

CERTIFICATE OF ANALYSIS

Product Name:	Amlodipine Besilate		
Report No.	200821-01	Batch No.	071200705
Manufacturing Date	July 9, 2020	Expiry Date	July 8, 2024
Packages	1Kg/Bag, 10Kg/Drum	Net weight	130Kg
Analytical results			
Items	Specifications		Results
Appearance	White or almost white powder		Almost white powder
Infrared Absorption	The IR spectrum of the sample corresponds to the IR spectrum of the CRS		Conform
Optical rotation	-0.10°~+0.10°		-0.003°
Water	Not more than 0.5%		0.1%
Sulfated ash	Not more than 0.2%		0.05%
Related substances(HPLC)	Impurity D NMT 0.3%		N.D.
	Impurity A NMT 0.15%		N.D.
	Impurity E NMT 0.15%		N.D.
	Impurity F NMT 0.15%		Less than 0.03%
	Other Unknown Impurity NMT 0.10%		0.03%
	The total impurities NMT 0.8%		0.03%
Ethanol	Not more than 5000ppm		N.D.
Methylamine	Not more than 20ppm		N.D.
Ethyl benzene sulfonate	Not more than 108ppm		N.D.
Methyl benzene sulfonate	Not more than 108ppm		N.D.
Assay	Calculate on anhydrous,it contains not less than 97.0% and not more than 102.0% of Amlodipine Besilate (C ₂₆ H ₃₁ CIN ₂ O ₈ S).		100.20%
According to	EP10.0		
Conclusion	Complies		

Inspector: Carlifor Wu

Verifier: Jack He

