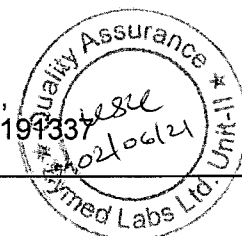


SYMED LABS LIMITED

UNIT-II, Plot No.25/B, Phase-III, IDA, Jeedimetla (V), Quthbullapur (M),
Medchal-Malkajgiri District – 500 055, Telangana State, INDIA. Tel:+ 91 4023194337
URL: <http://www.symedlabs.com>, CIN: U24231TG1998PLC029961



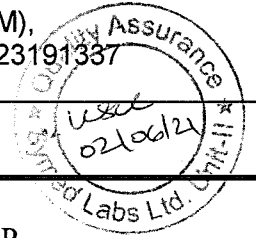
Certificate of Analysis

| | | | |
|---------------------|--|------------------|-----------------------|
| Product | : <u>HYDROXYZINE</u> | Reference | : <u>USP</u> |
| Batch No. | : <u>2HH0110521</u> | Batch Quantity | : <u>252.90 Kg</u> |
| Date of Manufacture | : <u>May²- 2021</u> | Date of analysis | : <u>01/06/2021</u> |
| Expiry date | : <u>Apr²- 2026</u> | A.R. No. | : <u>02FP21000818</u> |
| Storage conditions | : <u>Preserve in tight containers, Store at Controlled room temperature. Protect from light.</u> | | |

| S.No. | Test | Specifications | Results |
|-------|-----------------------------|--|---|
| *1. | Description | A white odorless powder. | A white odorless powder |
| *2. | Solubility | Very soluble in water, soluble in chloroform, slightly soluble in acetone and practically insoluble in ether. | Complies |
| **3. | Melting Range | Between 199.0°C and 205.0° C with decomposition. | Decomposition at 203.1°C |
| 4. | Identification by | A)IR : The Infrared absorption spectrum of the finely ground sample in KBr dispersion compressed into a disc should exhibit maxima only at the same wave numbers as that of a similar preparation of Hydroxyzine Hydrochloride working standard. | Matches with the spectrum of standard |
| | | *B) UV: Absorptivities at 230 nm calculated on anhydrous basis should not differ by more than 3.0% between working standard and test sample. | Complies |
| | | C) Test for chlorides: Positive test for chlorides. | Complies |
| | | D) UHPLC: The retention time of the major peak in the chromatogram of test solution corresponds to that in the chromatogram of the standard solution as obtained in the Assay. | Matches with the retention time of standard |
| 5. | Water content | Not more than 5.0 %w/w | 1.4%w/w |
| **6. | Residue on ignition | Not more than 0.50 %w/w | 0.03%w/w |
| 7. | Organic impurities by UHPLC | Decloxizine :Not more than 0.30% | Not detected (LOQ=0.0305%) |
| | | Hydroxyzine Related Compound-A:Not more than 0.30% | Not detected (LOQ=0.0112%) |
| | | 4-Chlorobenzophenone :Not more than 0.20% | Not detected (LOQ=0.0038%) |
| | | Any individual unspecified impurity: Not more than 0.20% | Not detected |
| | | Total impurities: Not more than 0.75% | Nil |

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Certificate of Analysis

Product : HYDROXYZINE Reference : USP
Batch No. : 2HH0110521 Batch Quantity : 252.90 Kg
Date of Manufacture : May'- 2021 Date of analysis : 01/06/2021
Expiry date : Apr'- 2026 A.R. No. : 02FP21000818
Storage conditions : Preserve in tight containers, Store at Controlled room temperature. Protect from light.

| S.No. | Test | Specifications | Results |
|-------|--|--|-------------------------------|
| 8. | Assay by UHPLC (on anhydrous basis) | Between 98.0% w/w and 102.0% w/w | 99.6%w/w |
| *9. | Residual solvents by GC | Methanol - Not more than 500 ppm | Not detected (LOQ=150 ppm) |
| | | Acetone - Not more than 500 ppm | Not detected (LOQ=33 ppm) |
| | | Isopropyl alcohol - Not more than 500 ppm | Not detected (LOQ=63 ppm) |
| | | Toluene - Not more than 100 ppm | Not detected (LOQ=36 ppm) |
| *10. | Particle Size | Not more than 10% of the material should retain on 40 mesh | 0.2% |
| *11. | Bulk density and Tapped density | Bulk Density : Between 0.20 and 0.40 g/mL | 0.26 g/mL |
| | | Tapped Density : Between 0.40 and 0.70 g/mL | 0.48 g/mL |
| #12. | AMC content by LC-MS | Not more than 3.75 ppm | Not tested |

The product **conforms** to the above specifications.

*In House tests.

**In House specifications.

LOQ = Limit of Quantitation.

#Test should be performed for every 10th batch or 1st batch per year, whichever is more frequent.

Approved Signatory (QC)

Name : V.Mukesh

Designation: Sr.Chemist

Date

V.M.
02.06.21

Authorized signatory (QA)

Name : A.Koushik Kumar

Designation: Sr.Supervisor

Date

A.K.
02/06/2021