



CERTIFICATE OF ANALYSIS

PRODUCT NAME	Lidocaine Hydrochloride, USP
BATCH NUMBER	09292601
MANUFACTURER CODE	ZZ1110
MANUFACTURING DATE	05/01/2025
EXPIRATION DATE	04/30/2030

ANALYSIS	SPECIFICATION	RESULTS
ASSAY ON ANHYDROUS BASIS*	97.5 - 102.5 %	100.5 %
DESCRIPTION	White, odorless, crystalline powder.	CONFORMS
IDENTIFICATION A <197>*	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 %	0.01 %
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 0.02 % 0.02 %
WATER <921> I*	5.0 - 7.0 %	6.3 %
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: 09/29/26

CERTIFIED BY: [Signature]

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: Swati Spentose Pvt. Ltd. Unit 1 A-1/2102, 2103 & A-2/2120, Phase-III, G.I.D.C, Vapi-396195, Dist-Valsad Gujarat India 0260-2433133, 2401533

SUPPLIER INFORMATION: Medisca® 1-800-932-1039

6641 N. Beltline Rd. #120 Irving, TX 75063

SUPPLIER LOT NUMBER HAS BEEN CHANGED FROM: 225617

TO BATCH NUMBER: 09292601

CERTIFICATE OF ANALYSIS

LIDOCAINE HYDROCHLORIDE, USP

Batch/Lot Number : 225617

Manufacturing Date : 05/01/2025

Expiration Date : 04/30/2030

CAS: 6108-05-0

This lot was manufactured by:

SWATI SPENTOSE PVT. LTD.
A-1/2102,2103, PHASE III,
GIDC-VAPI, GUJARAT, 396195
IN

TESTS

SPECIFICATIONS

RESULTS

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	≤ 0.01 % (Ropivacaine related compound A)	NOT DETECTED
	≤ 0.10 % (Any individual unspecified impurity)	0.02 %
	≤ 0.5 % (Total impurities)	0.02 %
WATER <921> I*	5.0 - 7.0 %	6.3 %
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:



PUBLISHED DATE:

10/10/2025

ISSUE DATE:

10/10/2025

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: ZZ1110.

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.

CERTIFICATE OF ANALYSIS

LIDOCAINE HYDROCHLORIDE, USP

Batch/Lot Number : 225617
Manufacturing Date : 05/01/2025
Expiration Date : 04/30/2030
CAS: 6108-05-0

This lot was manufactured by:

SWATI SPENTOSE PVT. LTD.
A-1/2102,2103, PHASE III,
GIDC-VAPI, GUJARAT, 396195
IN

TESTS

LABELING

SPECIFICATIONS

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.

RESULTS

****PACKAGING AND STORAGE****

Preserve in well-closed containers. Protected from light.
Store at controlled room temperature.

*TESTED ON 10/10/2025

Lot number has been changed from
LDH/125025 to 225617.

LOT TESTED BY:

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

PUBLISHED BY:



PUBLISHED DATE:

10/10/2025

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Swati Spentose Pvt.Ltd. Unit-I
Plot No.- A-1/2102, 2103 & A-2/2120, Phase-III, G.I.D.C,
Vapi-396195, Dist-Valsad,
Gujarat. India. Ph. No. 0260-2433133

Certificate Of Analysis
(Finished Product)

Product Name: Lidocaine Hydrochloride USP

Product Name	Lidocaine Hydrochloride USP	A.R. No.	SS01FP25000333
Batch No.	LDH/125025	Date of Release	24/06/2025 15:46
Batch Size	1695.000 Kg	Storage Condition	NMT 30°C & Excursion upto 40°C
Mfg. Date	May/2025	Specification Id	SPC/FP/0003
Exp. Date	Apr/2030	Retest Date	--

S. No.	TEST	SPECIFICATION	RESULT
1	Description	White, odorless, crystalline powder,	White crystalline powder
2	Solubility		
2.1	In Water	Very soluble in water	Very soluble in water
2.2	In Ethanol (96% Alcohol)	Very soluble in alcohol	Very soluble in alcohol
2.3	In Chloroform	Soluble in chloroform	Soluble in chloroform
2.4	In Ether	Insoluble in ether	Insoluble in ether
3	Identification By Infrared Absorption (IR)	The infrared absorption spectrum of sample should be concordant with the working standard / reference standard spectrum of Lidocaine Hydrochloride.	The infrared absorption spectrum of sample is concordant with the working standard spectrum of Lidocaine hydrochloride
4	Identification By HPLC	The retention time of the major peak of the sample solution corresponds to that of standard solution as obtained in assay.	The retention time of the major peak of the sample solution corresponds to standard solution as obtained in assay.
5	Identification By General Chloride Test	Should be positive.	positive
6	Organic Impurities By HPLC		
6.1	Ropivacaine Related Compound -A	Not More Than 0.005%	Not Detected
6.2	Lidocaine Related Compound-H	Not More Than 0.005%	Not Detected
6.3	Any Individual Unspecified Impurity	Not More Than 0.10%	0.02 %
6.4	Total Impurities	Not More Than 0.5%	0.05 %
7	Water Content	Between 5.0% and 7.0%.	6.3 %
8	Chloride and Sulfate - Sulfate test	Not More Than 0.1%	Less than 0.1%

Remarks: APPROVED (Sample Conforms to above Specification)

Comment(s): Approved

Analyzed By	Harshal.Patil	Analyzed By (Role)	Harshal.Patil (QC Analyst)	Analyzed On	22/06/2025 13:36
Checked By	Ajay.Mishra	Checked By (Role)	Ajay.Mishra (QC Head)	Checked On	24/06/2025 15:02
Approved By (QC)	Prashant.Patil	Approved By (Role)	Prashant.Patil (QC Head)	Approved On	24/06/2025 15:13
Approved By (QA)	P.N.Rao	Approved By (Role)	P.N.Rao (Quality Head)	Approved On	24/06/2025 15:46

Printed by: Ayush.Patel

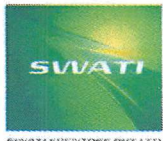
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Format No.COA/FP/001



Swati Spentose Pvt.Ltd. Unit-I
Plot No.- A-1/2102, 2103 & A-2/2120, Phase-III, G.I.D.C.,
Vapi-396195, Dist-Valsad,
Gujarat. India. Ph. No. 0260-2433133

**Certificate Of Analysis
(Finished Product)**

Product Name: Lidocaine Hydrochloride USP

Product Name	Lidocaine Hydrochloride USP	A.R. No.	SS01FP25000333
Batch No.	LDH/125025	Date of Release	24/06/2025 15:46
Batch Size	1695.000 Kg	Storage Condition	NMT 30°C & Excursion upto 40°C
Mfg. Date	May/2025	Specification Id	SPC/FP/0003
Exp. Date	Apr/2030	Retest Date	- -

9	Residue On Ignition	Not more than 0.1 %	0.03 %
10	pH (In House)	Between 4.0 to 5.5	5.22
11	Assay By HPLC	Lidocaine Hydrochloride contains Not Less Than 97.5% and Not More Than 102.5% of lidocaine hydrochloride (C ₁₄ H ₂₂ N ₂ O.HCl), calculated on the anhydrous basis	100.0 %
12	Residual Solvents By GC-HS		
12.1	Acetone	Not More Than 5000 ppm.	312 ppm
12.2	Toluene	Not More Than 890 ppm.	BLOD
13	Bulk Density	Informative	Untapped Density : 0.55 g/ml Tapped Density : 0.71 g/ml
14	Sieve Test	100% passes through 20 mesh sieve.	100%
15	Foreign & Black Particles	Should be free from foreign and black particles	Free from foreign and black particles

Test Plan Remarks: Storage Condition: Preserve in well closed container, protected from light & moisture. Store at a temperature not exceeding 30°C.Excursion allowed up to 40°C.

Remarks: APPROVED (Sample Conforms to above Specification)

Comment(s): Approved

Analyzed By	Harshal.Patil	Analyzed By (Role)	Harshal.Patil (QC Analyst)	Analyzed On	22/06/2025 13:36
Checked By	Ajay.Mishra	Checked By (Role)	Ajay.Mishra (QC Head)	Checked On	24/06/2025 15:02
Approved By (QC)	Prashant.Patil	Approved By (Role)	Prashant.Patil (QC Head)	Approved On	24/06/2025 15:13
Approved By (QA)	P.N.Rao	Approved By (Role)	P.N.Rao (Quality Head)	Approved On	24/06/2025 15:46

Printed by: Ayush.Patel

Printed on: 24/06/2025 15:48

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