



GABAPENTIN EP

CAS N. 60142-96-3

CODE 1542NP

BATCH B210001

MAN. DATE 04/2021

RETEST DATE 04/2025

TEST FOR	SPECIFICATIONS	RESULTS
Description	white or almost white crystalline powder	Complies
Identification		
· IR	positive	Complies
Appearance of solution	according to EP	Complies
pH	≥ 6.5 ≤ 7.5	7.3
Chlorides	≤ 100 ppm	34
Water (KF)	≤ 0.3 %	0.01
Sulphated ash (Residue on ignition)	≤ 0.1 %	0.00
Assay (HPLC, on anhydrous basis)	≥ 97.5 ≤ 102.0 %	100.4
Related substances (HPLC) - Test A		
· A) 2-Azaspiro[4.5]decan-3-one	≤ 0.15 %	Non quantifiable
· any other impurity (highest)	≤ 0.10 %	Non quantifiable
Related substances (HPLC) - Test B		
· any other impurity (highest)	≤ 0.05 %	Non quantifiable
total (test A + test B)	≤ 0.30 %	Non quantifiable
(EP. spec.: NMT 0.5%)		
<u>Additional specifications</u>		
Dicyclohexylamine (GC)	≤ 500 ppm	131
Residual solvents (GC)		
· methanol	≤ 1000 ppm	71
· isopropanol	≤ 1000 ppm	25

OBSERVATIONS:



Copies of this CoA are not valid

APPROVED

on May 21, 2021

QUALITY CONTROL

Dr. S. Patroni

Jun 04, 2021