Enovachem™
PHARMACEUTICALS

CERTIFICATE OF ANALYSIS

PRODUCT NAME	Lidocaine Hydrochloride, USP
BATCH NUMBER	10172402
MANUFACTURER CODE	ZZ1968
MANUFACTURING DATE	03/01/2023
EXPIRATION DATE	02/28/2028

ANALYSIS	SPECIFICATION	RESULTS
ASSAY ON DRIED BASIS*	97.5 - 102.5 %	100.1 %
DESCRIPTION	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 tests for chloride.	POSITIVE
RESIDUE ON IGNITION <281>	≤ 0.1 %	0.0 %
SULFATE <221>*	≤ 0.1 %	< 0.1 %
ELEMENTAL IMPURITIES <232>	Meets the requirements	CONFORMS
ORGANIC IMPURITIES*	≤ 0.10 % (Lidocaine related compound H) ≤ 0.01 % (Ropivacaine related compound A) ≤ 0.10 % (Any individual unspecified impurity) ≤ 0.5 % (Total impurities)	NOT DETECTED NOT DETECTED NOT DETECTED NOT DETECTED
WATER <921> I*	5.0 - 7.0 %	6.6 %
RESIDUAL SOLVENTS <467>	Meets the requirements.	CONFORMS
SOLUBILITY	Very soluble in water and in alcohol; soluble in chloroform; insoluble in ether.	
LABELING	Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms.	
PACKAGING AND STORAGE	Preserve in well-closed containers. Protected from light. Store at controlled room temperature.	

QC APPROVED

DATE APPROVED: 10/17/24

CERTIFIED BY: gr

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 INFORMATIO Apex Healthcare Limited 4707-A/8, 4707-A/9, 4710,4711 GIDC Estate Ankleshawar- 393 002, Dist-Bharuch, Gujarat, India N:
SUPPLIER INFORMATION: Medisca® 1-800-932-1039
6641 N. Beltline Rd Unit 120 Irving, TX 75063
SUPPLIER LOT NUMBER HAS BEEN CHANGED FROM: 205145
TO BATCH NUMBER: 10172402

Medisca®

CERTIFICATE OF ANALYSIS

LIDOCAINE HYDROCHLORIDE, USP

Batch/Lot Number :	205145
Manufacturing Date :	03/01/2023
Expiration Date :	02/28/2028
CAS:	6108-05-0

TESTS	SPECIFICATIONS	RESULTS
ASSAY ON ANHYDROUS BASIS*	97.5 - 102.5 %	100.1 %
DESCRIPTION	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 tests for chloride.	POSITIVE
RESIDUE ON IGNITION <281>*	≤ 0.1 %	0.0 %
SULFATE <221>*	≤ 0.1 %	< 0.1 %
ELEMENTAL IMPURITIES <232>	Meets the requirements	CONFORMS
ORGANIC IMPURITIES*	≤ 0.10 % (Lidocaine related compound H)	NOT DETECTED
	≤ 0.01 % (Ropivacaine related compound A)	NOT DETECTED
	≤ 0.10 % (Any individual unspecified impurity)	NOT DETECTED
	≤ 0.5 % (Total impurities)	NOT DETECTED
WATER <921> I*	5.0 - 7.0 %	6.6 %
RESIDUAL SOLVENTS <467>	Meets the requirements.	CONFORMS
SOLUBILITY	Very soluble in water and in alcohol; soluble in chloroform; insoluble in ether.	

LOT TESTED BY:

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

PUBLISHED BY:

SANAM

PUBLISHED DATE:

01/22/2024

ISSUE DATE:

01/22/2024

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: ZZ1968.

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

LIDOCAINE HYDROCHLORIDE, USP

Batch/Lot Number :	205145
Manufacturing Date :	03/01/2023
Expiration Date :	02/28/2028
CAS:	6108-05-0

TESTS	SPECIFICATIONS	RESULTS
LABELING	Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms.	
PACKAGING AND STORAGE	Preserve in well-closed containers. Protected from light. Store at controlled room temperature.	

*TESTED ON 01/19/2024

Lot number has been changed from LHAH0130323 to 205145.

LOT TESTED BY:

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

PUBLISHED BY:

SANAM

PUBLISHED DATE:

01/22/2024

ISSUE DATE:

01/22/2024

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: ZZ1968.

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APEX HEALTHCARE LIMITED

QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS

Product	LIDOCAINE HCL	**Page No.**	01 of 01
Standard for Release	USP	**Drug Lic. No.**	G/25/1642

Batch No.	LHAH0130323	**Batch Quantity**	809.550 Kgs.
Mfg. Date	MAR-2023	**Date of Sampling**	03/04/23
Exp. Date	FEB-2028	**Date of Approval**	07/04/23
A.R. No.	FP/LH/028/23	**Dispatched Quantity**	800.000 Kgs.

Sr. No.	Tests	Acceptance Criteria	Test Result
1.	**Description**	White, odorless, crystalline powder, having a slightly bitter taste.	Whitecrystalline powder.
2.	**Solubility**	Very soluble in water and in alcohol, soluble in chloroform, in soluble in ether.	Complies
3.	**Identification**	A) The infrared spectrum of sample should be concordant with that standard spectrum.. B) The Retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay. C) The white turbidity should be produced.	Complies Complies Complies
4.	**Organic Impurities**	Lidocaine related Compound H: NMT 0.10 % Ropivacaine related Compound A: NMT 0.01 % Any individual unspecified impurity: NMT 0.10 % Total Impurities: NMT 0.5 %	ND 0.0003% 0.007% 0.021 %
5.	**Sulphate**	NMT 0.1%	Complies
6.	**Residue on ignition**	NMT 0.1 %	0.04 %
7.	**Water determination**	Between 5.0 and 7.0 %	6.41%
8.	**Assay**	NLT 97.5 % and NMT 102.5 % on anhydrous basis.	99.99 %
9.	**Residual solvent (By GC-HS)**	Acetone: NMT 5000 ppm Toluene: NMT 890 ppm Benzene: NMT 2 ppm	1502ppm 2ppm ND

Remarks: Theproduct complies with respects to above tests and prescribed standard specification as per USP 43.

Name	Miss. Bhumika Patel	Mr. Somnath Kokate	Mr. Chetan Sardhara
Designation-Dept.	Sr. Officer-QC	Sr. Executive-QC	Assistant Manager-QC
Sign. /Date	26/04/23	26/04/23	26/04/23
	Prepared by	**Reviewed by**	**Approved by**

Factory & Corporate Office: 4707-A/8, 4707-A/9, 4710,4711 GIDC Estate Ankleshwar – 393 002,
Dist.-Bharuch, Gujarat, India. Phone no.: +91 2646 222525/223525/227289