

Gabapentin

CODE ARTICLE: 11476	BATCH: 0126850	Active pharmaceutical ingredient
TEST DATE: 15/04/2024	TEST: QC-00263280	
EXPIRY DATE: 30/09/2026	FABRICATION DATE: 01/10/2023	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	7,1 -		6,5	7,5	PH.EUR.*
WATER	0,1 %		-	0,3	PH.EUR.*
SULPHATED ASHES	0,02 %		-	0,1	PH.EUR.*
CHLORIDE	<100 ppm			100	PH.EUR.*
RELATED SUBSTANCES					
TEST A					
IMPURITY A	0,08% (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	0,1% (PASS) -			<=0,5	PH.EUR.*
ASSAY (ANHYDROUS BASIS)	99,7 %		97,5	102	PH.EUR.*
RESIDUAL SOLVENTS					
METHANOL	85 MG/KG			<=250	Manufacturer's Standard
ISOPROPANOL	N.D. ppm			<=1000	Manufacturer's Standard
ACETONE	34 ppm			<=100	Manufacturer's Standard
TRI n-BUTILAMINA	BDL (LOD=1) MG/KG			<=10	Manufacturer's Standard
SPECIFICATION	PH.EUR 11				Manufacturer's Standard
CORRECT BATCH	YES				Manufacturer's Standard
SAMPLING	COLLECT				Manufacturer'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: CGBE230031 Manufacturer original CoA available under request

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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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