· WRS B28-1

glenmark

GLENMARK PHARMACEUTICALS LIMITED BADDI(UNIT-I) QUALITY CONTROL DEPARTMENT

WORKING STANDARD CERTIFICATE OF ANALYSIS

Name of Working Standard	Bromhexine Hydrochloride BP		
W.S. No.	WS/009/15-A		
Manufacturer's Name	VEN PETROCHEM & PHARMA (I)P LTD.	Evaluated with	BP
Manufacturing Date	JUL. 2015	Effective Date	23.09.2015
Expiry Date	JUL. 2020	Valid Up To	27.08.2016*

S. No.	TESTS	SPECIFICATION ·	RESULTS White Crystalline powder.	
1.	Description	A White or almost white, crystalline powder.		
2.	Identification (By IR) By IR The infrared absorption spectrum of the sample should be concordant with the spectrum obtained from Bromohexine Hydrochloride WS/CRS.		The infrared absorption spectrum of the sample is concordant with the spectrum obtained from Bromohexine Hydrochloride RS.	
3.	Loss on Drying	Note more than 1.0 %	0.1 %	
4.	Assay (on dried basis)	Between 98.5 % and 101.5 %	99.9 %	
5.	Assay (As such Basis)	For information Only	99.8 %	

Storage: Store in a tightly closed light resistant container.

Remarks: Above material standardized against the reference standard (N°3) and found to be

suitable for use as working standard in routine use.

*Retest Date

Prepared By	Checked By	Approved By
Signature	Signature O	Signature \
Date 23/09/15	Date 23/09/15	Date 20 Mg

