



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 240015

Product:	PAPAVERINA HYDROCHLORIDE
Lot:	240015
Expiry date:	30/08/2027
Reference:	Cumple PhEur11.3
Synonyms:	
Formula:	C ₂₀ H ₂₂ ClNO ₄
Molecular weight:	375,9 g/mol

Assay	Result	Specification	
Identification	Conform(A,D)		
Organoleptic properties	Conform		
Appearance of solution S	Conform		
pH	3,3	3,0 - 4,0	
Related substances (HPLC)	Conform		
Loss on drying	0,01%	<= 0,5 %	
Sulphated ashes	0,04%	<= 0,1 %	
Assay	99,3%	99,0-101,0%	
Individual impurities	< 0,05 %	<= 0,1 %	
Total impurities	< 0,05 %	<= 0,5 %	
Elemental impurities	Conform	Test PhEur	#
Residual solvent: Chloroform	< 60 ppm	<= 60 ppm	#
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Nitrosamine impurities	Conform	Test PhEur	#

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

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 25/01/2024

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F01033 SYNNAT PHARMA PRIVATE LIMITED

Manufacturer batch: 64130922

Product	Name	Capacity	Batch
1370257	PAPAVERINA CLORHIDRATO (FLB) (INACTIVO)	10 g	240015-F-1
1370258	PAPAVERINA CLORHIDRATO (FLB) (INACTIVO)	50 g	240015-I-1
1370259	PAPAVERINA CLORHIDRATO (FLB) (INACTIVO)	100 g	240015-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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