



Safetab Life Science

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

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CERTIFICATE OF ANALYSIS

Product Name	:	GRIPEX(Paracetamol, Phenylephrine HCl, Chlorphenamine Maleate & Ascorbic Acid Oral Powder)			
Batch No.	:	G17250710	Batch Size	:	2.0 LAC
Mfg. Date	:	JUL'2025	Exp. Date	:	JUN'2028
Sampling Date	:	28/07/2025	Sample Quantity	:	23 SACHETS
Analysis Date	:	28/07//2025	Specification No.	:	SPEC-1048-00
Release Date	:	14/08/2025	A.R No.	:	SFP251242

Sr. No.	Test	Specification	Results
1.	Description	Light brown colored, free flowing powder with lemon flavor.	Light brown colored, free flowing powder with lemon flavor.
2.	IdentificationBy HPLC:		
	A. Paracetamol	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 hydrochloride	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. Chlorphenamine Maleate	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. Ascorbic acid (By Chemical)	A deep violet colour is produced and deep violet colourdisappears on add about 5ml of dilute sulfuric acid.	Complies
3.	Average Net Content/Sachet	4.5000 g \pm 5% (4.2750 g to 4.7250 g)	4.4185g
4.	Uniformity of weight	For Individual sachet: \pm 7.5% of Average Weight For two sachets: \pm 15%	(-): 5.74% (+): 0.12%
5.	Water Content (by KF)	Not more than 5.0%	3.28%

Particulars	Prepared By	Reviewed By	Approved By
Name	R.VIGNESH	K.SARAVANAN	M.VIJAYAKUMAR
Designation	Sr. Executive - QC	Dy.Manager - QC	GM - QC
Signature/Date			



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6.	Related Substances:		
	Single maximum unknown impurity	Not more than 0.5%	0.01%
	Total unknown impurities	Not more than 1.0%	0.01%
7.	Assay: Each 4.5 g Sachet Contains		
	Paracetamol BP650 mg	90.0 % to 110.0% of the labeled amount	668.38mg (102.8%)
	Phenylephrine HCl BP10mg	90.0 % to 110.0% of the labeled amount	10.64mg (106.4%)
	Chlorpheniramine Maleate BP20mg	90.0 % to 110.0% of the labeled amount	21.52mg (107.6%)
	Ascorbic acid BP50mg	90.0 % to 110.0% of the labeled amount	50.20mg (100.4%)
8.	Microbial Limits:		
	Total aerobic bacterial counts	Not more than 1000 cfu/g	<10cfu/g
	Fungi	Not more than 100 cfu/g	<10cfu/g
	<i>E. coli.</i>	Should be Absent	Absent
	<i>Salmonella.</i>	Should be Absent	Absent
	<i>S. aureus.</i>	Should be Absent	Absent
	<i>P. aeruginosa.</i>	Should be Absent	Absent

Remarks: The product complies/~~does not comply~~ as per BP/USP/In-house specification.

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Name	R.VIGNESH	K.SARAVANAN	M.VIJAYAKUMAR
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