



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 233872

Product:	CARBAMAZEPINE
Lot:	233872
Expiry date:	30/07/2027
Reference:	Cumple PhEur11.2
Synonyms:	
Formule:	C ₁₅ H ₁₂ N ₂ O
Poids moléculaire:	236.3 g/mol

Assay	Result	Specification	
Identification	Conform(A,B)	Test PhEur (A,B)	
Organoleptic properties	Conform	PhEur	
Related substances (HPLC)	Conform		
Acidity or alkalinity	Conform		
Elemental impurities	Conform	Test PhEur	#
Chlorides	< 140 ppm	<= 140 ppm	
Loss on drying	0,0 %	<= 0,5 %	
Sulphated ashes	0,14 %	<= 0,1 %	
Assay (HPLC)	100,9 %	98,0-102,0%	
Impurity A	< 0,05 %	<= 0,15 %	
Impurity E	< 0,05 %	<= 0,15 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	< 0,05 %	<= 0,5 %	
Residual solvent: chlorobenzene	< 360 ppm	<= 360 ppm	#

Organoleptic characteristics: White or almost white, crystalline powder. Very slightly soluble in water, freely soluble in methylene chloride, quite soluble in acetone and in alcohol.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 25/04/2024

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00289 ZHEJIANG JIUZHOU PHARMACEUTICAL CO., LTD.

Manufacturer batch: 200100A230820

Produit	Nom	Capacité	Lot
1118253	CARBAMAZEPINA (INACTIVO)	5 g	233872-E-2
1118256	CARBAMAZEPINA	100 g	233872-J-1
1118256	CARBAMAZEPINA	100 g	233872-J-2

1118258	CARBAMAZEPINA	500 g	233872-O-1
1118258	CARBAMAZEPINA	500 g	233872-O-2
1370183	CARBAMAZEPINA (FLB) (INACTIVO)	5 g	233872-E-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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