Safetab Life Science

Plot No. A-67 to 72, PIPDIC
Electronic Park, Thirubuvanai,
Puducherry-605107

Tel: 0413 – 2641099
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CERTIFICATE OF ANALYSIS

Product Name	:	**LITACOLD FLU** (Paracetamol, Phenylephrine, Chlorphenamine Maleate & Caffeine Tablets)			
Batch No.	:	G17250706	**Batch Size**	:	12.5LAC
Mfg. Date	:	JUL'2025	**Exp. Date**	:	JUN'2028
Sampling Date	:	23/07/2025	**Sample Quantity**	:	13X4'S
Analysis Date	:	23/07/2025	**Specification No.**	:	SPEC-978-00
Release Date	:	28/07/2025	**A.R. No.**	:	SFP251219

Sr. No.	Test	Specifications	Results
1.	**Description**	Light yellow coloured, flat, round beveled edged uncoated tablet with break line on one side and plain on other side.	Light yellow coloured, flat, round beveled edged uncoated tablet with break line on one side and plain on other side.
2.	**Identification** (By HPLC)		
	A. Paracetamol BP	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
	B. Phenylephrine HCl BP	The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Phenylephrine HCl in the standard preparation as obtained in assay.	Complies
	C. Chlorphenamine Maleate BP	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
	D. Caffeine BP	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
3.	Average Weight of tablets	635.0 mg ± 3.0% (615.9 mg to 654.0 mg)	638.2mg

Particulars	Prepared By	Reviewed By	Approved By
Name	**C.K.SARAVANAN**	**K.SARAVANAN**	**M.VIJAYAKUMAR**
Designation	**Asst. Manager - QC**	**Dy. Manager - QC**	**GM - QC**
Signature/Date	C.K.Saravanan Digitally signed by C.K.Saravanan Date: 2025.07.29 16:18:51 +05'30'	SARA VANAN Digitally signed by SARA VANAN Date: 2025.07.29 18:59:05 +05'30'	VIJAYA KUMAR Digitally signed by VIJAYA KUMAR Date: 2025.07.29 19:27:56 +05'30'

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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%	(-) 0.71% (+) 2.17%
5.	**Diameter**	12.70 mm ± 0.2 mm (12.50 to 12.90 mm)	12.84mm
6.	**Thickness**	4.30 mm ± 0.2 mm (4.10 to 4.50 mm)	4.18mm
7.	**Hardness**	100 N to 250 N	188.91N
8.	**Friability**	Not more than 1.00%	0.18%
9.	**Disintegration time**	Not more than 15 minutes	05 minutes 22 seconds
10.	**Dissolution:**		
	Chlorphenamine Maleate BP..... 2 mg	Not less than 80.0% of the labeled amount	Min: 96.9%; Max: 99.4%; Avg: 98.1%
	Phenylephrine HCl BP …5 mg	Not less than 80.0% of the labeled amount	Min: 95.7%; Max: 98.1%; Avg: 96.7%
	Caffeine (anhydrous) BP……30 mg	Not less than 80.0% of the labeled amount	Min: 98.4%; Max: 102.4%; Avg: 100.1%
	Paracetamol BP... 500 mg	Not less than 80.0% of the labeled amount	Min: 97.9%; Max: 100.9%; Avg: 99.4%
11.	**Uniformity Content:**		
	Chlorphenamine Maleate BP..... 2 mg	Not less than 85.0 % and not more than 115.0 % of labeled claim	Min: 94.7%; Max: 100.4%; Avg: 97.6%
	Phenylephrine HCl BP …5mg	Not less than 85.0 % and not more than 115.0 % of labeled claim	Min: 96.1%; Max: 102.6%; Avg: 99.6%

Particulars	Prepared By	Reviewed By	Approved By
Name	**C.K.SARAVANAN**	**K.SARAVANAN**	**M.VIJAYAKUMAR**
Designation	**Asst. Manager - QC**	**Dy. Manager - QC**	**GM - QC**
Signature/Date	C.K.Saravanan Digitally signed by C.K.Saravanan Date: 2025.07.29 16:19:01 +05'30'	SARA VANAN Digitally signed by SARA VANAN Date: 2025.07.29 18:59:24 +05'30'	VIJAYA KUMAR Digitally signed by VIJAYA KUMAR Date: 2025.07.29 19:28:06 +05'30'

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Sr. No.	Test	Specifications	Results
12.	**Related Substances**		
	Single maximum unknown impurity	Not more than 0.20%	Not Detected
	Total impurities	Not more than 0.50%	Not Detected
13.	**Assay:** Each uncoated tablet contains:		
	Chlorphenamine Maleate BP..... 2 mg	1.9mg to 2.2mg (95.0% to 110.0% of the labeled claim)	1.98mg (98.9%)
	Phenylephrine HCl BP …5 mg	Not less than 95.0% and not more than 110.0% of labeled claim	4.92mg (98.3%)
	Caffeine (anhydrous) BP……30 mg	Not less than 95.0% and not more than 110.0% of labeled claim	30.45mg (101.5%)
	Paracetamol BP.. 500mg	Not less than 95.0% and not more than 110.0% of labeled claim	494.24mg (98.8%)
14.	**Microbial Limits:**		
	Total aerobic bacterial counts	Not more than 1000 cfu/g	<10cfu/g
	Fungi	Not more than 100 cfu/g	<10cfu/g
	E. coli.	Should be Absent	Absent
	Salmonella.	Should be Absent	Absent
	S. aureus.	Should be Absent	Absent
	P. aeruginosa.	Should be Absent	Absent

Remarks: The sample Complies/~~Does not Complies~~ as per ~~BP / USP~~ / In-House specification.

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Signature/Date	C.K.Saravanan Digitally signed by C.K.Saravanan Date: 2025.07.29 16:19:11 +05'30'	SARA VANAN Digitally signed by SARA VANAN Date: 2025.07.29 18:59:36 +05'30'	VIJAYA KUMAR Digitally signed by VIJAYA KUMAR Date: 2025.07.29 19:28:16 +05'30'