

Plot No. A-67 to 72, PIPDIC Electronic Park, Thirubuvanai, Puducherry-605107 Tel: 0413 – 2641099 2641199 2641666 info@safetab.net www.safetab.net

CERTIFICATE OF ANALYSIS						
Product Name	:	LITACOLD FLU	LITACOLD FLU			
		(Paracetamol, Phenylephrine,	(Paracetamol, Phenylephrine, Chlorphenamine Maleate & Caffeine Tablets)			
Batch No.	••	G17250705	G17250705 Batch Size : 12.5LAC			
Mfg. Date	:	JUL'2025	Exp. Date	:	JUN'2028	
Sampling Date	:	21/07/2025	Sample Quantity	:	13X4'S	
Analysis Date	:	21/07/2025				
Release Date	:	26/07/2025	A.R. No.	:	SFP251199	

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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 HCI 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)	636.9mg		

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			

Format No: ST/QC/070:F7



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Analysis Date	:	21/07/2025	Specification No.	:	SPEC-978-00	
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Sr. No.	Test	Specifications	Results
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%	(-): 1.56% (+): 1.80%
5.	Diameter	12.70 mm ± 0.2 mm (12.50 to 12.90 mm)	12.80mm
6.	Thickness	4.30 mm ± 0.2 mm (4.10 to 4.50 mm)	4.20mm
7.	Hardness	100 N to 250 N	173.64N
8.	Friability	Not more than 1.00%	0.20%
9.	Disintegration time	Not more than 15 minutes	05 minutes 11 seconds
10.	Dissolution:		
	Chlorphenamine Maleate BP 2 mg	Not less than 80.0% of the labeled amount	Min: 91.1%; Max: 98.8%; Avg: 97.0%
	Phenylephrine HCI BP5 mg	Not less than 80.0% of the labeled amount	Min: 94.8%; Max: 97.6%; Avg: 96.1%
	Caffeine (anhydrous) BP30 mg	Not less than 80.0% of the labeled amount	Min: 94.7%; Max: 100.2%; Avg: 97.3%
	Paracetamol BP 500 mg	Not less than 80.0% of the labeled amount	Min: 97.8%; Max: 99.8%; Avg: 98.6%
11.	Uniformity Content:		,
	Chlorphenamine Maleate BP 2 mg	Not less than 85.0 % and not more than 115.0 % of labeled claim	Min: 95.3%; Max: 99.4%; Avg: 97.5%
	Phenylephrine HCI BP5mg	Not less than 85.0 % and not more than 115.0 % of labeled claim	Min: 96.2%; Max: 101.8%; Avg: 98.0%

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Test	Specifications	Results	
Related Substances			
Single maximum unknown impurity	Not more than 0.20%	Not Detected	
Total impurities	Not more than 0.50%	Not Detected	
Assay: Each uncoated tal	olet contains:		
Chlorphenamine Maleate BP 2 mg	1.9mg to 2.2mg (95.0% to 110.0% of the labeled claim)	1.97mg (98.7%)	
Phenylephrine HCI BP5 mg	Not less than 95.0% and not more than 110.0% of labeled claim	4.93mg (98.6%)	
Caffeine (anhydrous) BP30 mg	Not less than 95.0% and not more than 110.0% of labeled claim	29.69mg (99.0%)	
Paracetamol BP 500mg	Not less than 95.0% and not more than 110.0% of labeled claim	487.05mg (97.4%)	
Microbial Limit Test			
Total aerobic microbial count	Not more than 1000 cfu/g	<10cfu/g	
Total Yeast & Mould count	Not more than 100 cfu/g	<10cfu/g	
E. Coli	Should be absent/g	Absent	
Salmonella	Should be absent/10g	Absent	
P. aeruginosa	Should be absent/g	Absent	
S. aureus	Should be absent/g	Absent	
	Related Substances Single maximum unknown impurity Total impurities Assay: Each uncoated tal Chlorphenamine Maleate BP	Related Substances Single maximum unknown impurity Total impurities Not more than 0.20% Assay: Each uncoated tablet contains: Chlorphenamine Maleate BP	

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

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