Certificate Of Analysis

Item Number	ADG-00009	Lot Number	1NJ0271
Item	Lidocaine, USP	Manufacturer Lot	LDB/123036
CAS Number	137-58-6	Manufacturer Code	7068
Molecular Formula	$C_{14}H_{22}N_2O$	Molecular Weight	234.34

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY	97.5	102.5 %	100.2 % (M)
CHLORIDE (Cl)		0.0035 %	<0.0035 % (M)
RESIDUE ON IGNITION		0.1 %	0.021 % (M)
SULFATE		0.1 %	<0.1 % (M)
ORGANIC IMPURITIES:			.
LIDOCAINE RELATED COMPOUND H		0.10 %	<0.10 % (M)
2,6- DIMETHYLANILINE		0.01 %	<0.01 % (M)
ANY UNSPECIFIED IMPURITY		0.10 %	0.0229 % (M)
TOTAL IMPURITIES		0.5 %	0.04 % (M)
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT (M)
IDENTIFICATION (A)	Adva Tech MATCHES REFERENCE		Adva Tech MATCHES REFERENCE

IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD (M)
EXPIRATION DATE			01-SEP-2028
DATE OF MANUFACTURE			01-OCT-2023
APPEARANCE			WHITE CRYSTALLINE POWDER
RESIDUAL SOLVENTS	AS REPORTED		.
MONOGRAPH EDITION			(USP-NF) 2024
CLASS 2 (solvent) / TOLUENE			<890 ppm (M)
NOTE:All results reported with (M) are from manufacturer certificate of analysis			NOTE:All results reported with (M) are from manufacturer certificate of analysis

Certificate of Analysis Results Entered By:

JSANCHEZ
Job Sanchez
18-DEC-24 08:22:17

Certificate of Analysis Results Approved By:

JSANCHEZ
Job Sanchez
18-DEC-24 10:08:11

Adva Tech Group Inc
100 S. Saunders Road Suite 150, Lake Forest, IL 60045

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Adva Tech Group Inc are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Adva Tech Group Inc can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

Adva Tech Group Inc repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Adva Tech Group Inc Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by Swati Spentose Private Limited at A-1/2102,2103, Phase III, GIDC-Vapi, Gujarat 396195, India (IND). Copies of the original Certificate of Analysis are available upon request from your Adva Tech Group Inc Sales Representative or by calling Adva Tech Group Inc Quality Department at 1-224-659-6379.