



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 241267

Product:	AMBROXOL HYDROCHLORIDE
Lot:	241267
Expiry date:	30/10/2029
Reference:	Cumple PhEur11.5
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	100,5 %	99,0 - 101,0 %	
Sulphated ashes	0,01 %	<= 0,1 %	=
Loss on drying	0,05 %	<= 0,5 %	
Appearance of solution S	Conform	Test PhEur	=
pH	4,9	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: 15/07/2024

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00406 ERREGIERRE S.p.A.

Manufacturer batch: B230065

Product	Name	Capacity	Batch
1100054	AMBROXOL HIDROCLORURO	100 g	241267-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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Date of edition: 17/06/2026

