benepure®
青益纯

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No.: BPAP-617-A-00/3.0

CERTIFICATE OF ANALYSIS

Product Name	Levocetirizine Dihydrochloride	**CAS No.**	130018-87-0
Batch No.	P011261719A	**Mfg. Date**	Dec. 06, 2019
Quantity	100kg	**Retest Date**	Dec. 05, 2021
Packing	25kg/drum	**Report Date**	Dec. 11, 2019
Specification	Enterprise standard		

ITEM	SPECIFICATION	RESULT
Appearance	White or almost white powder	White powder
Solubility	Freely soluble in water and methanol	Complies
Identification	A. IR	Complies
	B. The retention time of the major peak of the sample solution corresponds to that of the levocetirizine peak in the system suitability solution, as obtained in the test for Enantiomer Purity	Complies
pH	1.20~1.80	1.35
Specific Rotation	-11.0°～-13.0°	-11.23°
Loss on Drying	≤0.5%	0.32%
Residue on Ignition	≤0.2%	0.08%
Heavy Metals	≤10ppm	Complies
Assay(On the dried basis)	98.0%~102.0%	99.16%
Enantiomer	≤0.5%	0.13%
Related Substances		
Any Individual Impurity	≤0.5%	0.13%
Total Impurities	≤1.0%	0.18%
Conclusion	Comply with the specification.	
Storage	Preserve in tight containers, protected from strong light and high heat.	

Analyst: Reviewed by: Approved by: