Enovachem™
PHARMACEUTICALS

CERTIFICATE OF ANALYSIS

PRODUCT NAME	Cyclobenzaprine Hydrochloride, USP
BATCH NUMBER	06162601
MANUFACTURER CODE	ZZ1934
MANUFACTURING DATE	11/01/2025
EXPIRATION DATE	10/31/2030

ANALYSIS	SPECIFICATION	RESULTS
ASSAY ON DRIED BASIS	98.0 - 102.0 %	98.9 %
DESCRIPTION	White to off-white, odorless, crystalline powder.	CONFORMS
IDENTIFICATION A: <197A>*	IR: Reference to standard spectrum	POSITIVE
IDENTIFICATION B:*	Reference to standard chromatogram	POSITIVE
IDENTIFICATION C: <191>*	Responds to the test for chloride	POSITIVE
LOSS ON DRYING <731>	<= 1.0 %	0.25 %
RESIDUE ON IGNITION <281>	<= 0.1 %	0.03 %
ELEMENTAL IMPURITIES <232>	Meets the requirements	CONFORMS
ORGANIC IMPURITIES	<= 0.15 % Cyclobenzaprine related compound A <= 0.15 % Cyclobenzaprine related compound B <= 0.15 % Cyclobenzaprine N –oxide <= 0.1 % Dibenzocycloheptenol <= 0.15 % Amitriptyline <= 0.15 % Dibenzocycloheptenone <= 0.10 % Any individual unspecified impurity <= 1.0 % Total impurities	NOT DETECTED 0.004 % NOT DETECTED NOT DETECTED NOT DETECTED NOT DETECTED 0.002 % 0.01 %
RESIDUAL SOLVENTS <467>	Meets the requirements	CONFORMS
SOLUBILITY	Freely soluble in water, in alcohol, and in methanol; sparingly soluble in isopropanol; slightly soluble in chloroform and in methylene chloride; insoluble in hydrocarbons.	
PACKAGING AND STORAGE	Preserve in well-closed containers	

QC APPROVED

DATE APPROVED: 06/16/26

CERTIFIED BY: _____

THE ABOVEMENTIONED PRODUCT CONFORMS TO THE SPECIFICATIONS OF USP.

ENOVACHEM PHARMACEUTICALS REPACKAGES ACTIVE PHARMACEUTICAL INGREDIENT CHEMICALS PROVIDED BY OTHER SUPPLIERS. ENOVACHEM'S CERTIFICATE OF ANALYSIS REFLECTS TEST RESULTS THAT ARE A DIRECT TRANSCRIPTION OF INFORMATION PROVIDED ON THE SUPPLIER'S CERTIFICATE OF ANALYSIS. ORIGINAL AND SUPPLIER CERTIFICATE OF ANALYSIS HAS BEEN ATTACHED.
ORIGINAL MANUFACTURER INFORMATION:R.L. FINE CHEMICALS PVT. LTD.PLOT NO.IP-27-29,KIADB IND.AREA,1ST PHA. KUDUMALAKUNTE VILL.,CHIKKABALAPUR DIST. GOWRIBIDANOOR, BENGALURU, KARNATAKA, 561208 IN
SUPPLIER INFORMATION: Medisca® 1-800-932-1039
6641 N. Beltline Rd. #120 Irving, TX 75063
SUPPLIER LOT NUMBER HAS BEEN CHANGED FROM: 228825
TO BATCH NUMBER: 06162601

Medisca®

CERTIFICATE OF ANALYSIS

CYCLOBENZAPRINE HYDROCHLORIDE, USP

Batch/Lot Number :	228825
Manufacturing Date :	11/01/2025
Expiration Date :	10/31/2030
CAS:	6202-23-9

This lot was manufactured by:

R.L. FINE CHEMICALS PVT. LTD.
(CHIKKABALLAPUR)
PLOT NO.IP-27-29,KIADB IND.AREA,1ST PHA.
KUDUMALAKUNTE
VILL.,CHIKKABALAPUR DIST.
GOWRIBIDANOOR, BENGALURU,
KARNATAKA, 561208
IN

TESTS	SPECIFICATIONS	RESULTS
RESIDUAL SOLVENTS <467>	Meets the requirements	CONFORMS
SOLUBILITY	Freely soluble in water, in alcohol, and in methanol; sparingly soluble in isopropanol; slightly soluble in chloroform and in methylene chloride; insoluble in hydrocarbons.	
PACKAGING AND STORAGE	Preserve in well-closed containers	

*TESTED ON 01/19/2026

Lot number has been changed from CBZ/225050 to 228825.

LOT TESTED BY:

CED Analytical Laboratory Inc.
6641 N Beltline Rd Unit 120
Irving, TX 75063

PUBLISHED BY:

PUBLISHED DATE:

01/20/2026

ISSUE DATE:

01/19/2026

The above mentioned product conforms to the specifications of USP.

The above test results are a direct transcription of information provided to MEDISCA from the Certificate of Analysis provided by the manufacturer / supplier. Additional testing conducted by MEDISCA is represented by an asterisk. This lot was manufactured by M: ZZ1934.

All dates in this document are in format mm/dd/yyyy unless otherwise specified

This document has been electronically approved through MEDISCA's Quality Management System.

Medisca®

CERTIFICATE OF ANALYSIS

CYCLOBENZAPRINE HYDROCHLORIDE, USP

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(CHIKKABALLAPUR)
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KUDUMALAKUNTE
VILL.,CHIKKABALAPUR DIST.
GOWRIBIDANOOR, BENGALURU,
KARNATAKA, 561208
IN

TESTS	SPECIFICATIONS	RESULTS
ASSAY ON DRIED BASIS	98.0 - 102.0 %	98.9 %
DESCRIPTION	White to off-white, odorless, crystalline powder.	CONFORMS
IDENTIFICATION A: <197A>*	IR: Reference to standard spectrum	POSITIVE
IDENTIFICATION B:*	Reference to standard chromatogram	POSITIVE
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LOSS ON DRYING <731>	<= 1.0 %	0.25 %
RESIDUE ON IGNITION <281>	<= 0.1 %	0.03 %
ELEMENTAL IMPURITIES <232>	Meets the requirements	CONFORMS
ORGANIC IMPURITIES	<= 0.15 % Cyclobenzaprine related compound A	NOT DETECTED
	<= 0.15 % Cyclobenzaprine related compound B	0.004 %
	<= 0.15 % Cyclobenzaprine N -oxide	NOT DETECTED
	<= 0.1 % Dibenzocycloheptenol	NOT DETECTED
	<= 0.15 % Amitriptyline	NOT DETECTED
	<= 0.15 % Dibenzocycloheptenone	NOT DETECTED
	<= 0.10 % Any individual unspecified impurity	0.002 %
	<= 1.0 % Total impurities	0.01 %

LOT TESTED BY:

CED Analytical Laboratory Inc.
6641 N Beltline Rd Unit 120
Irving, TX 75063

PUBLISHED BY:

PUBLISHED DATE:

01/20/2026

ISSUE DATE:

01/19/2026

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This document has been electronically approved through MEDISCA's Quality Management System.

Certificate of Analysis

R.L. Fine Chem Pvt. Ltd.,
Plot No. IP No.27-29, Parts of Sy. No.s.18, 273, 274 & 313, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanur Taluk, Chickkaballapura Dist.-561208. Karnataka, India.
Contact No: 080-42488900, 42488999.Fax No:080-28566630

Product Name: CYCLOBENZAPRINE HYDROCHLORIDE
Compendial Designation: USP/IHS

Batch No: CBZ/225050

Mfg. Date: NOVEMBER-2025
Retest Date: OCTOBER-2030
Date of Approval: 27.11.2025

TEST	OBSERVATION	SPECIFICATION	Reference to the test method
Description	White crystalline Powder odorless.	White to off- white, odorless, crystalline powder.	USP
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 hydrocarbons.	USP
IDENTIFICATION:			
A. Identification by IR	The IR Spectrum of the sample is concordanted with working standard spectrum.	The IR spectrum of the sample should be concordant with that of the working standard or reference standard spectrum.	USP
B. Identification by HPLC	Complies	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.	USP
C. Chloride Test	A white curdy precipitate is formed	A white curdy precipitate is formed.	USP
Assay by HPLC (in % w/w on dried bass)	98.9 %	Not less than 98.0 and Not more than 102.0	USP
Loss on drying (in % w/w)	0.25 %	Not more than 1.0	USP
Residue on ignition (in % w/w)	0.03 %	Not more than 0.1	USP

Prepared by:	Checked by:	Approved by:	Authorized by:
N. Lavanya 27/11/25	K.G. Karibasappa 27/11/25	27/11/2025	27/11/2025
Name: N Lavanya	Name: K.G.Karibasappa	Name: A Mohan Reddy	Name: G.V.Gopala Krishna Reddy
Designation: Executive-QC	Designation: Dy.Manager-QC	Designation: AGM-QC	Designation: Manager-QA

Certificate of Analysis

R.L. Fine Chem Pvt. Ltd.,
Plot No. IP No.27-29, Parts of Sy. No.s.18, 273, 274 & 313, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanur Taluk, Chickkaballapura Dist.-561208. Karnataka, India.
Contact No: 080-42488900, 42488999.Fax No:080-28566630

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Batch No: CBZ/225050

Mfg. Date: NOVEMBER-2025
Retest Date: OCTOBER-2030
Date of Approval: 27.11.2025

TEST	OBSERVATION	SPECIFICATION	Reference to the test method
Organic Impurities by HPLC (in %)			
(a).Cyclobenzaprine Related compound -A	Not detected	Not more than 0.15	
(b).Cyclobenzaprine Related compound –B	0.004 %	Not more than 0.15	
(c).Cyclobenzaprine N-oxide	Not detected	Not more than 0.15	USP
(d).Dibenzocycloheptenol	Not detected	Not more than 0.1	
(e).Amitriptyline	Not detected	Not more than 0.15	
(f).Dibenzocycloheptenone	Not detected	Not more than 0.15	
(g).Any individual unspecified impurity	0.002 %	Not more than 0.10	
(h).Total impurities	0.01 %	Not more than 1.0	
Residual solvents by GC (in ppm)			
(a).Methanol	375 ppm	Not more than 3000	
(b).Toluene	15 ppm	Not more than 890	IHS
(c).Tetrahydrofuran	0.58 ppm	Not more than 720	
(d).Acetone	70 ppm	Not more than 5000	
(e).Isopropyl alcohol	Not detected	Not more than 5000	

Certification and Compliance statements
The above material complies as per USP /IHS

Prepared by:	Checked by:	Approved by:	Authorized by:
27/11/25	27/11/25	27/11/2025	27-11-2025
Name: N Lavanya	Name: K.G.Karibasappa	Name: A Mohan Reddy	Name: G.V.Gopala Krishna Reddy
Designation: Executive-QC	Designation: Dy.Manager-QC 27/11/25	Designation: AGM-QC	Designation: Manager-QA