

Certificate of Analysis

Accumax Lab Devices Pvt Ltd is ISO 9001:2015 certified organization and all products mentioned in annexure-1 are manufactured under strictly defined and monitored conditions as per product specifications. This here by certifies that the supplied product complies with following standards of production.

Quality System Compliance: The product conforms to written material specifications and was manufactured under the ISO 9001/2015 quality system.

Test Report		
Material: Polypropylene		
Test	Limit	Test Result
Endotoxin	≤ 0.03 EU/ ml	Product is free from Endotoxin
DNase	$\leq 9.4 \times 10^{-4}$ U/Tip	Product is free from DNase
RNase	$\leq 6.5 \times 10^{-8}$ U/Tip	Product is free from RNase

Material Free of Bisphenol A (BPA), phthalates and cytotoxic effects. Resins are USP Class-VI certified, RoHS, FDA regulation CFR 21, and are free of Substances of Very High Concern (SVHC), REACH compliant, and are FDA approved for food contact..

BSE/TSE Statement: (Bovine Spongiform Encephalopathy/Transmissible Spongiform Encephalopathy) The product above is free from and manufactured from materials that do not contain any raw materials or substances derived from animal origin as defined in EC Directive 1069/2009/EC and EC Directive 142/2011/EC.

Latex Statement: No Latex was used in the manufacturing of the product. This also includes all the packaging and shipping materials used in the production of the items.

Sterilization Process: Products marked as sterile are processed by irradiation. This dosage is enough to ensure a sterility assurance level (SAL) of 10^{-6} . Our sterilization program is an ISO 11137 validated process.(Sterilization validity is 3 years from the date of manufacturing)

Pyrogen Testing: Endotoxin levels were tested by the Limulus Amoebocyte Lysate (LAL) Assay. A representative sampling of the products is extracted according to current FDA guidelines in pyrogen-free water and the extract solutions are assayed along with positive & negative controls.

DNase Test: Samples were rinsed one after another with DNA-free water. These solutions were mixed with DNase-buffer containing DNA-ladder in a DNase-free tube. A positive control was spiked with DNase, a negative control contains DNA-free water. All tubes were incubated at 37 °C. The presence of DNase was analysed by agarose-gel electrophoresis. DNase contamination is indicated by degradation of the DNA ladder.

RNase Test: Samples were rinsed one after another with RNA-free water. These solutions were mixed with RNase-buffer containing RNA-ladder in a RNase-free tube. A positive control was spiked with RNase, a negative control contains RNA-free water. All vessels were incubated at 37 °C. The presence of RNase is analysed by agarose-gel electrophoresis. RNase contamination is indicated by degradation of the RNA ladder.

Quality Assurance Department

Date: 09/10/2020

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ANEXURE-1

Sr. No.	Product Name	Catalogue No.	Batch No.	Quantity in Packs
1	200µL LONG UNIVERSAL GRAD TIP, STERILE, LOW RETENTION, FILTER,RACK	XR-300-SLF	8LCI0411R	500