



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 211214

Product:	AMBROXOL HYDROCHLORIDE
Lot:	211214
Expiry date:	01/12/2025
Reference:	Cumple PhEur 10.4
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)	
pH	5,5	4,5 - 6,0	
Appearance of solution S	Conform	Test PhEur	
Loss on drying	0,02 %	<= 0,5 %	
Sulphated ashes	0,00 %	<= 0,1 %	
Assay	100,2 %	99,0 - 101,0 %	
Elemental impurities	Conform	Test PhEur	#
Residual solvents	Conform	Test PhEur	#
Related substances (HPLC)	Conform	Test PhEur	
Total impurities	<= 0,3 %	<= 0,3 %	
Organoleptic properties	Conform		
Unspecified Impurities	<= 0,05 %	<= 0,10 %	

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: 07/04/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00406 ERREGIERRE S.p.A.

Manufacturer batch: B200005

Product	Name	Capacity	Batch
1100054	AMBROXOL HIDROCLORURO	100 g	211214-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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