Safetab Life Science

ANNUAL STABILITY REPORT

Product Name: GRIPEX

Strength: Paracetamol 650mg + Phenylephrine Hcl 10mg + Chlorphenamine maleate 20mg + Ascorbic acid 50mg

Batch No: G17230101

Mfg. Date: Jan-23

Exp.Date: Dec-25

Pack : Sachet packing (4.5g x 10's)

Study Started on : 28/01/2023

Study Completed on : 28/01/2025

Reason for study : Ongoing stability

Tests	Specifications	Initial	6 Months	12 Months	18 Months	24 Months	36 Months
Condition>>	NA	NA	25 ± 2ºC & 60 ± 5% RH	25 ± 2ºC & 60 ± 5% RH	30 ± 2ºC & 75 ± 5% RH	30 ± 2ºC & 75 ± 5% RH	-
Description	Light brown colored, free flowing powder, with lemon flavour.	Light brown colored, free flowing powder, with lemon flavour.	Light brown colored, free flowing powder, with lemon flavour.	Light brown colored, free flowing powder, with lemon flavour.	Light brown colored, free flowing powder, with lemon flavour.	Light brown colored, free flowing powder, with lemon flavour.	-
Average net content weight	4.5000 g ± 5.0% (4.2750g to 4.7250g)	4.6627g	4.5308g	4.5000g	4.5000g	4.5000g	-
Water Content by (KF)	Not more than 5.0%	3.92%	3.53%	3.54%	3.08%	3.49%	-
Related Substances (By HPLC) (i) Single maximum unknown impurity (ii) Total unknown impurities	 Not more than 0.5% Not more than 1.0%	Not applicable	Not applicable	 0.02% 0.04%	 Not detected Not detected	 Not detected Not detected	
Assay: Each 4.5gm sachet contains: Paracetamol BP 650mg	90.0% to 110.0% of the labeled claim I.e. 585.0mg to 715.0mg	641.80mg (98.7%)	649.95mg (100.0%)	619.34mg (95.3%)	619.39mg (95.3%)	631.85mg (97.2%)	-
Phenylephrine Hydrochloride BP 10mg	90.0% to 110.0% of the labeled claim I.e. 9.0 to 11.0mg	10.22mg (102.2%)	10.51mg (105.1%)	10.44mg (104.4%)	9.74mg (97.4%)	10.22mg (102.2%)	-
Chlorphenamine Maleate BP 20mg	90.0% to 110.0% of the labeled claim I.e. 18.0 to 22.0mg	21.27mg (106.4%)	20.82mg (104.1%)	21.93mg (109.6%)	21.19mg (106.0%)	21.77mg (108.9%)	-
Ascorbic acid BP 50mg	90.0% to 110.0% of the labeled claim I.e. 45.0mg to 55.0mg	52.19mg (104.4%)	53.26mg (106.5%)	53.66mg (107.3%)	50.84mg (101.7%)	50.86mg (101.7%)	-
Microbiological parameters:							
I) Total Viable aerobic count							
a) Total aerobic microbial count	Not more than 1000 cfu/g	20cfu/g		10cfu/g		10cfu/g	
b) Total yeast and mould count	Not more than 100 cfu/g	<10cfu/g		<10cfu/g		<10cfu/g	
ii) Pseudomonas aeruginosa	Should be absent	Found absent	NA	Found absent	NA	Found absent	-
iii) Salmonella Species	Should be absent/10g	Found absent		Found absent		Found absent	
iv) Esherichia Coli	Should be absent	Found absent		Found absent		Found absent	
v) Staphylococcus aureus	Should be absent	Found absent		Found absent		Found absent	
Remarks		Pass	Pass	Pass	Pass	Pass	-

NA : Not applicable

Conclusion: The above refered batch meets the acceptance criteria when stored at above mentioned condition for 24 months.

Note: 1. As per customer requirement stability sample has been transferred to 30 ± 2ºC & 75 ± 5% RH condition from 25 ± 2ºC & 60 ± 5% RH Condition from 12month interval

2. The Related substances test has been incorporated from 12 months as per Change control number: ST/CC/23/149.

Particulars	Prepared By	Checked By	Approved By
Name	C.K.SARAVANAN	M. VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager - QC	GM - QC	AGM - QA
Signature			
Date	18/06/25	18/06/25	18/06/25

Safetab Life Sciences QUALITY ASSURANCE Puducherry-107

Format No: ST/QC/056:F7