



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 220381

Product:	EPHEDRINE HYDROCHLORIDE
Lot:	220381
Expiry date:	25/11/2026
Reference:	Cumple PhEur10.6
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	-34,3°	(-33,5°) - (-35,5°)
Related substances (HPLC)	Conform	Test PhEur
Sulphates	< 100 ppm	<= 100 ppm
Loss on drying	0,03 %	<= 0,5 %
Sulphated ashes	0,00 %	<= 0,1 %
Assay	99,3 %	99,0 - 101,0 %
Impurity A	NDT	<= 0,2 %
Unspecified Impurities	NDT	<= 0,1 %
Sum of impurities different from A	NDT	<= 0,5 %
Residual solvents	Conform	

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: 17/03/2022

Judgement:
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F00368 SIEGFRIED PHARMACHEMICKALIEN MINDEN GmbH

Manufacturer batch: 21472094

Product	Name	Capacity	Batch
1100136	EFEDRINA HIDROCLORURO	1 kg	220381-P-1
1100136	EFEDRINA HIDROCLORURO	1 kg	220381-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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