



四川青益纯医药科技有限公司
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CERTIFICATE OF ANALYSIS

Product Name	Loratadine	CAS No.	79794-75-5
Batch No.	P010161817A	Mfg. Date	Jan. 18, 2017
Quantity	200kg	Retest Date	Jan. 17, 2019
Packing	25kg/Drum	Report Date	Jan. 26, 2017
Specification	USP38		

ITEM	SPECIFICATION	RESULT
Appearance	White or off white crystalline powder	White crystalline powder
Solubility	Freely soluble in acetone, in chloroform, in methanol and in toluene; insoluble in water.	Complies
Identification	A) By IR absorption, To match with the standard. 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	Complies
Loss on Drying	≤0.5%	0.31%
Residue on Ignition	≤0.1%	0.03%
Heavy Metals	≤10ppm	Complies
Related Substances		
Related compound A	≤0.1%	Undetected
Related compound B	≤0.1%	Undetected
Related compound C	≤0.1%	Undetected
Impurity B	≤0.1%	Undetected
Impurity C	≤0.1%	Undetected
Impurity D	≤0.1%	0.003%
Impurity E	≤0.1%	Undetected
Any individual unknown impurity	≤0.1%	0.06%
Total impurities	≤0.3%	0.21%
Assay(Anhydrous basis)	98.5%-101.0%	99.21%
Conclusion	The product conforms to USP38.	
Remarks	N/A	

Analyst:

QC Manager:

QA: