


 VASUDHA PHARMA CHEM LIMITED Unit-I	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	Page 1 of 3
	CERTIFICATE OF ANALYSIS	

Name of the Product	: CYCLOBENZAPRINE HYDROCHLORIDE		
Batch Number	: ACBP/2508042	Analyzed on	: 30/08/2025
Manufacturing Date	: AUG-2025	Expiry Date	: JUL-2030
Quantity	: 184.10Kg	AR No.	: FP/25930

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 Spectroscopy (In mineral oil) or by ATR	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 Reference / working standard of Cyclobenzaprine HCl.
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 (% w/w)	0.55	Not more than 1.0
5.0	Residue on ignition (% w/w)	0.04	Not more than 0.1

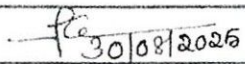
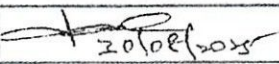
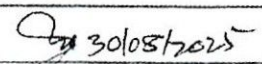
	Prepared By QC	Checked By QC	Approved By QC
Signature & date	<i>P. Keerthi</i> 30/08/2025	<i>P. Govardhan</i> 30/08/2025	<i>B. Srinivasa Raju</i> 30/08/2025
Name	P. KEERTHI	P. GOVARDHAN	B. SRINIVASA RAJU
Designation	Sr.Executive	Asst.Manager	Sr.Manager

QUALITY ASSURANCE RELEASE
Customer Name: **mls ZUCHEM**
Dispatch Qty: **50.00kg**
Date: **30/08/25**

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6.0	Organic impurities by HPLC (%)		
	Cyclobenzaprine related compound A	BDL (LOD: 0.0072)	Not more than 0.15
	Cyclobenzaprine related compound B	0.02	Not more than 0.15
	Cyclobenzaprine N-oxide	BDL (LOD: 0.0041)	Not more than 0.15
	Dibenzocycloheptenol	BDL (LOD: 0.0073)	Not more than 0.1
	Amitriptyline	BDL (LOD: 0.0137)	Not more than 0.15
	Dibenzocycloheptenone	BDL (LOD: 0.0041)	Not more than 0.15
	Any individual unspecified impurity	0.003	Not more than 0.10
	Total impurities	0.03	Not more than 1.0
7.0	Assay by HPLC (On dried basis, % w/w)	100.1	Not less than 98.0 and not more than 102.0

	Prepared By QC	Checked By QC	Approved By QC
Signature & date	 30/08/2025	 30/08/2025	 30/08/2025
Name	P. KEERTHI	P. GOVARDHAN	B. SRINIVASA RAJU
Designation	Sr.Executive	Asst.Manager	Sr.Manager

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S.No.	TEST	RESULT	SPECIFICATION
8.0	ADDITIONAL TESTS		
8.1	Residual Solvents by GC HS (ppm)		
	Methanol	BDL (LOD: 46.2)	Not more than 1500
	Acetone	BDL (LOD: 28.4)	Not more than 2500
	Isopropyl alcohol	BQL (LOQ: 284.8)	Not more than 2500
	Tetrahydrofuran	BDL (LOD: 10.1)	Not more than 500
	Toluene	62	Not more than 500

BDL: Below Detection Limit, BQL: Below Quantitation Limit.
REMARKS: The material complies as per USP Specification.

	Prepared By QC	Checked By QC	Approved By QC
Signature & date	<i>P. Keerthi</i> 30/08/2025	<i>P. Govardhan</i> 30/08/2025	<i>B. Srivasa Raju</i> 30/08/2025
Name	P. KEERTHI	P. GOVARDHAN	B. SRINIVASA RAJU
Designation	Sr.Executive	Asst.Manager	Sr.Manager