



Certificate of Analysis

Product name	Argatroban	Manufacture date	Sep.20.2023
Batch number	SW230920	Analysis date	Sep.22.2023
Batch quantity	50kg	Expiry date	Sep.20.2025

Analysis	Specification	Results
Assay	NLT 99.0%	99.67%
Appearance	White to off white crystalline powder	Complies
Residue on ignition	≤ 0.2%	Complies
Related Substances		
Single Impurity	≤ 0.5%	Complies
Total Impurities	≤ 1.0%	Complies
Melting point	166-170 °C	167.3-168.1 °C
Identification	Positive reaction	Positive reaction
Related substances	≤1.0%	0.16%
Loss on drying	≤0.5%	0.06%
Residue on ignition	≤0.1%	0.02%
Chloride	≤0.014%	<0.014
Heavy Metals	≤20ppm	<20ppm
Clarity of solution	Conform to standard	Complies
Microbial Limit	≤20ppm	<20ppm

Packing description:	Sealed export grade drum & double of sealed plastic bag
Storage:	Store in cool & dry place not freeze., keep away from strong light and heat
Shelf life:	2 years when properly stored

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Analyst: 方琼

