WRS M38-1



Certificate of Analysis Working Standard

Name of the Raw Material

: Metoclopramide Hydrochloride BP

WIS No.

: QC/WS/047

Date of Preparation

21/08/15

Use Before

: 20/08/16

Evaluated against EPCRS

: Batch No.: 2

| Sr. | Test | Downst | T |
|-----|---|--|--|
| No. | | Result | , Specification |
| 1 | Description | Almost white crystalline powder. | A white or almost white crystalline powder or crystals. |
| 3 | Identification : IR Related Substances | The IR absorption spectrum of substance is concordant with the reference spectrum of Metoclopramide HCI CRS. | The IR absorption spectrum of substance should be concordant with the reference spectrum of Metoclopramide HCI CRS. |
| 3 | By TLC | Complies | Any spot in the chromatogram obtained with test solution apart from the principle spot should not more Intense than the spot in the chromatogram obtained with reference solution (b) (0.5 %). Any spot in the chromatogram obtained with test solution (a) that has not been visualised in ultraviolet light at 254 nm is not more intense than the spot in the chromatogram obtained with reference solution (c) (0.5%) after spraying with dimethylaminobenzaldehyde solution. |
| 4 | * Waler | 5.0176 % | Between 4.5 % and 5.5 %. |
| 5 | * Assay | 100.19 % | Between 99.0 % and 101.0 % on anhydrous substances. |
| 6. | * Potency | 95.17 % | ouosidices. |

* Average Result of Triplicate Analysis.

Conclusion: The sample complies with the specification.

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(presidente Grafia