WR'S G16-1

G glenmark

GLENMARK PHARMACEUTICALS LIMITED BADDI(UNIT-I)

QUALITY CONTROL DEPARTMENT

ANNEXURE-I

WORKING STANDARD CERTIFICATE OF ANALYSIS

Name of Working Standard	Guaifenesin USP		
W.S. No.	WS/004/15-A		
Manufacturer's Name	Gennex Laboratories Ltd	Evaluated with	USP
Manufacturing Date	Jul 2015	Effective Date	19/10/2015
Expiry Date	Jun 2020	Valid Up To	30/07/2016

S. No.	TESTS	SPECIFICATION	RESULTS	
1.	Description	White to slightly gray, crystalline powder. May have a slight characteristic odor.	White crystalline powder.	
2.	Identification By IR The infrared absorption spectrum of the sample should be concordant with the spectrum obtained from Guaifenesin RS/WS.		The infrared absorption spectrum of the sample is concordant with the spectrum obtained from Guaifenesin RS.	
3.	Loss on Drying	Note more than 0.5 %	0.2 %	
4.	Assay Total (on dried basis)	Between 98.0% and 102.0%	99.9 %	
5.	Assay (As such Basis)	For information Only	99.7 %	

Storage: Store in a tightly closed light resistant container.

Remarks: Above material standardized against the reference standard (J0G257) and found to be

suitable for use as working standard in routine use.

Prepared By	Checked By	Approved By
Signature	Signature /	Signature 💯
Date 19/1./15	Date 191014	Date 19/10/2015

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