

*Signature*

02/07/2024.

# METAPHARMACEUTICAL

N DE LOTE:

0029124

**SOHAN**  
Healthcare Pvt.Ltd

## CERTIFICATE OF ANALYSIS

| PRODUCT : METFORMIN HYDROCHLORIDE EP |   |   |  |
|--------------------------------------|---|---|--|
| Batch No.                            | MET06590724                                   | Mfg. Lic No.  | PD-181   |
| Batch Size                           | 2452.20 Kg                                    | Manufacturing Date  | JUL.2024   |
| Specification No.                    | QC/FP/EP M 018.12                             | Expiry Date   | JUN.2029   |
| A. R. No.                            | FPA/0952/24                                   | Date  | 09.07.2024   |
| Grade                                | MAG 100 EP                                    | CAS No  | 1115-70-4  |
| Sr. No                               | TEST  | SPECIFICATIONS  | OBSERVATIONS   |
| 1                                    | Appearance                                    | White or almost white crystals.   | White crystals.  |
| 2                                    | Solubility                                    | Freely soluble in water, slightly soluble in ethanol (96%), practically insoluble in acetone and in methylene chloride.   | Freely soluble in water, slightly soluble in ethanol (96%), practically insoluble in acetone and in Methylene chloride.  |
| 3                                    | Identification                                | <i>First Identification (B,E)</i><br>B.IR spectrum of sample should be concordant with similarly recorded spectrum of working standard of Metformin Hydrochloride<br>E. Chloride: - It gives reaction of chloride | IR spectrum of sample is concordant with similarly recorded spectrum of working standard of Metformin Hydrochloride<br>Chloride: - It gives reaction of chloride |
| 4                                    | Appearance of solution.                       | A 10% w/v solution S in water shall be clear and colorless.   | A 10% w/v solution S in water is clear and colorless.  |
| 5                                    | Impurity F by HPLC                            | Not more than 0.05 %  | 0.013 %  |
| 6                                    | Related substances by HPLC                    |   |  |
|                                      | Impurity A (Cyanoguanidine)                   | Not More Than 0.02%   | 0.004 %  |
|                                      | Unspecified impurities                        | Not More Than 0.05% each  | Below Disregard limit  |
|                                      | Total impurities                              | Maximum 0.2%  | 0.004 %  |
| 7                                    | Loss on drying                                | Maximum 0.5% w/w  | 0.29 %   |
| 8                                    | Sulfated ash                                  | Maximum 0.1% w/w  | 0.03 %   |
| 9                                    | Assay by Potentiometer (% w/w on dried basis) | 98.5% to 101.0 %  | 99.8 %   |
| Remarks                              |   | The product confirms to EP 11.0 specifications.   |  |

| ---  | Prepared by      | Checked by       | Approved by      |
|------|------------------|------------------|------------------|
| Name | S.K. Ghule       | N.N. Mhatre      | M.J. Gore        |
| Sign | <i>Signature</i> | <i>Signature</i> | <i>Signature</i> |
| Date | 09.07.2024       | 09.07.2024       | 10.07.2024       |

**SH** Life is too precious




ADMIN :  
Marvel Fuego, office No.7110 / 7120  
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| Additional Tests |                          |   |              |
|------------------|--------------------------|---|--------------|
| Sr. No.          | TEST                     | SPECIFICATIONS  | OBSERVATIONS |
| 1                | Particle Size by Malvern | D90 : Not more than 150µm   | 66.8 µm      |
| 2                | Residual Solvent         |   |              |
|                  | Methanol                 | Not more than 3000 ppm  | BLQ          |
|                  | Xylene                   | Not more than 2170 ppm  | Not Detected |
| 3                | Bulk Density             |   |              |
|                  | Untapped Density         | NLT 0.40 to NMT 0.60 gm/ml  | 0.45 gm/ml   |
|                  | Tapped Density           | NLT 0.60 to NMT 0.80 gm/ml  | 0.67 gm/ml   |
| Remarks          |                          | The product confirms to COS (R1-CEP 2009-233-Rev 01) and customer specifications. |              |

|      |   |   |   |
|------|---|---|---|
| ---  | Prepared by   | Checked by  | Approved by   |
| Name | S.K. Ghule  | N.N. Mhatre   | M.J. Gore   |
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| Date | 09-07-2024  | 09-07-2024  | 10-07-2024  |

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