



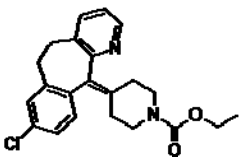
HANGZHOU DINGYAN CHEM CO.,LTD

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CERTIFICATE OF ANALYSIS

NO: **DYC041608181**

Product name	Loratadine
CAS Number	79794-75-5
Molecule Structure	
Molecule Formula	C ₂₂ H ₂₃ ClN ₂ O ₂
Batch number	20151221
Manuf&Exp. Date	2015-12-21, 2017-12-20
Testing date	2015-12-21

Items	Standard	Result
Appearance	White or off-white crystalline powder	Complies
Solubility	Freely soluble in acetone, in chloroform, in methanol and in toluene; insoluble in water.	Complies
Identification	A. By IR absorption, To match with working standard.	Complies
	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
Melting Point	132°C~ 137°C	132~134.5°C
Loss on drying	≤0.5%	0.26%
Residue on ignition	≤0.1%	0.04%
Related compound A	≤0.1%	Not Detected
Related compound B	≤0.1%	Not Detected
Each individual unknown impurity	≤0.1%	0.07%
Total impurities	≤ 0.3%	0.1%
Heavy metal	<20ppm	<20ppm
Residual solvents	Meet the requirements	Complies
Assay	98.5%~101.0%	99.7%
Conclusion: the material conforms to the USP31		

Hangzhou Dingyan Chem Co., Ltd.
QUALITY CONTROL: *Cristina*
Quality Control
Signature(s)

CHECK: 姚仙娟

INSPECTOR: 刘清风

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