



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 230206

Product:	AMBROXOL HYDROCHLORIDE
Lot:	230206
Expiry date:	31/10/2028
Reference:	Cumple PhEur11.0
Synonyms:	
Formula:	C ₁₃ H ₁₉ Br ₂ CIN ₂ O
Molecular weight:	414.6 g/mol

Assay	Result	Specification	
Identification	Conform(B,D)	Test PhEur (B,D)	
Organoleptic properties	Conform		
Related substances (HPLC)	Conform	Test PhEur	
Elemental impurities	Conform	Test PhEur	#
Assay	99,1 %	99,0 - 101,0 %	
Sulphated ashes	0,03 %	<= 0,1 %	
Loss on drying	0,00 %	<= 0,5 %	
Appearance of solution S	Conform	Test PhEur	
pH	5,5	4,5 - 6,0	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	< 0,05%	<= 0,3 %	
Residual solvents	Conform	Test PhEur	#

Organoleptic characteristics: White or yellowish, crystalline powder. Sparingly soluble in water, soluble in methanol, practically insoluble in methylene chloride.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 24/01/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00406 ERREGIERRE S.p.A.

Manufacturer batch: B220057

Product	Name	Capacity	Batch
1100054	AMBROXOL HIDROCLORURO	100 g	230206-J-1

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer
(=) UE certificate

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