	%RSD		0.027	0.079	2.784	0.990

ID#3 Compound Name: CAFFEINE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
2	CU-SPL-02.lcd	PHE+PARA+CAFF+CPM-AS-STD-01	12.400	264694	99326	1.172
2	CU-SPL-03.lcd	PHE+PARA+CAFF+CPM-AS-STD-02	12.392	265871	90846	1.164
2	CU-SPL-04.lcd	PHE+PARA+CAFF+CPM-AS-STD-03	12.384	264616	92117	1.158
2	CU-SPL-05.lcd	PHE+PARA+CAFF+CPM-AS-STD-04	12.389	265924	95854	1.168
2	CU-SPL-06.lcd	PHE+PARA+CAFF+CPM-AS-STD-05	12.381	264278	91163	1.165
	Average		12.389	265077	93861	1.166
	%RSD		0.061	0.289	3.887	0.432

ID#4 Compound Name: CPM

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
2	CU-SPL-02.lcd	PHE+PARA+CAFF+CPM-AS-STD-01	14.770	212078	88374	1.124
2	CU-SPL-03.lcd	PHE+PARA+CAFF+CPM-AS-STD-02	14.763	214229	88674	1.130
2	CU-SPL-04.lcd	PHE+PARA+CAFF+CPM-AS-STD-03	14.746	216540	87527	1.148
2	CU-SPL-05.lcd	PHE+PARA+CAFF+CPM-AS-STD-04	14.740	215791	88647	1.145
2	CU-SPL-06.lcd	PHE+PARA+CAFF+CPM-AS-STD-05	14.725	218205	86223	1.157
	Average		14.749	215368	87889	1.141
	%RSD		0.122	1.082	1.184	1.197

Analysed By

Date : 12/04/2022

Checked By

Date : 13/04/2022

Safetab Life Science

Puducherry- 605 107

Quality control Department

Sample Information

Acquired by	: C.K.Saravanan
Sample Name	: LITACOLD FLU
Sample ID	: LITA COLDFLU-CA+P-301-AS-SPL-01
Tray#	: 1
Vial#	: 4
Injection Volume	: 20
Data File	: 07042020 LITACOLD FLU-TAB-301-304-AS&CU-SPL-09.lcd
Method File	: LITACOLD FLU-AHPL-METHOD -AS_SPL-PC-P.lcm
Batch File	: 07042020 LITA COLD FLU-TAB-301-304-AS&CU.lcb
Report Format File	: DEFAULT.lsr
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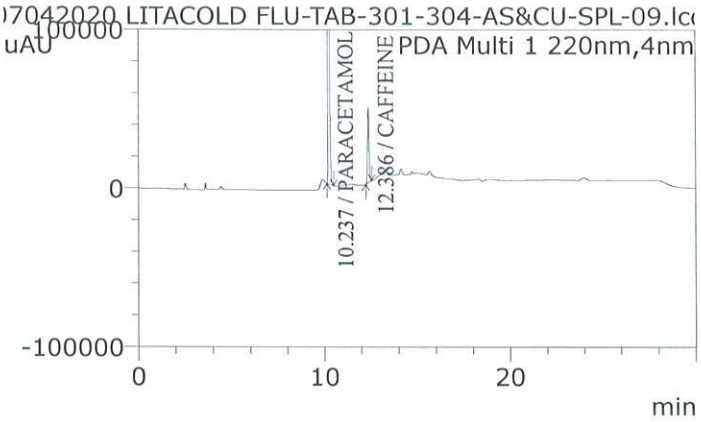
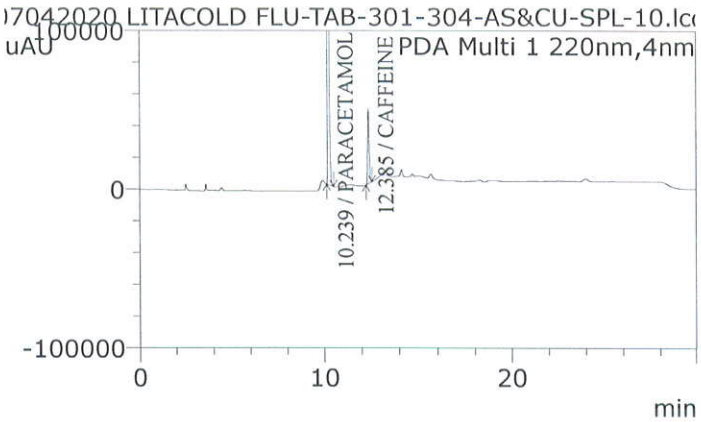
Date Processed	: 11/04/2020 14:51:26





<< PDA >>

ID#1 Compound Name: PARACETAMOL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
4	CU-SPL-09.lcd	LITA COLDFLU-CA+P-301-AS-SPL-01	10.237	2982013	121729	1.425
4	CU-SPL-10.lcd	LITA COLDFLU-CA+P-301-AS-SPL-02	10.239	2980841	123380	1.413
	Average		10.238	2981427	122555	1.419
	%RSD		0.013	0.028	0.952	0.632

ID#2 Compound Name: CAFFEINE

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
4	CU-SPL-09.lcd	LITA COLDFLU-CA+P-301-AS-SPL-01	12.386	259013	91933	1.158
4	CU-SPL-10.lcd	LITA COLDFLU-CA+P-301-AS-SPL-02	12.385	258993	91974	1.156
	Average		12.385	259003	91954	1.157
	%RSD		0.006	0.006	0.031	0.104

Analysed By

Date : 11/04/2020

Checked By

Date : 11/04/2020

Safetab Life Science

Puducherry- 605 107

Quality control Department

Sample Information

Acquired by	: C.K.Saravanan
Sample Name	: LITACOLD FLU
Sample ID	: LITA COLDFLU-C+PH-301-AS-SPL-01
Tray#	: 1
Vial#	: 3
Injection Volume	: 20
Data File	: 07042020 LITACOLD FLU-TAB-301-304-AS&CU-SPL-07.lcd
Method File	: LITACOLD FLU-AHPL-METHOD -AS_SPL-PH&CPM-P.lcm
Batch File	: 07042020 LITA COLD FLU-TAB-301-304-AS&CU.lcb
Report Format File	: DEFAULT.lsr
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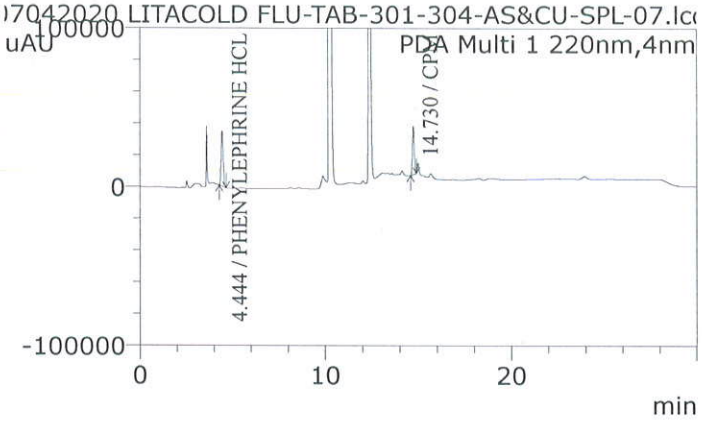
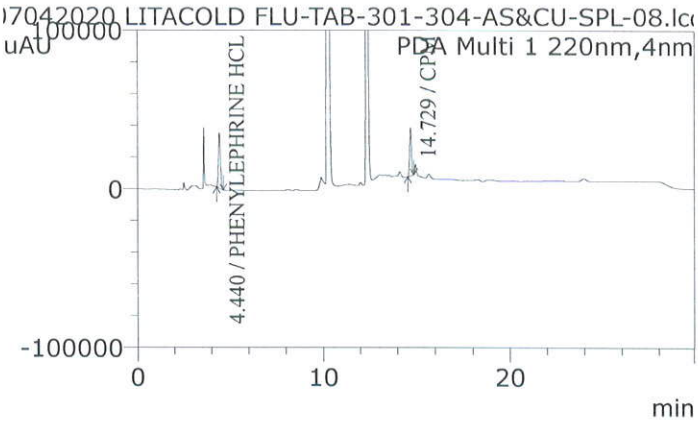
Date Processed	: 11/04/2020 14:26:58





<< PDA >>

ID#1 Compound Name: PHENYLEPHRINE HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	CU-SPL-07.lcd	LITA COLDFLU-C+PH-301-AS-SPL-01	4.444	264853	6672	1.109
3	CU-SPL-08.lcd	LITA COLDFLU-C+PH-301-AS-SPL-02	4.440	264172	6669	1.108
	Average		4.442	264513	6670	1.109
	%RSD		0.073	0.182	0.038	0.065

ID#2 Compound Name: CPM

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	CU-SPL-07.lcd	LITA COLDFLU-C+PH-301-AS-SPL-01	14.730	205732	90600	1.101
3	CU-SPL-08.lcd	LITA COLDFLU-C+PH-301-AS-SPL-02	14.729	206286	90190	1.103
	Average		14.730	206009	90395	1.102
	%RSD		0.004	0.190	0.321	0.088

Analysed By **Checked By**

Date : 12/04/2020 **Date :** 15/04/2020

Safetab Life Science

Puducherry- 605 107

Quality control Department

Sample Information

Acquired by	: C.K.Saravanan
Sample Name	: LITACOLD FLU
Sample ID	: LITA COLDFLU-C+PH-301-CU-SPL-01
Tray#	: 1
Vial#	: 11
Injection Volume	: 20
Data File	: 07042020 LITACOLD FLU-TAB-301-304-AS&CU-SPL-25.lcd
Method File	: LITACOLD FLU-AHPL-METHOD -AS_SPL-PH&CPM-P.lcm
Batch File	: 07042020 LITA COLD FLU-TAB-301-304-AS&CU.lcb
Report Format File	: DEFAULT.lsr
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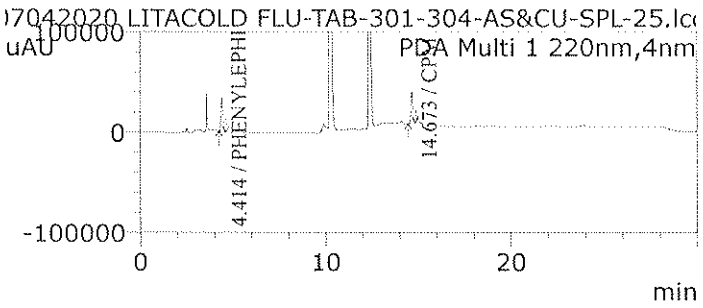

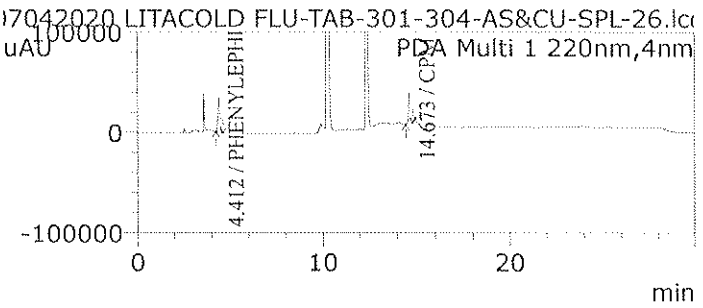

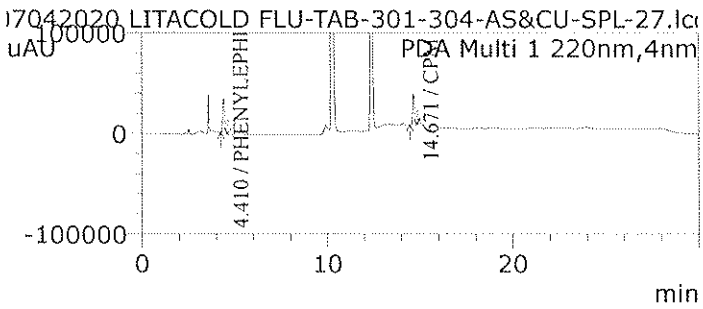

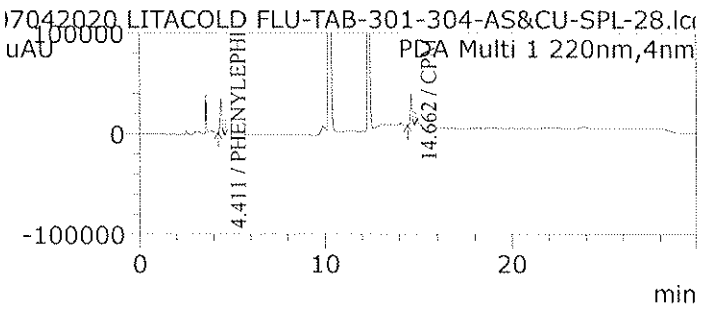

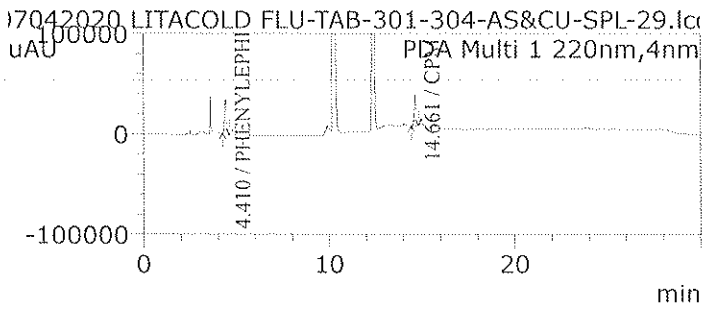

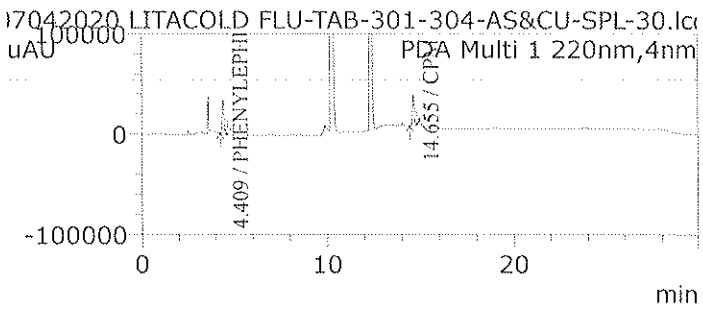

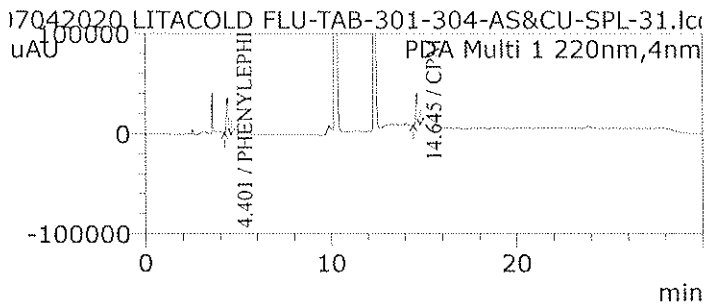

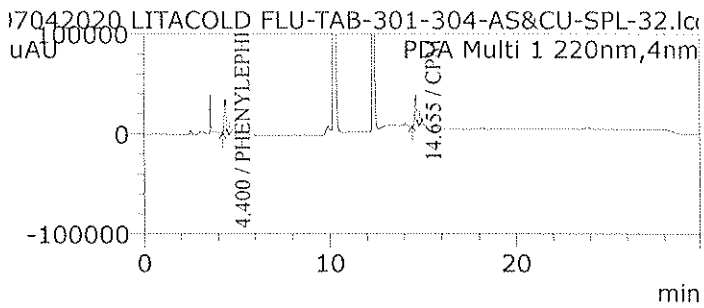

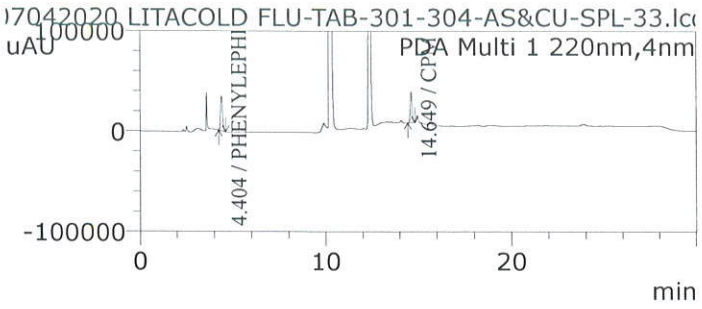

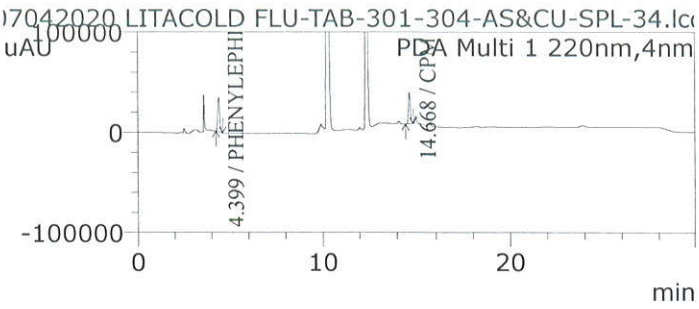

<< PDA >>

ID#1 Compound Name: PHENYLEPHRINE HCL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
11	CU-SPL-25.lcd	LITA COLDFLU-C+PH-301-CU-SPL-01	4.414	258594	6667	1.111
12	CU-SPL-26.lcd	LITA COLDFLU-C+PH-301-CU-SPL-02	4.412	259278	6772	1.115
13	CU-SPL-27.lcd	LITA COLDFLU-C+PH-301-CU-SPL-03	4.410	256673	6751	1.115
14	CU-SPL-28.lcd	LITA COLDFLU-C+PH-301-CU-SPL-04	4.411	259838	6792	1.115
15	CU-SPL-29.lcd	LITA COLDFLU-C+PH-301-CU-SPL-05	4.410	256279	6749	1.115
16	CU-SPL-30.lcd	LITA COLDFLU-C+PH-301-CU-SPL-06	4.409	255592	6732	1.114
17	CU-SPL-31.lcd	LITA COLDFLU-C+PH-301-CU-SPL-07	4.401	269426	6710	1.112
18	CU-SPL-32.lcd	LITA COLDFLU-C+PH-301-CU-SPL-08	4.400	256802	6727	1.114
19	CU-SPL-33.lcd	LITA COLDFLU-C+PH-301-CU-SPL-09	4.404	257751	6653	1.109
20	CU-SPL-34.lcd	LITA COLDFLU-C+PH-301-CU-SPL-10	4.399	256442	6749	1.115
	Average		4.407	258667	6730	1.114
	%RSD		0.122	1.557	0.645	0.179

ID#2 Compound Name: CPM

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
11	CU-SPL-25.lcd	LITA COLDFLU-C+PH-301-CU-SPL-01	14.673	210808	88387	1.138
12	CU-SPL-26.lcd	LITA COLDFLU-C+PH-301-CU-SPL-02	14.673	209923	88368	1.139
13	CU-SPL-27.lcd	LITA COLDFLU-C+PH-301-CU-SPL-03	14.671	207977	87857	1.143
14	CU-SPL-28.lcd	LITA COLDFLU-C+PH-301-CU-SPL-04	14.662	210345	88097	1.141
15	CU-SPL-29.lcd	LITA COLDFLU-C+PH-301-CU-SPL-05	14.661	209746	87443	1.143
16	CU-SPL-30.lcd	LITA COLDFLU-C+PH-301-CU-SPL-06	14.655	208825	89558	1.140
17	CU-SPL-31.lcd	LITA COLDFLU-C+PH-301-CU-SPL-07	14.645	217229	89660	1.143
18	CU-SPL-32.lcd	LITA COLDFLU-C+PH-301-CU-SPL-08	14.655	210635	88849	1.140
19	CU-SPL-33.lcd	LITA COLDFLU-C+PH-301-CU-SPL-09	14.649	209846	89054	1.148
20	CU-SPL-34.lcd	LITA COLDFLU-C+PH-301-CU-SPL-10	14.668	210548	89804	1.143
	Average		14.661	210588	88708	1.142
	%RSD		0.068	1.183	0.912	0.258

Analysed By

Date : 12/09/2020

Checked By

Date : 15/09/2020

Safetab Life Science

Puducherry- 605 107

Quality control Department

<Sample Information>

Acquired by	: C.K.Saravanan
Sample Name	: LITACOLD FLU
Sample ID	: PHE+PARA+CAFF+CPM-AS-BKT-STD-3
Data Filename	: 07042020 LITACOLD FLU-TAB-301-304-AS&CU-SPL-35.lcd
Method Filename	: LITACOLD FLU-AHPL-METHOD -AS_STD_P.lcm
Batch Filename	: 07042020 LITA COLD FLU-TAB-301-304-AS&CU.lcb
Vial #	: 1-2
Injection Volume	: 20 uL
Date Acquired	: 08/04/2020 16:45:17
Date Processed	: 11/04/2020 15:03:53

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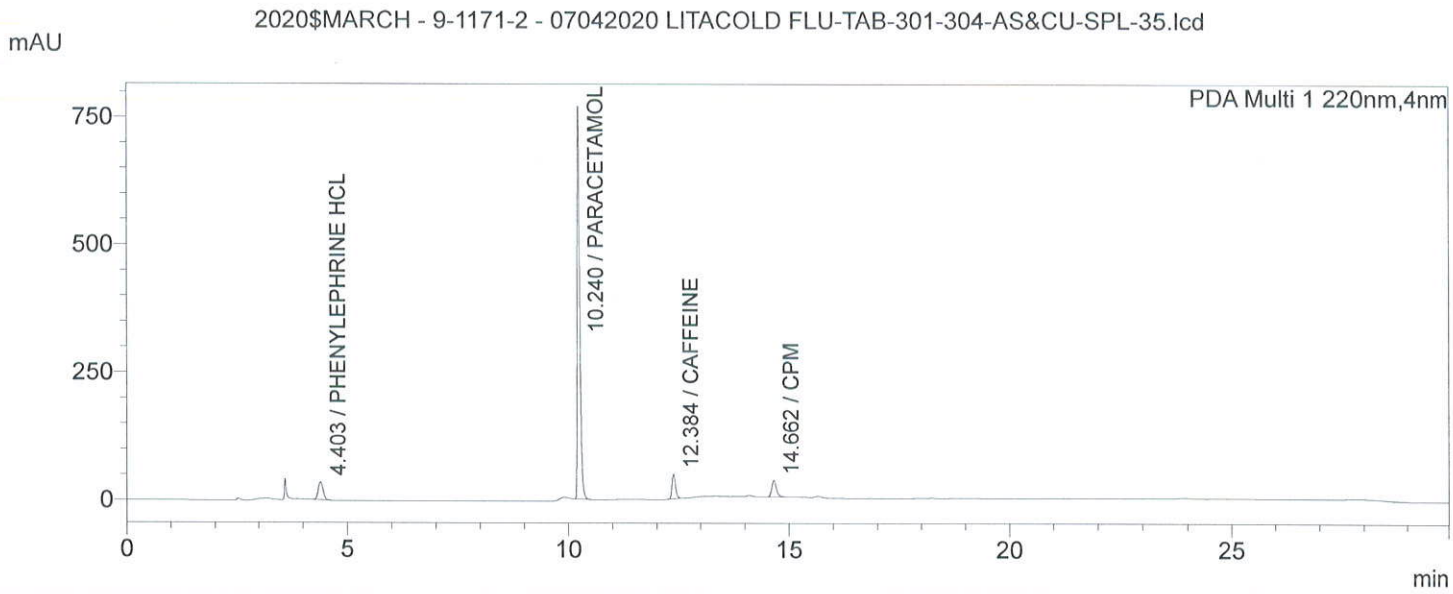


<Peak Table>

PDA Ch1 220nm

Peak#	Ret. Time	Area	Area%	T.Plate	T.Factor	Resolution	R.R.Time	Name
1	4.403	260817	6.971	6695	1.110	--	--	PHENYLEPHRINE HCL
2	10.240	3000046	80.185	123074	1.412	35.16	--	PARACETAMOL
3	12.384	261074	6.978	92533	1.162	15.34	--	CAFFEINE
4	14.662	219470	5.866	86939	1.161	12.59	--	CPM
Total		3741406	100.000					

Analysed By

Date : 11/04/2020

Checked By

Date : 13/04/2020

Safetab Life Science

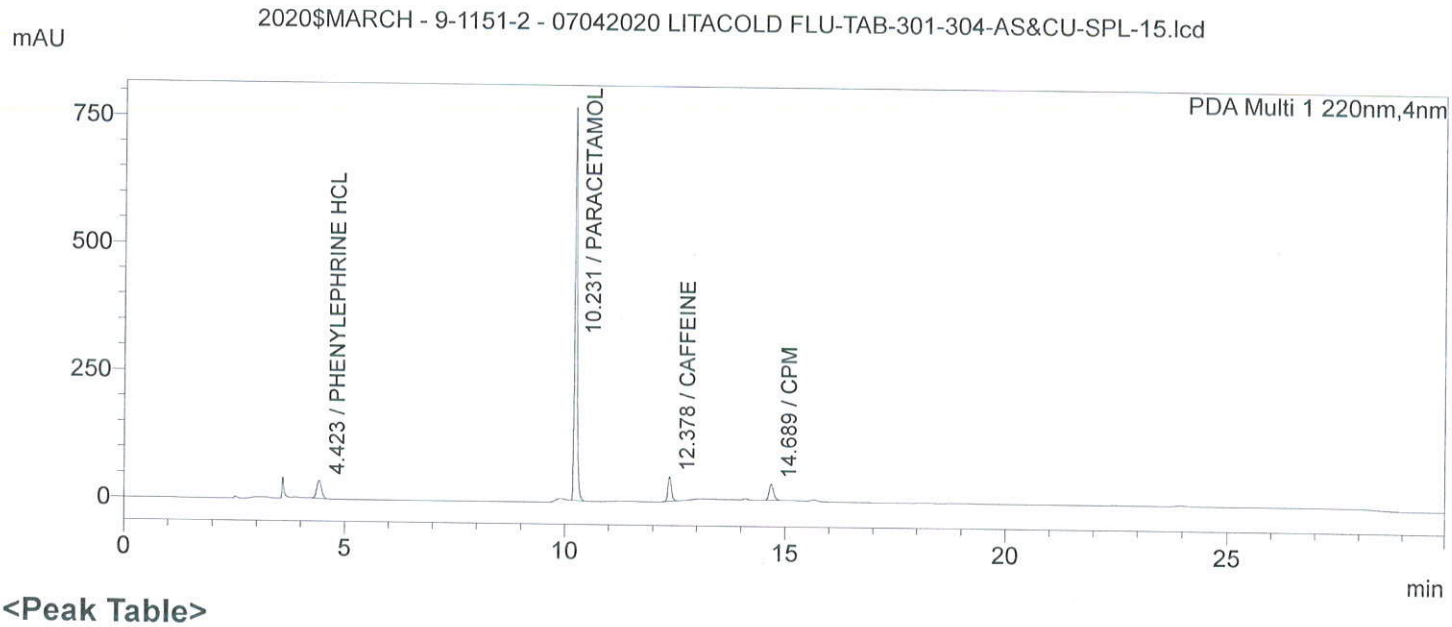
Puducherry- 605 107

Quality control Department

<Sample Information>

Acquired by	: C.K.Saravanan
Sample Name	: LITACOLD FLU
Sample ID	: PHE+PARA+CAFF+CPM-AS-BKT-STD-1
Data Filename	: 07042020 LITACOLD FLU-TAB-301-304-AS&CU-SPL-15.lcd
Method Filename	: LITACOLD FLU-AHPL-METHOD -AS_STD_P.lcm
Batch Filename	: 07042020 LITA COLD FLU-TAB-301-304-AS&CU.lcb
Vial #	: 1-2
Injection Volume	: 20 uL
Date Acquired	: 08/04/2020 06:34:11
Date Processed	: 11/04/2020 15:03:51

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak#	Ret. Time	Area	Area%	T.Plate	T.Factor	Resolution	R.R.Time	Name
1	4.423	263680	7.032	6675	1.110	--	--	PHENYLEPHRINE HCL
2	10.231	3004856	80.135	123088	1.408	34.86	--	PARACETAMOL
3	12.378	263056	7.015	93460	1.167	15.41	--	CAFFEINE
4	14.689	218141	5.817	87828	1.160	12.84	--	CPM
Total		3749732	100.000					

Analysed By

Date : 11/04/2020

Checked By

Date : 11/04/2020

Brand Name	LITACOLD FLU TABLETS	Product ID No.:	978	Batch Size	1000000 Tablets
Generic Name:	Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate and Caffeine Anhydrous Tablets	MFC NO:	ST/MFC/119/R0	Supersedes MFC No:	Nil
Batch No.:	LD200301	Mfg.Date:	03/2020	Exp.Date:	02/2023

BMR COPY/QUALITY CONTROL COPY

22.0 TEST REQUEST FORM FOR BULK TABLETS:

From: Manufacturing Department	To: Q.A. Department
To be filled by production Date of Mfg.: Mar. 2020 Date of exp : Feb. 2023 Test Request for .: Content TRF raised by [signature] on date 31/03/2020	**To be filled by IPQA** Quantity Sampled : 100 tabs Sampled by : [signature] on date: 31/03/20 No. of containers : 46 Sample received by : [signature] on date 31/03/2020
To be filled by QC TRF received on : 31/03/2020 Sample tested on 07/04/2020	
Test Results	
Each tablet contains:- phenylephrine HCl:- 4.88mg (97.5%) Disso: Avg:- 96.0% Min:- 95.1% max:- 97.0% paracetamol:- 491.09mg (98.20%) Disso: Avg:- 100.3% Min:- 97.4% max:- 109.2% caffeine:- 29.60mg (98.7%) Disso: Avg: 101.1% Min:- 98.6% max:- 110.1% CPM:- 1.90mg (95.2%) Disso: Avg:- 92.6% Min: 87.9% max:- 95.0% Related substances:- paracetamol:- (1) single max:- 0.02% / Total Imp:- 0.03%	
Analytical Reference no.: SFP/C/00345/2020 Analysed By : [signature] on : 15/04/2020	**Space for QC Approval** (Stamping and Signing) APPROVED Sign [signature] Date 15/04/20

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	[signature] 28/02/2020	[signature] 28/02/2020	[signature] 28/02/2020	CONTROLLED COPY

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IDEAL ANALYTICAL AND RESEARCH INSTITUTION

Plot No.1 and 2 (PT),Brindhavanam Nagar,Pazhani samy Nagar, Villianur, Puducherry-605110

CERTIFICATE OF ANALYSIS

Form 39 (Rule 150-E(f))

(As per Drugs & Cosmetics Act, 1940 and the rules made there under) Approval No. :20 30 4332

Analytical Report No. :	AR/20/05/05/025
Date :	11.05.2020

1) Name of the manufacturer from whom sample received with manufacturing license number	Safetab Life Science,Plot No, A-68, PIPDIC Electronic Park, Thirubuvanai, Puducherry - 605 107.				
2) Reference number & date of the sample forwarding letter	**3) Date of receipt of sample**	**4) Name of drug / cosmetics / raw material / final product in bulk / final product (in finished pack) as obtained from the manufacturer**			
05.05.2020	05.05.2020	LITACOLD FLU TABLETS			
5) Details of drug / cosmetics / raw material / final product in bulk / final product (in finished pack) as obtained from the manufacturer as follows					
a)Original manufacturer's name (in case of raw materials and drugs repacked)	**b)Batch No/ Control No.**	**c)Batch size as represented by sample**	**d)Date of manufacture, if any**	**e)Date of expiry, if any**	**f)Quantity submitted**
Safetab Life Science	GD200301	10.0Lac	03/2020	02/2023	5strips

6) Results of test for analysis: *SAMPLE NOT DRAWN BY US*

Description: Pale yellow colour circular shaped slightly biconvex uncoated bilayered tablet plain on both sides.

PARAMETERS	SPECIFICATIONS	RESULTS
Microbial Contamination		
Total Viable aerobic count		
i. Bacteria	NMT1000cfu/g	80cfu/gm
ii. Fungi	NMT 100cfu/g	Found Absent
E-coli	Absent/gm	Found Absent
Salmonella	Absent/gm	Found Absent
Pseudomonas aeruginosa	Absent/gm	Found Absent
Staphylococcus aureus	Absent/gm	Found Absent

In the opinion of the undersigned, the sample referred to above is ***of standard quality / ~~is not of standard quality~~*** as defined in the Act and Rules made there under for the reasons given below.

Observation: The sample complies as per IHS specifications with respect to above parameters.

11/06/2020

Signature of Person-in-charge of testing