KalChem™
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Compounding Chemicals You Can Trust

VASUDHA PHARMA CHEM LIMITED
78/A, Vengalrao Nagar, Hyderabad-500 038,
Telangana State, India
Phone: 91-40-2381 2046, 2371 1717, FAX: 91-40-2381 1576
E-Mail: vasudha@vasudhapharma.com,
Website:www.vasudhapharma.com



# CERTIFICATE OF ANALYSIS

| | | | | | |
|---|---|---|---|---|---|
| Name of the Product | : | CYCLOBENZAPRINE HYDROCHLORIDE | | | |
| Batch Number | : | ACBP/2107031 | Analyzed on | : | 10/08/2021 |
| Manufacturing Date | : | JUL'2021 | Expiry Date | : | JUN'2026 |
| Quantity | : | 189.000Kg | A.R.No. | : | FP/21979 |

| S.No. | TEST | | RESULT | SPECIFICATION |
|---|---|---|---|---|
| 1.0 | Description | | White odorless crystalline powder | White to off-white, odorless, crystalline powder. |
| 2.0 | Solubility | | Complies | Freely soluble in water, in alcohol, and in methanol, sparingly soluble in isopropanol, slightly soluble in chloroform and in methylene chloride, insoluble in n-Hexane. |
| 3.0 | IDENTIFICATION | | | |
| | A | Infrared absorption (In mineral oil/ATR Method) | Complies | The IR absorption spectrum obtained with the test sample should be concordant with that of reference spectrum of Cyclobenzaprine HCl or with the spectrum obtained with Cyclobenzaprine HCl Reference/working standard. |
| | B | Assay by HPLC | Complies | The retention time of major peak of the sample solution corresponds to that of the standard solution as obtained in the assay. |
| | C | Test for chloride | Complies | Should responds to the test for chloride |
| 4.0 | Loss on drying | | 0.24% w/w | Not more than 1.0 % w/w |
| 5.0 | Residue on Ignition | | 0.03% w/w | Not more than 0.1% w/w |

QUALITY ASSURANCE RELEASE
Customer Name: M/s Suan farma
Dispatch Quantity: 175 KG Sign & Date: 11/08/21

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| S.No. | TEST | RESULT | SPECIFICATION |
|---|---|---|---|
| 6.0 | Organic impurities by HPLC | | |
| | Cyclobenzaprine related compound A | BDL | Not more than 0.15% |
| | Cyclobenzaprine related compound B | 0.01% | Not more than 0.15% |
| | Cyclobenzaprine N-oxide | BQL | Not more than 0.15% |
| | Dibenzocycloheptenol | BDL | Not more than 0.1% |
| | Amitriptyline | BDL | Not more than 0.15% |
| | Dibenzocycloheptenone | BDL | Not more than 0.15% |
| | Any individual unspecified impurity | Not detected | Not more than 0.10% |
| | Total impurities | 0.01% | Not more than 1.0% |
| 7.0 | Assay by HPLC (On dried basis) | 99.8% w/w | Not less than 98.0% and not more than 102.0% w/w |
| 8.0 | ADDITIONAL TESTS | | |
| 8.1 | Residual Solvents by GC HS | | |
| | Methanol | 445 ppm | Not more than 1500 ppm |
| | Acetone | BDL | Not more than 2500 ppm |
| | Isopropyl alcohol | 201 ppm | Not more than 2500 ppm |
| | Tetrahydrofuran | BDL | Not more than 500 ppm |
| | Toluene | 47 ppm | Not more than 500 ppm |

NDC No: 66577-013-01.
BDL: Below Detection Limit, BQL: Below Quantitation Limit.
REMARKS: The material complies as per USP-43 Specification.

| | Prepared By QC | Checked By QC | Approved By QC |
|---|---|---|---|
| Signature & date | 11/08/2021 | 11/08/2021 | 11/08/2021 |
| Name | Bh. UMA SANDHYA | P. GOVARDHAN | D. VENKATA PADMANABHESWARA RAO |
| Designation | Sr.Executive-QC | Asst.Manager-QC | Dy.Manager-QC |