1709000047

VASUDHA PHARMA CHEM LIMITED
78/A, VENGALRAO NAGAR, HYDERABAD –38
TELANGANA, INDIA
PHONE: 91-40-2381 2046, 2371 1717, FAX: 91-40-2381 1576
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VASUDHA PHARMA CHEM LTD

CERTIFICATE OF ANALYSIS

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%

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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 µm 15.59 µm	90% < 10 µm 100% < 20 µm
**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/s. CHEMO AG
125 Kg

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S.No	TEST	RESULT	SPECIFICATION
**9.4	MICROBIOLOGY TESTS		
	Total Aerobic microbial count	Complies	Not more than 1000 cfu/g
	Total Combined Yeast and Molds count	Complies	Not more than 100 cfu/g
	PATHOGENS		
	Enterobacteriacea	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	30/06/2017	30/06/17	
Name	P. GOVARDHAN	N. BHARAT KUMAR	D.V.V.G VARMA
Designation	Jr.Manager-QC	Jr.Manager-QC	Manager-QC