



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 230038

Product:	EPHEDRINE HYDROCHLORIDE
Lot:	230038
Expiry date:	03/12/2026
Reference:	Cumple PhEur11.0
Synonyms:	
Formula:	C10H16ClNO
Molecular weight:	201,7 g/mol

Assay	Result	Specification	
Identification	Conform (B,E)	Test PhEur (B,E)	
Organoleptic properties	Conform	Test PhEur	
Melting point (Mettler)	219 °C	Approx. 219 °C	
Appearance of solution	Conform	Clear and colorless	
Acidity or alkalinity	Conform	Test PhEur	
Specific rotation	(-33,6 °)	(-33,5°) - (-35,5°)	
Related substances (HPLC)	Conform	Test PhEur	
Sulphates	< 100 ppm	<= 100 ppm	
Loss on drying	0,01 %	<= 0,5 %	
Sulphated ashes	0,03 %	<= 0,1 %	
Assay	99,6 %	99,0 - 101,0 %	
Elemental impurities	Conform	Test PhEur	#
Impurity A	ND	<= 0,2 %	
Unspecified Impurities	< 0,05 %	<= 0,1 %	
Sum of impurities different from A	< 0,05 %	<= 0,5 %	
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Nitrosamine impurities	Conform	Test PhEur	#

Organoleptic characteristics: White or almost white, crystalline powder or colourless crystals. Freely soluble in water, soluble in ethanol (96 per cent).

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 14/02/2023

Judgement:
APPROVED

Responsible: M.Mesa

Technical director: Montserrat Enrique

Manufacturer: F00368 SIEGFRIED PHARMACHEMICKALIEN MINDEN GmbH

Manufacturer batch: 21482159

Product

Name

Capacity

Batch

1100136	EFEDRINA HIDROCLORURO	1 kg	230038-P-1
1100136	EFEDRINA HIDROCLORURO	1 kg	230038-P-2

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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