

**ACCENT PHARMA, JAMMU**  
**QUALITY CONTROL DEPARTMENT**  
**Finished Product Certificate of Analysis**

(Under Drugs & Cosmetics Act 1940 & rules made there under)

|                                     |                                                              |                                                   |
|-------------------------------------|--------------------------------------------------------------|---------------------------------------------------|
| <b>PRODUCT:</b>                     |                                                              | <b>MINISPRIN 75</b>                               |
| <b>GENERIC NAME :</b>               |                                                              | <b>ASPIRIN GASTRO - RESISTANT TABLETS IP 75MG</b> |
| A.R. No.: AP/02/FP/26/397           | Batch Size: 30.0 Lac.                                        |                                                   |
| Batch No.: AMR26003                 | Date of Sampling: 18/07/2026                                 |                                                   |
| Mfg. Date: JUL. 2026                | Quantity Sampled: 154 Tablets                                |                                                   |
| Exp. Date: JUN. 2028                | Date of Analysis: 20/07/2026                                 |                                                   |
| Manufactured for: American Remedies | Date of Release : 28/07/2026                                 |                                                   |
| STP No.: AP/02/FP/M002/01           | Mother B.No.of Aspirin Gastro-resistant tablet used:AGA26003 |                                                   |

| Sr. No. | Test                                                                       | Limit                                                                                                                                                                                                                                                                                                                     | Observation                                                                                                                                                                                                                     |
|---------|----------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.      | Description                                                                | <b>Bulk:-</b> White coloured,circular shaped, slightly biconvex plain surface gastro resistant tablet.<br><br><b>FG Stage:-</b> Gastro resistant tablet packed in plain and printed Aluminum foil with 1X14's tablets per strip                                                                                           | <b>Bulk:-</b> White coloured,circular shaped, slightly biconvex plain surface gastro resistant tablet.<br><br><b>FG Stage:-</b> Gastro resistant tablet packed in plain and printed Aluminum foil with 1X14's tablets per strip |
| 2.      | Identification                                                             | <b>A(By HPLC)</b> Retention time of the major peak of sample preparation corresponds to that of standard as obtained in the assay.<br><b>B(BY IR)</b> The infra red spectrum of a KBr dispersion of it, previously dried exhibits maxima only at the same wavelengths as that of similar preparation of working standard. | Complies                                                                                                                                                                                                                        |
| 3.      | Average Weight of tablet                                                   | 112.00mg $\pm$ 5% (106.4mg - 117.6 mg)                                                                                                                                                                                                                                                                                    | 110.55mg                                                                                                                                                                                                                        |
| 4.      | Uniformity of weight                                                       | Average weight $\pm$ 10.0%                                                                                                                                                                                                                                                                                                | +3.09%<br>-1.41%                                                                                                                                                                                                                |
| 5.      | Thickness of tablets                                                       | 3.2 $\pm$ 0.2mm (3.0mm-3.4 mm)                                                                                                                                                                                                                                                                                            | Min.3.03mm.<br>Max.3.18mm.                                                                                                                                                                                                      |
| 6.      | Diameter of tablets                                                        | 6.0 $\pm$ 0.2mm (5.8mm-6.2mm)                                                                                                                                                                                                                                                                                             | Min.6.03mm.<br>Max.6.16mm.                                                                                                                                                                                                      |
| 7.      | Hardness of tablets                                                        | NLT 30 Newton (N)                                                                                                                                                                                                                                                                                                         | Min.69.98N<br>Max.87.87N                                                                                                                                                                                                        |
| 8.      | Disintegration Test                                                        | <b>In Acid (0.1M HCl):</b><br>No tablet show any evidence of disintegration, cracking or softening (apart from fragments of coating ) or cracks for 2 hour at 37 <sup>o</sup> C $\pm$ 2 <sup>o</sup> C                                                                                                                    | complies                                                                                                                                                                                                                        |
|         |                                                                            | <b>In Buffer (Phosphate buffer PH 6.8):</b><br>Not more than 60 minutes at 37 <sup>o</sup> C $\pm$ 2 <sup>o</sup> C                                                                                                                                                                                                       | 12 min. 33 Sec.                                                                                                                                                                                                                 |
| 9.      | <b>Dissolution: (By UV) For Aspirin</b><br>a) In 0.1M HCl acid for 2 hours | Not more than 10.0%                                                                                                                                                                                                                                                                                                       | Avg.1.97%<br>Max.2.59%<br>Min.1.29%                                                                                                                                                                                             |
|         | b) In mix phosphate buffer pH 6.8 for 45 minutes.                          | Not less than 70.0% (Q)                                                                                                                                                                                                                                                                                                   | Avg.92.05%<br>Max.94.49%<br>Min.89.47%                                                                                                                                                                                          |
| 10.     | Salicylic acid (By HPLC)                                                   | Not more than 3.0%                                                                                                                                                                                                                                                                                                        | 0.03%                                                                                                                                                                                                                           |

| Prepared By |               | Checked By    | APPROVED<br>Approved By |
|-------------|---------------|---------------|-------------------------|
| Name        | Jeovan        | Ashwan Kumar  | Rajesh SHARMA           |
| Sign.       | <i>Jeovan</i> | <i>Ashwan</i> | <i>RS</i>               |
| Date        | 28/07/2026    | 28/07/2026    | 28/07/2026              |

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**PRODUCT: MINISPRIN 75**

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| STP No.: AP/02/FP/M002/01           | Mother B.No.of Aspirin Gastro-resistant tablet used:AGA26003 |

|     |                                                                         |                                                       |                                      |
|-----|-------------------------------------------------------------------------|-------------------------------------------------------|--------------------------------------|
| 11. | <b>Assay: (By HPLC)</b> Gastro resistant tablet contains:               |                                                       |                                      |
|     | For Aspirin IP 75mg                                                     | (95.0%-105% of label claim)                           | 74.971mg<br>99.96%                   |
| 12. | <b>Uniformity of content(By weight variation)</b><br>For Aspirin        | Acceptance Value NMT 15                               | 2.37 (Aspirin)                       |
| 13. | <b>Additional test*</b>                                                 |                                                       |                                      |
|     | Microbial limit Test:<br>Total bacterial count<br>Total fungal count    | Not more than 1000 CFU/gm<br>Not more than 100 CFU/gm | 35/cfu gm<br><10/cfu gm              |
|     | E coli<br>Salmonella<br>Staphylococcus aureus<br>Pseudomonas aeruginosa | Absent/gm<br>Absent/10gm<br>Absent/gm<br>Absent/gm    | Absent<br>Absent<br>Absent<br>Absent |

\*: The test will be performed based on customer request.

**Remarks:** In the opinion of the undersigned, the sample referred to above is of Standard Quality/~~Not of Standard Quality~~ as defined in the Drugs & Cosmetics Act 1940 & Rules made there under as per Specification No.: **AP/02/SPC/FP/M002/01**.

| Prepared By |               | Checked By   | Approved By    |
|-------------|---------------|--------------|----------------|
| Name        | Jeevan        | Asman Kumar  | Rishabh SHARMA |
| Sign.       | <i>Jeevan</i> | <i>Asman</i> | <i>21</i>      |
| Date        | 28/07/2026    | 28/07/2026   | 28/07/2026     |