



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 240001

Product:	EPHEDRINE HYDROCHLORIDE
Lot:	240001
Expiry date:	24/05/2027
Reference:	Cumple PhEur11.3
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 - 220 °C	Approx. 219 °C	=
Appearance of solution	Conform	Clear and colorless	=
Acidity or alkalinity	Conform	Test PhEur	=
Specific rotation	-34,0°	(-33,5°) - (-35,5°)	=
Related substances (HPLC)	Conform	Test PhEur	=
Sulphates	< 100 ppm	<= 100 ppm	=
Loss on drying	0,03%	<= 0,5 %	
Sulphated ashes	< 0,1 %	<= 0,1 %	=
Assay	100,3%	99,0 - 101,0 %	
Elemental impurities	Conform	Test PhEur	#
Impurity A	< 0,05 %	<= 0,2 %	=
Unspecified Impurities	<= 0,1 %	<= 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: 05/02/2024

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00368 SIEGFRIED PHARMACHEMICKALIEN MINDEN GmbH

Manufacturer batch: 22212047

Product Name Capacity Batch

1100134	EFEDRINA HIDROCLORURO (INACTIVO)	5 kg	240001-Q-1
1100136	EFEDRINA HIDROCLORURO	1 kg	240001-P-1
1100136	EFEDRINA HIDROCLORURO	1 kg	240001-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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