

Gabapentin (Cas No 60142-96-3)

Molecular Weight 207.70

Systematic (IUPAC) name

2-[1-(aminomethyl)cyclohexyl]acetic acid

Identifiers

CAS number 60142-96-3

ATC code N03AX12

PubChem 3446

DrugBank APRD00015

Chemical data

Formula C₉H₁₇NO₂ Mol. mass 171.237 g/mol

Pharmacokinetic data

Bioavailability Rapid, in part by saturable carrier-mediated L-amino acid transport system

60% for 0.9 g daily to 27% for 4.8 g daily dose

Food increases absorption by 14%

Protein binding Less than 3%

Metabolism Not appreciably metabolized

Half life 5 to 7 hours

Excretion Renal

Specification For : Gabapentin

Test Specification

Description White to off white crystalline powder

Identification A) Test A The IR spectrum of sample is concordant with the IR Spectrum of Gabapentin working std. Obtain in same manner

B) Test B Retention time of the major peak in the chromatogram of assay Preparation corresponds to that in the chromatogram of the std. Preparation as obtained in the assay

Solubility Soluble in water & 0.1N NaOH solution, sparingly soluble in methanol.

Residue on Ignition Limit : Max. 0.1% w/w

Heavy Metals Limit: Max.0.002 % w/w

Ph Limit : between 6.5 to 7.5

Chloride Related Substances (By HPLC) Limit : Max. 0.01% w/w

a) Impurity at RRt about 0.5 Limit : Max.0.1%

b) Gabapentin related compound A (Lactum) Limit : Max.0.1%

c) Individual impurity Limit : Max. 0.3%

d) Total impurity Limit : Max.0.5%

Water Content Limit: Max. 0.3% w/w

Organic Volatile Impurity & Residual Solvent Acetone : Max. 5000µg/g

Methanol : Max. 3000µg/g

Methylene Chloride : Max. 600µg/g

Assay by HPLC (On dried Basis) Limit: 99% to 101% w/w