WRS L24-2

(47)

ANNEXURE QCD/MT/025/A20

LIFEPharma FZE
Dubai

CERTIFICATE OF ANALYSIS FOR WORKING STANDARD

SUBJECT : COMPARISION DATA OF WORKING STANDARD WITH OFFICIAL REFERENCE STANDARD

ITEM	: Loratadine USP	**EVALUATED WITH**	: EP CRS
DATE OF STANDARDISATION	: 21.03.2015	**BATCH No.**	: 3.1
DIRECTION FOR STORAGE	: Store at 2-8°C in well closed container protected from light		
DIRECTION FOR USE	: Use as such.		
VALIDITY OF USE (PERIOD)	: 20.03.2016		
WORKING STANDARD No.	: WS/L1/3		
A.R. No.	: 15GE00156		
SOURCE BATCH No.	: LRD/1308087		

REFERENCE : QC/SPEC/RM/011

TEST	STANDARDS	RESULTS
Description	White to off-white powder.	Complies
Identification by IR	The infrared absorption spectrum is concordant with reference spectrum of Loratadine	Complies
Loss on drying	NMT 0.5 %.	0.3 % w/w
Related Compounds (Test -1)	4-(8-chloro-11-fluoro-6,11-dihydro-5H-benzo[5,6]cyclohepta[1,2-b]pyridin-11-yl)-1-piperidinecarboxylate ethyl : NMT 0.2 %	Not detected
	Any other individual impurity NMT 0.1%	Not detected
	Total impurities: NMT 0.3%	Not detected
Related Compounds (Test -2)	Loratadine related compound A: NMT 0.1%,	Not detected
	Loratadine related compound B: NMT 0.1%,	Not detected
	Each individual unknown impurity: NMT 0.1%	Not detected
	Total impurities: NMT 0.3%	Nil
Assay	98.5 % To 101.0 % (On dried basis) 18 DEC 2015	99.3%
	On Asis Basis	99.0%

REMARKS: Compares with EP STANDARDS and certified to be used as working standard.

QUALITY CONTROL : 23/03/2015
DATE :

QUALITY ASSURANCE:
DATE : 23/03/2015

(QCD/MT/025/F13)