

LIAOYUAN CITY BAIKANG PHARMACEUTICAL CO., LTD.

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CERTIFICATE OF ANALYSIS

Product Name	DIPHENHYDRAMINE HYDROCHLORIDE		
Batch No	200503	Quantity	1856.2KGS
Mfg. Date	MAY.13, 2020	Exp. Date	APR. 2024
Testing Date	MAY.15, 2020	Packing	25kg/drum
Standard	CP2015	Shelf Life	4 years

Tests	Specification	Results
Characters		
Appearance	White or almost white, crystalline powder	White crystalline powder odourless
Solubility	Very soluble in water, freely soluble in ethanol or chloroform, slightly soluble in acetone, and very slightly soluble in ether.	Conforms
Melting point	167-171°C	168.5-169.5°C
Identification		
(1)Chemical Reaction	positive	positive
(2)Ultraviolet and visible absorption spectrophotometry	Absorption maxima at 253nm and 258nm	Absorption maxima at 252.60nm and 257.90nm
(3)Infrared absorption spectrophotometry	Comparison diphenhydramine hydrochloride CRS	Conforms
(4)Chemical Reaction	Positive	Positive
Test		
Appearance of solution	The solution should be clear and colorless	Clear and colorless
Related Substances	Should Conform	Conforms
Loss on drying	≤0.5%	0.23%
Residue on ignition	≤0.1%	0.04%
Assay	98.0%-102.0%	100.1%
Microbial Limit	Conforms to CP2015	Conforms
Conclusion:	Complies with CP2015	

Reported by: WANG Xue

Reviewed by: MENG Yuan

Approved by: JIANG Mingjie

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