

Gabapentin

CODE ARTICLE: 11476	BATCH: 0122778	Active pharmaceutical ingredient
TEST DATE: 24/10/2023	TEST: QC-00257884	
EXPIRY DATE: 30/06/2026	FABRICATION DATE: 01/07/2023	MR: 171,20
CAS: [60142-96-3]	FORMULA: C9H17NO2	
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	CONFORM			CRYSTAL WHITE POWDER	PH.EUR.*
SOLUBILITY					
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.
IDENTIFICATION					
IR IDENTIFICATION	CONFORM				PH.EUR.*
DISSOLUTION ASPECT	CONFORM -			The solution is clear and colorless	PH.EUR.*
PH	7,2 -		6,5	7,5	PH.EUR.*
WATER	0,03 %		-	0,3	PH.EUR.*
SULPHATED ASHES	0,1 %		-	0,1	PH.EUR.*
CHLORIDE	<100 ppm			100	PH.EUR.*
RELATED SUBSTANCES					
TEST A					
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.*
TEST B					
UNSPECIFIED IMPURITIES	<LQ=0,03% (PASS) -			<=0,05% (<=1,5xÁrea SR D)	PH.EUR.*
SUM. IMPUREZAS TOTALES TEST A Y B	<LQ=0,05% (PASS) -			<=0,5	PH.EUR.*
ASSAY (ANHYDROUS BASIS)	99,8 %		97,5	102	PH.EUR.*
RESIDUAL SOLVENTS					
METHANOL	67 MG/KG			<=250	Manufacture's Standard
ISOPROPANOL	N.D. ppm			<=1000	Manufacture's Standard
ACETONE	45 ppm			<=100	Manufacture's Standard
TRI n-BUTILAMINA	BQL (LOQ=3 PPM) MG/KG			<=10	Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	CONFORM				
Elemental Impurities ICHQ3D	CONFORM				

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: CGBE230026 Manufacturer original CoA available under request
 GUINAMA S.L. C/ OSLO,3 (before C/Praga) POL.IND. GUTENBERG 46185 La Pobra 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



Gabapentin

CODE ARTICLE: 11476	BATCH: 0122778	Active pharmaceutical ingredient
TEST DATE: 24/10/2023	TEST: QC-00257884	
EXPIRY DATE: 30/06/2026	FABRICATION DATE: 01/07/2023	MR: 171,20
CAS: [60142-96-3]	FORMULA: C9H17NO2	
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
------	---------	-------	-----	-----	--------



Silvia Sancho-Tello Ripoll
Technical Director.

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: CGBE230026 Manufacturer original CoA available under request

GUINAMA S.L. C/ OSLO,3 (before C/Praga) POL.IND. GUTENBERG 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

