KORGIP 2015 11565

NRS AGI-1



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): AMBROXOL HYDROCHLORIDE BP

Manufacturer's / Supplier's Name: Ami Lifesciences Pvt. Ltd, India

Batch/Lot Number: AMX/40010115

R. Number: 332487

Date of Manufacturing: JAN,2015

Date of Expiry: DEC,2018

Date of Standardization: 01.12.15

Retest Date : 01.12.17

Reference Standard Used: EP

Batch/Lot Number: 3.1

Reference of Methods of Analysis: FP-182

SI. No.	Tests	Specifications	Results
01.	Description	A white to yellowish, crytalline powder.	A white crystalline powder
02.	Identification: a. IR Method	a. Conforms	a. Conforms
03.	Related substances: a) Individual impurity b) Total impurities	a) Not more than 0.10 % b) Not more than 0.30 %	a) 0.04 % b) 0.04 %
04.	Loss on drying	Not more than 0.5 %	0.02 %
05.	Assay (On dried basis)	Not less than 99.0 % and Not more than 101.0 %	99.92 % (as Ambroxol Hydrochloride)
υ.,	Assay (as is basis)		99,90 % (as Ambroxol Hydrochloride)

Comments: Qualified for use as working standard.

	Name	Designation	Sign & Date
Standardization By	MD.LUTFUL HYDER	SR.OFFICER, QUALITY CONTROL	01.12.15
Checked By	ARJUMAN BANU	SR.ASST.MANAGER, QUALITY CONTROL	X 61.12.16
Checked Dy	MD.DELWAR HOSSAIN	DEPUTY MANAGER, QUALITY CONTROL	(4.01-12-15
Approved By	MD. SALIM HOSSAIN	SR.MANAGER, QUALITY CONTROL	Hosting 15

FRM No.: FQC/140-01

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