

No.: BPAP-618-A-00/3.0

**CERTIFICATE OF ANALYSIS**

<b>Product Name</b>	Loratadine	<b>CAS No.</b>	79794-75-5
<b>Batch No.</b>	P020661820A	<b>Mfg. Date</b>	Jun. 15, 2020
<b>Quantity</b>	200kg	<b>Retest Date</b>	Jun. 14, 2022
<b>Packing</b>	25kg/Drum	<b>Report Date</b>	Jun. 20, 2020
<b>Specification</b>	USP40		

ITEM	SPECIFICATION	RESULT
<b>Appearance</b>	White or off white crystalline powder	Complies
<b>Solubility</b>	Freely soluble in acetone, in chloroform, in methanol and in toluene; insoluble in water.	Complies
<b>Identification</b>	A. By IR absorption, to match with the standard.	Complies
	B. The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.	
<b>Loss on Drying</b>	≤0.5%	0.07%
<b>Residue on Ignition</b>	≤0.1%	0.05%
<b>Related Substances</b>		
-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%	Undetected
-Impurity E	≤0.1%	Undetected
-Any individual unknown impurity	≤0.1%	0.07%
-Total impurities	≤0.3%	0.11%
<b>Residual Solvents</b>		
-Isopropyl Ether	≤0.5%	Undetected
-Ethyl Acetate	≤0.5%	Undetected
-Toluene	≤0.089%	Undetected
<b>Assay(Anhydrous basis)</b>	98.5%~101.0%	99.63%
<b>Conclusion</b>	Comply with the specification.	
<b>Storage</b>	Preserve in tight containers, protected from strong light and high heat.	

Analyst:

Reviewed by:

Approved by: