



# UNISPEED PHARMACEUTICALS PVT.LTD

445/2 Behind Wrigley Village Katha, Baddi, Dist- Solan (H.P.) 173205

Quality Control Department

## FINISH PRODUCT CERTIFICATE OF ANALYSIS

|                  |                                                                  |                  |                  |
|------------------|------------------------------------------------------------------|------------------|------------------|
| PRODUCT NAME     | GOMONT - LC TABLET                                               | A.R. NO.         | QCFT/191124/5198 |
| GENERIC NAME     | Montelukast Sodium & Levocetirizine Dihydrochloride Tablets I.P. |                  |                  |
| BATCH NO.        | T241160B                                                         | MFG. DATE        | 11/2024          |
| BATCH SIZE       | 1.0 Lac                                                          | EXP. DATE        | 10/2026          |
| DATE OF RECEIVED | 15/11/2024                                                       | DATE OF ANALYSIS | 15/11/2024       |
| SAMPLE QTY.      | 60 Tablets                                                       | DATE OF RELEASE  | 20/11/2024       |
| FORMAT NO.       | USP/QA-064/FR01-00                                               | PAGE NO.         | 1 To 1           |

| Sr.No | TEST                                                                                   | SPECIFICATION                                                                                                                                                                |           | RESULTS                                                                                                        |                 |
|-------|----------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|----------------------------------------------------------------------------------------------------------------|-----------------|
| 01.   | Description                                                                            | Light yellow coloured, round shape biconvex uncoated tablet having scored on one side and plain on other side.                                                               |           | Light yellow coloured, round shape biconvex uncoated tablet having scored on one side and plain on other side. |                 |
| 02.   | Identification<br>(By HPLC)<br>For Levocetirizine Dihydrochloride & Montelukast Sodium | In the assay, the retention time of the principal peak s in the chromatogram obtained with test solution correspond to the chromatogram as obtained with reference solution. |           | Complies                                                                                                       |                 |
| 03.   | Average Weight                                                                         | 175 mg $\pm$ 7.5 %                                                                                                                                                           |           | 169.41 mg                                                                                                      |                 |
| 04.   | Uniformity of Weight                                                                   | Average weight $\pm$ 7.5 %                                                                                                                                                   |           | Complies                                                                                                       |                 |
| 05.   | Uniformity of Content                                                                  |                                                                                                                                                                              |           |                                                                                                                |                 |
|       | For Levocetirizine Dihydrochloride                                                     | Between: (85 % to 115 %)                                                                                                                                                     |           | Average = 102.74 %                                                                                             |                 |
|       | For Montelukast                                                                        | Between: (85 % to 115 %)                                                                                                                                                     |           | Average = 100.28 %                                                                                             |                 |
| 06.   | Dissolution                                                                            |                                                                                                                                                                              |           |                                                                                                                |                 |
|       | For Levocetirizine Dihydrochloride                                                     | Not less than :70 % (Q)                                                                                                                                                      |           | Average = 99.25 %                                                                                              |                 |
|       | For Montelukast                                                                        | Not less than :70 % (Q)                                                                                                                                                      |           | Average = 104.37 %                                                                                             |                 |
| 07.   | Related Substances                                                                     | To comply                                                                                                                                                                    |           | Complies                                                                                                       |                 |
| 08.   | Friability Test                                                                        | Not More than 1.0 %                                                                                                                                                          |           | 0.17 %                                                                                                         |                 |
| 09.   | ASSAY: (Composition)<br>Each uncoated tablet contains:                                 | Claim                                                                                                                                                                        | Obtained  | %age                                                                                                           | Limit           |
|       | Levocetirizine Dihydrochloride I.P.                                                    | 5 mg                                                                                                                                                                         | 5.348 mg  | 106.96 %                                                                                                       | 90.0 % -110.0 % |
|       | Montelukast Sodium I.P.<br>Eq. to Montelukast                                          | 10 mg                                                                                                                                                                        | 10.135 mg | 101.35 %                                                                                                       | 90.0 % -110.0 % |

REMARKS: In the opinion of the above undersigned sample Complies / ~~Does not comply~~ as per IP/BP/USP & ~~In House~~ Specification.

|                 |                |                |                |
|-----------------|----------------|----------------|----------------|
|                 | Analyzed By    | Checked By     | Approved By    |
| Designation     | Officer Q.C.   | Executive Qc   | Officer Q.C.   |
| Name            | Manish Prasad. | Sandeep Yadav  | Manish Prasad  |
| Signature/ Date | <br>20/11/2024 | <br>20/11/2024 | <br>20/11/2024 |

