



Safetab Life Science

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

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

CERTIFICATE OF ANALYSIS

| | | | | | |
|---------------|---|--|-------------------|---|-------------|
| Product Name | : | GENFORTE TABLET (Ibuprofen and Paracetamol Tablets) | | | |
| Batch No. | : | G17250714 | Batch Size | : | 8.0 LAC |
| Mfg. date | : | JUL'2025 | Exp date | : | JUN' 2028 |
| Sampling date | : | 01/08/2025 | Sample quantity | : | 5 x 10'S |
| Analysis date | : | 01/08/2025 | Specification No. | : | SPEC-977-00 |
| Release date | : | 06/08/2025 | A.R. No. | : | SFP251274 |

| Sr. No. | Test | Specification | Results |
|---------|--------------------------|--|--|
| 1. | Description | Light orange coloured, oval shaped biconvex uncoated tablet with break line on one side and plain on other side. | Light orange coloured, oval shaped biconvex 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. Ibuprofen BP | The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Ibuprofen in the standard preparation as obtained in assay. | Complies |
| 3. | Average weight of tablet | 1040.00 mg \pm 3.0% (1008.8 mg to 1071.2 mg) | 1040.9mg |
| 4. | Uniformity of weight | Not more than 2 of the individual weights deviate from the average weight by more than \pm 5.0% and none deviate by more than \pm 10.0% | (-): 0.94% (+): 0.86% |
| 5. | Length | 19.30 mm \pm 0.2 mm (19.10 to 19.50 mm) | 19.30mm |
| 6. | Width | 9.00 mm \pm 0.2 mm (8.80 to 9.20 mm) | 9.02mm |
| 7. | Thickness | 7.70 mm \pm 0.3 mm (7.40 to 8.00 mm) | 7.65mm |
| 8. | Hardness | 150 N to 300 N | 216.63N |
| 9. | Friability | Not more than 1.0% | 0.28% |

| 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 | | | |



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|---------|--------------------------------------|--|--|
| 10. | Disintegration Time | Not more than 15 minutes | 01 minutes 00 seconds |
| 11. | Dissolution: | | |
| | Ibuprofen BP..... 400 mg | Not less than 80% of labelled amount | Min: 99.4%; Max: 101.8%; Avg: 100.1% |
| | Paracetamol BP.... 500mg | Not less than 80% of labelled amount | Min: 100.3%; Max: 101.8%; Avg: 100.7% |
| 12. | Assay: Each Uncoated Tablet contains | | |
| | Ibuprofen BP..... 400 mg | Not less than 90.0% and not more than 110.0% of labelled claim | 394.80g (98.7%) |
| | Paracetamol BP.... 500 mg | Not less than 90.0% and not more than 110.0% of labelled claim | 498.00mg (99.6%) |
| 13. | Related Substances: | | |
| | Single maximum unknown impurity | Not more than 0.20% | 0.030% |
| | Total impurities | Not more than 0.50% | 0.030% |
| 14. | 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 |

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

| 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 | | | |