

## **CERTIFICATE OF ANALYSIS**

Product Name:	Cilostazol		
Lot No.	0102220200401	Lot Size	300kg
Manufacturing Date	April 8, 2020	Expiry Date	April 7, 2023
Sampling Date	April 9, 2020	Report Date	April 18, 2020
Packing	3g/Bag	Reference	USP42
Analytical Results			
ltems	Specifications (USP40)		Results
Appearance	White to light yellow crystalline powder		White crystalline powder
Identification	A: The IR spectrum is consistent with that obtained with Cilostazol RS		Consistent with that obtained with Cilostazol RS
	B: The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation, as obtained in the assay		consistent with that obtained with standard preparation
Loss on drying	≤0.30%		0.11%
Residue on ignition	≤0.1%		0.06%
Chloride	≤0.018%		Conforms
Heavy metals	≤0.001%		Conforms
Related compounds	Impurity A ≤0.10%		Not detected
	Impurity B ≤0.10%		<0.05%
	Impurity C ≤0.10%		<0.05%
	Any other individual impurity ≤0.10%		<0.05%
	Total impurities ≤0.40%		0.08%
Residual solvents	N,N-Dimethylacetamide ≤1090ppm		Not detected
	Chloroform ≤60ppm		Not detected
	Ethanol ≤3000ppm		Not detected
	Methanol ≤3000ppm		Not detected
Assay by HPLC	98.0%~102.0% (calculated on dried basis)		99.9%
Conclusion	It compllies with the requirement of USP42		
Note 1	Any other individual impurity (≤0.10%)		
Relative retention time	Results		
0.5	N.D.		
0.7	N.D.		

Inspector: Carlifor Wu

Verifier: Jack He

