


1709000047

 VASUDHA PHARMA CHEM LTD	<b>VASUDHA PHARMA CHEM LIMITED</b> 78/A, VENGALRAO NAGAR, HYDERABAD -38 TELANGANA, INDIA PHONE: 91-40-2381 2046, 2371 1717, FAX: 91-40-2381 1576 E-MAIL: vasudha@vasudhapharma.com, Website: www.vasudhapharma.com		
	<b>CERTIFICATE OF ANALYSIS</b>		
	Name of the Product : LORATADINE		
	Batch Number : LRD/1706069	Analyzed on : 30/06/2017	
	Manufacturing Date : JUN'2017	Expiry Date : MAY'2022	
Quantity : 126.310Kg	A.R.No : FP/171075		

S.No	TEST	RESULT	SPECIFICATION
1.0.	Description	Off white powder	White to off-white powder.
2.0.	Solubility	Complies	Freely soluble in acetone, in chloroform, in methanol and in toluene, insoluble in water.
3.0	IDENTIFICATION		
A	By Infrared spectrum (In Mineral oil)	Complies	The IR absorption spectrum of the preparation of the test specimen exhibits maxima only at the same wavelengths as that of a similar preparation of the corresponding Loratadine reference standard / Working Standard.
B	By HPLC	Complies	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.
4.0	Loss on drying	0.35%	Not more than 0.5% w/w
5.0	Residue on ignition	0.04%	Not more than 0.1% w/w
6.0	Heavy metals	Complies	Not more than 0.001%
7.0	Organic impurities by HPLC		
	TEST 2		
	Loratadine Related compound A	BDL	Not more than 0.10%
	Loratadine Related compound B	BDL	Not more than 0.10%
	Loratadine Related compound C	BDL	Not more than 0.10%
	Hydroxy deacyl analog	BDL	Not more than 0.10%
	Hydroxy loratadine	BDL	Not more than 0.10%
	*Dehydro loratadine isomer-A	0.03%	Not more than 0.10%
	*Dehydro loratadine isomer-B	0.04%	Not more than 0.10%
	Any individual unknown impurity	0.01%	Not more than 0.10%
	Total impurities	0.08%	Not more than 0.30%

Manufactured at: Vasudha Pharma Chem Ltd, Unit-1, Plot No 39, A&B, Phase-I, I.D.A, Jeedimetla, Hyderabad-500 055, TELANGANA, India.  
CQA/002/T05/00

EFFECTIVE DATE: 01/10/2014

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78/A, VIENGALRAO NAGAR, HYDERABAD - 38

TELANGANA, INDIA


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S No	TEST	RESULT	SPECIFICATION		
8.0	Assay by HPLC (on dried basis)	99.5%	Not less than 98.5% and not more than 101.0% w/w		
9.0	ADDITIONAL TESTS				
9.1	Residual solvents by GC HS				
	Tetrahydrofuran	BDL	Not more than 500 ppm		
	Toluene	BDL	Not more than 500 ppm		
	Di-Isopropyl ether	75 ppm	Not more than 500 ppm		
	Triethylamine	BDL	Not more than 50 ppm		
*9.2	Particle size	7.21 $\mu$ m 15.59 $\mu$ m	90% < 10 $\mu$ m 100% < 20 $\mu$ m		
*9.3	Bulk density				
	Untapped density	0.17 gr/ml	0.16-0.30 gr/ml		
	Tapped density	0.29 gr/ml	0.20-0.40 gr/ml		

M/L: CHEM AG  
125 kg  
16/06/17



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**9.4	<b>MICROBIOLOGY TESTS</b>		
	Total Aerobic microbial count	Complies	Not more than 1000 cfu/g
	Total Combined Yeast and Molds count	Complies	Not more than 100 cfu/g
	<b>PATHOGENS</b>		
	Enterobacteriaceae	Absent	Should be absent
	Staphylococcus aureus	Absent	Should be absent
	Escherichia coli	Absent	Should be absent
	Pseudomonas aeruginosa	Absent	Should be absent

\*In-house impurities.

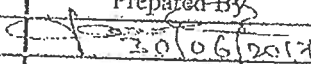
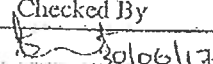
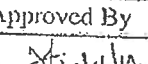
\*\*As per customer Requirement.

BDL: Below Detection Limit.

Note: 1) These two impurities "Dichloro benzo cyclo hepta pyridinone" and "4-Chloro loratadine" will not form in our manufacturing process. These impurities will comply with USP requirement if tested.

2) Acetonitrile is not used in our manufacturing process. If tested will comply as per specification.

Remarks: The material complies as per USP-38 Specification.

	Prepared By	Checked By	Approved By
Signature			
Name	P. GOVARDHAN	N. BHARAT KUMAR	D.V.V.G VARMA
Designation	Jr. Manager-QC	Jr. Manager-QC	Manager-QC

Manufactured at: Vasudha Pharma Chem Ltd. Unit-1, Plot No.39, A&B, Phase-I, I.D.A, Jeedimetla, Hyderabad-500 055, TELANGANA, India.

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