

CERTIFICATE OF ANALYSIS
QUALITY CONTROL DEPARTMENT

Product Name	:	LORATADINA COMPRIMIDOS 10 mg			
Generic Name	:	LORATADINE TABLETS USP - 10 mg			
Batch Size	:	900000 TAB	A.R. Number	:	FG/DHLK/1900675
Batch Number	:	ET162E9017	Pack Style	:	N/A
Mfg. Date	:	Feb. 2019	Exp. Date	:	Jan. 2022
Specification Number	:	REL-L-184-02	STP No.	:	STP-L-184-01
Date of Analysis	:	15/02/2019	Date of Report	:	22/02/2019

S.No.	TESTS	RESULTS	SPECIFICATION
1	Description	White, round, smooth, flat, beveled edged, uncoated tablets with breakline on one side and "LFT" on other side.	White, round, smooth, flat, beveled edged, uncoated tablets with breakline on one side and "LFT" on other side.
2	Identification	The Rf value of the principal spot obtained from the test solution corresponds to that obtained from the standard solution.	(A) By Thin-Layer Chromatography : The Rf value of the principal spot obtained from the test solution should correspond to that obtained from the standard solution.
		The retention time of major peak in the chromatogram of the assay preparation corresponds to that in chromatogram of standard preparation, as obtained in the Assay.	(B) By HPLC : The retention time of major peak in the chromatogram of the assay preparation should correspond to that in chromatogram of standard preparation, as obtained in the Assay.
3	Average weight	107.678 mg	108.10 mg \pm 5% (102.695 mg to 113.505 mg)
4	Uniformity of weight	-1.6 % to +2.4%	Not more than two of the individual weights deviate from the average weight by more than \pm 7.5% and none deviate by more than \pm 15%.
5	Dimensions (Diameter)	6.39 to 6.43mm	6.35 mm \pm 0.10 mm (6.25 mm to 6.45 mm)
	Dimensions (Thickness)	2.2 to 2.37mm	2.20 mm \pm 0.20 mm (2.00 mm to 2.40 mm)
6	Hardness	2.5 to 3.9kg/cm ²	2 to 5 kg/cm ² or 20 N to 50 N
7	Friability	0.32 % w/w	Not more than 1.0% w/w
8	Disintegration time	01 Minutes 21 Seconds	Not more than 15 minutes
9	Dissolution	Min.98%, Max.101%, Mean 99%	Not less than 80% (Q) of the labeled amount should dissolve in 60 minutes.

Prepared By :

Date :


(Executive-Q.C) :


 28/02/19

Checked By :

Date :


(Manager-Q.C) :


 28/02/19

Approved By :

Date :

(Head-Q.C) :


 28/02/19

FORM No. : FQC214-04/00

Reprint Date : 28/02/2019

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10	Uniformity of dosage units (By content Uniformity)	5.3	-The acceptance value of the first 10 dosage units should be less than or equal to L1, where L1 is 15.0. -If the acceptance value is greater than L1, test the next 20 units and calculate the acceptance value the final acceptance value of the 30 dosage units should be less than or equal to L1, and no individual content of any dosage unit should be less than $(1-L2 \times 0.01) M$ or more than $(1+L2 \times 0.01) M$, where L1 is 15.0 and L2 is 25.0	
11	Related Compounds			
	4-(8-chloro-11-fluoro-6,11-dihydro-5H-benzo[5,6] cyclohepta[1,2-b] pyridin-11-yl)-1-piperidinecarboxylate ethyl	0.02 %	Not more than 0.2%	
	Any other individual impurity	0.01 %	Not more than 0.1%	
	Total impurities (Excluding 4-(8-chloro-11-fluoro-6,11-dihydro-5H-benzo[5,6] cyclohepta[1,2-b] pyridin-11-yl)-1-piperidinecarboxylate ethyl	0.01 %	Not more than 0.1%	

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CERTIFICATE OF ANALYSIS QUALITY CONTROL DEPARTMENT

QUALITY CONTROL DEPARTMENT

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Date of Analysis	:	15/02/2019	Date of Report	:	22/02/2019
S.No.	TESTS	RESULTS		SPECIFICATION	
12	Assay - Each uncoated tablets contains :				
	Loratadine	9.82 mg 98.2%		NLT 9.00mg/Tab and NMT 11.00mg/Tab NLT 90.0% and NMT110.0% of label claimed	
	Additional tests				
13	Loss on drying	5.6 %w/w		Not more than 6.0% w/w	
14	Microbial limit test @				
	(A) Total Microbial Count				
	Bacteria	20 cfu/g		Not more than 1000 cfu/g	
	Yeast / Mould	< 10 cfu/g		Not more than 100 cfu/g	
	(B) Pathogens				
	Pseudomonas aeruginosa	Absent		Should be absent	
	Salmonella	Absent		Should be absent	
	Escherichia Coli	Absent		Should be absent	
	Staphylococcus Aureus	Absent		Should be absent	

@ Microbial Limit Test shall be carried out only for first three commercial batches (Validation batches) at release stage.

Conclusion: The Product is standard quality in respect of above specification.

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