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Certificate of Analysis

Product	: GUAIFENESIN USP
Synonym	: Glyceryl guaiacolate, Guaiacol glyceryl ether, Guaiphenesin, 1,2-Propanediol,3-(2-methoxyphenoxy)-(±)-
CAS Number	: 93-14-1
Lot Number	: 211-18164
Manufacture Date	: Jul 28, 2018
Retest Date	: Jul 27, 2023
Testing Date	: Aug 09, 2018
Batch Size	: 4650 Kg

Tests	Results	Specifications	Reference
Description	Conforms	A white to slightly gray, crystalline powder	USP 41
Identification:			USP 41
A. IR Absorption	Conforms	Corresponds to Reference Standard	
B. UV Absorption	Conforms	Corresponds to Reference Standard	
Loss on drying	0.04%	NMT 0.5%	USP 41
Assay (Calculated on Dried basis)	100.3%	98.0 – 102.0%	USP 41
Chromatographic purity (HPLC)			Modified USP
Impurity A Ph. Eur. (Guaiacol)	LT 0.001%	NMT 0.03%	
Impurity B Ph. Eur. (Guaifenesin β-Isomer)	0.005%	NMT 0.5%	
Impurity C Ph. Eur. (OXY-BIS)	0.02%	NMT 0.1%	
Impurity D Ph. Eur. (1,3-DI)	0.03%	NMT 0.1%	
Other Impurities			
Other single unspecified impurity	0.01%	NMT 0.05%	
Total Impurities (excluding Impurity A and Impurity B)	0.05%	NMT 0.7%	
Color (A _{420nm})	0.006	< 0.03	In-house
Tapped density	0.72 g/mL	0.63 – 0.85 g/mL	In-house
Particle Size			In-house
D ₁₀	4 μm	≤ 6 μm	
D ₅₀ Mean	36 μm	20 – 50 μm	
D ₉₀	89 μm	≤ 120 μm	
Residual Solvents	No organic solvents are used in the synthesis of Guaifenesin.		

Delta Quality Assurance hereby confirms these data in this Certificate of Analysis have been reviewed, and the release of the lot has been **approved**.

Signed by:

; Date August 14, 2018