

# METAPHARMACEUTICAL

N DE LOTE:

0170625

10/06/2025



| QUALITY CONTROL DEPARTMENT                                       |            |                                  |                    |
|------------------------------------------------------------------|------------|----------------------------------|--------------------|
| CERTIFICATE OF ANALYSIS                                          |            |                                  |                    |
| FINISHED GOODS                                                   |            |                                  |                    |
| Product Name : METOCLOPRAMIDE HYDROCHLORIDE MONOHYDRATE Ph. Eur. |            |                                  |                    |
| Batch No. :                                                      | 25004MIRII | Batch Size :                     | 580.30 Kgs.        |
| Mfg Date :                                                       | Mar/2025   | Retest Date :                    | NA                 |
| Expiry Date :                                                    | Feb/2030   | A.R.No. :                        | IBD-251428         |
| LIMS AR No.:                                                     | 2102-83287 | LIMS Specification Id.:          | 2102-241           |
| Page No. :                                                       | 1 of 2     | Specification No./ Revision No.: | TS/API/M/COS/4.0/2 |

| Tests | Specifications | Results |
|-------|----------------|---------|
|-------|----------------|---------|

|                              |                                                                                                  |                           |
|------------------------------|--------------------------------------------------------------------------------------------------|---------------------------|
| Characters (Appearance)      | White or almost white, crystalline powder or crystals.                                           | White crystalline powder. |
| Characters (Solubility)      | Very soluble in water, freely soluble in ethanol (96%), sparingly soluble in methylene chloride. | Conforms                  |
| Characters (Melting Point)   | It melts at about 183°C with decomposition.                                                      | 185°C                     |
| Identification 1             | The pH of solution S is 4.5 to 6.0.                                                              | 5.08                      |
| Identification 2             | The infrared absorption spectrum of sample and standard are concordant.                          | Conforms                  |
| Identification 3             | The solution gives reaction (a) of chlorides.                                                    | Conforms                  |
| Appearance of Solution       | A 10% solution is clear and colourless.                                                          | Conforms                  |
| Impurity E (By TLC)          | Impurity E : NMT 0.5%                                                                            | < 0.5%                    |
| Related Substances (By UPLC) | Any Unspecified Impurity:NMT 0.10%                                                               | BQL                       |
|                              | Total Impurities:NMT 0.20%                                                                       | BQL                       |
| Water                        | 4.5% w/w to 5.5% w/w.                                                                            | 5.11 %w/w                 |
| Sulphated ash                | NMT 0.1% w/w.                                                                                    | 0.03 %w/w                 |

|                             |                            |                  |                             |
|-----------------------------|----------------------------|------------------|-----------------------------|
| Checked By (QC)             | AMIT SINGH<br>(Manager QC) | Approved By (QA) | SANJAY SAHU<br>(Manager QA) |
| Checked On                  | 12/04/2025 17:23           | Approved On      | 15/04/2025 16:12            |
| Printed By :<br>SANJAY SAHU | Printed on :               | 15/04/2025 16:28 | Copy No. : 1                |

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| Page No. :                                                       | 2 of 2     | Specification No./ Revision No.: | TS/API/M/COS/4.0/2 |

| Tests                                                                  | Specifications                                                       | Results      |
|------------------------------------------------------------------------|----------------------------------------------------------------------|--------------|
| Assay                                                                  | 99.0% - 101.0% w/w of $C_{14}H_{23}Cl_2N_3O_2$ (on anhydrous basis). | 100.8 %w/w   |
| Residual Solvents (By GC)                                              | Methanol:NMT 3000 ppm                                                | Not Detected |
|                                                                        | Isopropyl Alcohol:NMT 3000 ppm                                       | 519 ppm      |
|                                                                        | Toluene:NMT 50 ppm                                                   | <10 ppm      |
| REMARKS : The sample CONFORMS with respect to the above specifications |                                                                      |              |

|                                                                                       |                            |                  |                             |
|---------------------------------------------------------------------------------------|----------------------------|------------------|-----------------------------|
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