

BEXIMCO PHARMACEUTICALS LTD.

TONGI-1711, GAZIPUR, BANGLADESH

QUALITY CONTROL DEPARTMENT

Certificate of Analysis for Analytical Working Standard (AWS)

Name of the Analytical Working Standard (AWS): DESLORATADINE

Manufacturer's / Supplier's Name: GLENMARK GENERICS LTD, MUMBAI

Batch/Lot Number: 071400014

R. Number: 30813

Date of Manufacturing: JAN,2014

Date of Expiry: JAN,2018

Date of Standardization: 03.03.14

Retest Date : 02.03.16

Reference Standard Used: WS

Batch/Lot Number : 071100970

Reference of Methods of Analysis: RM-353

SI.	Tests	Specifications	Results
No.		of A in the Addition	A white enertalline
01.	Description	A white to off white crystalline powder.	A white crystalline powder.
02.	Identification : i) IR Spectroscopy ii) Melting point	i) Conforms ii) 151° C to 158° C	i) Conforms ii) 158º
03.	Related substances : By HPLC : i) 'ndividual Impurity ii)Total impurities	i)Not more than 0.5 % ii)Not more than 1.0 %	i) 0. 04 % ii)0.04 %
04.	Loss on drying	Not more than 0.5 %	0.16 %
05.	Assay (On dried basis)	Not less than 98.0% and Not more than 102.0 %	100.2 % (as Desloratadine)
	ASSAV (as is basis)	100.0 % (as Designatedine)	

Comments: Qualified for use as working standard.

	Name	Designation	Sign & Date
Standardization By	LIMIA NAHIAN	OFFICER QUALITY CONTROL	dink 25.08.15
	ARJUMAN BANU	SR ASSTT MANAGER, QUALITYCONTROL	125.08.1h
Checked By	MD. DELWAR HOSSAIN	DEPUTY MANAGER, QUALITY CONTROL	\$ 350 DEVIS
Approved By	MD. SALIM HOSSAIN	SR.MANAGER, QUALITY CONTROL	-855-66 L

Form No. QC 019-02