

Certificate of analysis



Article	4249	Guaifenesin, API	
Synonym		Guaifenesinum, Guajacolglycerinäther	
Synonym		Guaifenesin, API	
Batch	20000429		
Specification	Ph.Eur. 9.6		
Production date	01-19	Retest date	31-24

Test	Specification	Result	
Characters	Complies, Not carried out	Complies	
Appearance	Complies, Not carried out	Complies	
Solubility	Complies, Not carried out	Complies	
Identification	Complies, Not carried out	Complies	
Melting point	79 ... 83 °C	82 °C	
IR spectrophotometry	Complies, Not carried out	Complies	
Tests	Complies, Not carried out	Complies	
Appearance of solution	Complies, Not carried out	Complies	
Acidity or alkalinity	Complies, Not carried out	Complies	
Related substances	Complies, Not carried out	Complies	#
Impurity B	Max. 0,5 %	0,1 %	#
Impurity C	Max. 0,1 %	0,0 %	#
Impurity D	Max. 0,1 %	0,0 %	#
Each unspecified impurity	Max. 0,05 %	0,04 %	#
Total of all impurities	Max. 0,7 %	0,1 %	#
Chloride, monochlorohydrin	Max. 250 ppm	< 250 ppm	#
Loss on drying	Max. 0,5 %	0,1 %	
Sulphated ash	Max. 0,1 %	0,0 %	#
Assay	98,0 ... 102,0 %	100,2 %	#
Correction factor weighing (f, NRF)		0,999	
Complies specification	Yes, Yes, except*	Yes	

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Release date	03-30-20	Released by	Fr. Dr. Haßel
Manufacturer	Zhejiang Haizhou Pharmaceutical		
Manufacturer batch	19GF10797		
Manufacturer street	Yanhai Industrial Zone		
Manufacturer city	317016 Linhai City, Zhejiang		
Manufacturer country	Volksrepublik China		

Results marked with # were taken from the manufacturer's certificate.

The batch 20000429 complies specification.

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