

## Gabapentin

<b>CODE ARTICLE:</b> 11475	<b>BATCH:</b> 0119440	<b>Active pharmaceutical ingredient</b>
<b>TEST DATE:</b> 25/05/2023	<b>TEST:</b> QC-00253635	
<b>EXPIRY DATE:</b> 30/03/2026	<b>FABRICATION DATE:</b> 01/04/2023	<b>MR:</b> 171,20
<b>CAS:</b> [60142-96-3]	<b>FORMULA:</b> C9H17NO2	
<b>STORAGE:</b> Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	CONFORM			POLVO BLANCO	PH.EUR.*
<b><u>SOLUBILITY</u></b>					
SOLUBLE	SPARINGLY SOLUBLE IN WATER				PH.EUR.*
SOLUBLE	SLIGHTLY SOLUBLE IN				PH.EUR.*
INSOLUBLE	PRACTICALLY INSOLUBLE IN DICHLOROMETHANE				PH.EUR.*
SOLUBLE	DILUTED ACID OR ALKALI				PH.EUR.
<b><u>IDENTIFICATION</u></b>					
IR IDENTIFICATION	CONFORM				PH.EUR.*
DISSOLUTION ASPECT	CONFORM -			La solución es clara e incolora	PH.EUR.*
PH	7,2 -		6,5	7,5	PH.EUR.*
WATER	0,04 %		-	0,3	PH.EUR.*
SULPHATED ASHES	0,03 %		-	0,1	PH.EUR.*
CHLORIDE	<100 ppm			100	PH.EUR.*
<b><u>RELATED SUBSTANCES</u></b>					
<b><u>TEST A</u></b>					
IMPURITY A	<LQ=0,05% (PASS) -			<=0,15% (<=1,5xÁrea SR B)	PH.EUR.*
UNSPECIFIED IMPURITIES	<LQ=0,05% (PASS) -			<=0,10% (<=Área SR A)	PH.EUR.*
<b><u>TEST B</u></b>					
UNSPECIFIED IMPURITIES	<LQ=0,03% (CONFORME) -			<=0,05% (<=1,5xÁrea SR D)	PH.EUR.*
SUM. IMPUREZAS TOTALES TEST A Y B	<LQ=0,03% (CONFORME) %			<=0,5	PH.EUR.*
ASSAY (BASE ANHIDRA)	100,3 %		97,5	102	PH.EUR.*
<b><u>RESIDUAL SOLVENTS</u></b>					
METHANOL	52 MG/KG			<=250	Manufacture's Standard
ISOPROPANOL	N.D. ppm			<=1000	Manufacture's Standard
ACETONE	28 ppm			<=100	Manufacture's Standard
TRI n-BUTILAMINA	3 MG/KG			<=10	Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (\*) are verified in Guinama.

Manufacturer: 55565 S.L.P. SCIENCES LIMITED (India) Manufacturer Batch: CGBE230012 Manufacturer original CoA available under request

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain

Phone: +34 96 186 90 90 / 902 11 98 16 Fax: 96 185 03 52 E-mail: ventas@guinama.com - www.guinama.com



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TEST	RESULTS	Units	MIN	MAX	METHOD
Risk Assessment Evaluation for Nitrosamines	CONFORM				
Elemental Impurities ICHQ3D	CONFORM				



**Silvia Sancho-Tello Ripoll**  
Technical Director.

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