



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 242090

Product:	BENZOCAINE
Lot:	242090
Expiry date:	24/04/2027
Reference:	Cumple PhEur11.5
Synonyms:	Anestesia. Etilo p-aminobenzoato.
Formula:	C9H11NO2
Molecular weight:	165,2 g/mol

Assay	Result	Specification	
Identification	Conform (A)		
Organoleptic properties	Conform	PhEur	
Loss on drying	0,00 %	<= 0,5 %	
Sulphated ashes	0,03 %	<= 0,1 %	
Related substances (HPLC)	Conform	Test PhEur	
Assay	100,0 %	99,0-101,0%	
Elemental impurities	Conform	Test PhEur	#
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	< 0,05 %	<= 0,2 %	
Residual solvents	Conform	Test PhEur	#
Nitrosamine impurities	Conform	Test PhEur	#

Organoleptic characteristics: White or almost white, crystalline powder or colourless crystals. Very slightly soluble in water, freely soluble in ethanol (96 per cent). It shows polymorphism (5.9).

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 15/11/2024

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00080 CHANGZHOU SUNLIGHT PHARMACEUTICAL CO., LTD.

Manufacturer batch: C0012404017

Product	Name	Capacity	Batch
1115022	BENZOCAINA	25 g	242090-G-1
1115022	BENZOCAINA	25 g	242090-G-2
1115022	BENZOCAINA	25 g	242090-G-3
1115022	BENZOCAINA	25 g	242090-G-4
1115023	BENZOCAINA	250 g	242090-N-1
1115023	BENZOCAINA	250 g	242090-N-2

1115023	BENZOCAINA	250 g	242090-N-3
1115023	BENZOCAINA	250 g	242090-N-4
1115024	BENZOCAINA	100 g	242090-J-1
1115024	BENZOCAINA	100 g	242090-J-2
1115024	BENZOCAINA	100 g	242090-J-3
1115024	BENZOCAINA	100 g	242090-J-4

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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