

Gabapentin

CODE ARTICLE: 11475	BATCH: 0132002	Active pharmaceutical ingredient
TEST DATE: 17/06/2024	TEST: QC-00265376	
EXPIRY DATE: 30/01/2027	FABRICATION DATE: 01/02/2024	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	PASS			CRYSTAL WHITE POWDER	PH.EUR.*
<u>SOLUBILITY</u>					
SOLUBLE	SPARINGLY SOLUBLE IN WATER				PH.EUR.*
SOLUBLE	SLIGHTLY SOLUBLE IN ETHANOL				PH.EUR.*
	96°				
INSOLUBLE	PRACTICALLY INSOLUBLE IN DICHLOROMETHANE				PH.EUR.*
SOLUBLE	DILUTED ACID OR ALKALI				PH.EUR.
<u>IDENTIFICATION</u>					
IR IDENTIFICATION	PASS				PH.EUR.*
DISSOLUTION ASPECT	PASS -			The solution is clear and colorless	PH.EUR.*
PH	7,2 -		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.*
<u>RELATED SUBSTANCES</u>					
<u>TEST A</u>					
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.*
<u>TEST B</u>					
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)	100,1 %		97,5	102	PH.EUR.*
<u>RESIDUAL SOLVENTS</u>					
METHANOL	52 ppm			<=250	Manufacture's Standard
ISOPROPANOL	N.D. ppm			<=1000	Manufacture's Standard
ACETONE	42 ppm			<=100	Manufacture's Standard
TRI n-BUTILAMINA	BDL (LOD=1) ppm			<=10	Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
CORRECT BATCH	YES				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: CGBE240005 Manufacturer original CoA available under request

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TEST	RESULTS	Units	MIN	MAX	METHOD
SAMPLING	COLLECT				Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	PASS				
Elemental Impurities ICHQ3D	PASS				



Silvia Sancho-Tello Ripoll
Technical Director.

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