olon s.p.a.

GABAPENTIN
Ph. Eur. / USP

Batch N°:	1840003120	**ANALYSIS CERTIFICATE N° 642**	Man. Date:	October 2018
Date:	October 31, 2018		Retest date:	October 2023

TESTS	SPECIFICATIONS	RESULTS
Characteristics	White or almost white, crystalline powder. Freely soluble in water, slightly soluble in ethanol (96%), practically insoluble in methylene chloride. It dissolves in dilute acids and dilute solutions of alkali hydroxides. It shows polymorphism.	Complies
Appearance of solution	The solution is clear and colorless	Complies
Identification:		
IR spectrum	Conforms to Gabapentin WS (form II)	Complies
pH	Between 6.5 and 7.5 in a 0.02 g/ml solution	7.2
Water (K.Fischer)	Not more than 0.3%	0.03%
Chloride	Not more than 100 ppm	Complies
Sulphated ash	Not more than 0.1%	0.01%
Related substances (HPLC) :		
TEST A		
Gabapentin related compound A	Not more than 0.10%	0.03%
Gabapentin related compound B	Not more than 0.06%	< Disregard limit (0.05%)
Each unspecified impurity	Not more than 0.10%	< Disregard limit (0.05%)
TEST B		
Each unspecified impurity	Not more than 0.05%	< Disregard limit (0.03%)
Total impurities (for TEST A and B)	Not more than 0.5%	0.03%
Assay (HPLC)	Not less than 98.5% and not more than 101.5%, calculated on the anhydrous base	99.3%
Residual Solvents:		
Isopropyl alcohol	Not more than 1000 ppm	767 ppm
	ADDITIONAL TESTS	
Particle size	Not less than 90% ≤ 150 microns	95%

This material has been prepared following the current Good Manufacturing Practice (cGMP).

It has been tested according and conforms to the requirements of current Pharmacopoeias.

Q.C. Manager .....

Qualified Person 31/10/2018

original release on Oct 26, 2018

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