

PRODUCTO: PREGABALIN

ITEMS	SPECIFICATIONS
APPEARANCE	White to off-white crystalline powder
IDENTIFICATION a) IR b) HPLC	The IR spectrum of the sample conforms to that of standard The retention time of the sample peak should conform to that of standard in enantiomeric purity method
X-RAY POWDER DIFFRACTION PATTERN	To match with the working standard
ENANTIOMERIC PURITY PRB-IV: (R)-(-)-3-Aminomethyl-5-methyl-hexanoic acid (R-Isomer)	NMT 0.5%
RELATED COMPOUNDS ➤ Purity ➤ Identified impurities <ul style="list-style-type: none"> • PRB-I: (R)-(-)-3-Carbamoylmethyl-5-methyl-hexanoic acid • PRB-II: 3-Isobutyl glutaric acid • PRB-III: 4-Isobutyl-pyrrolidin-2-one • Largest unidentified impurity • Total impurities 	NLT 99.0% NMT 0.15% NMT 0.15% NMT 0.15% NMT 0.10% NMT 1.0%

ASSAY	98.0% ~ 102.0% (on anhydrous basis and solvent free basis)
RESIDUAL SOLVENTS a) Ethanol b) Isopropyl alcohol c) Isobutyl alcohol d) Ethyl acetate e) Chloroform f) Triethylamine	NMT 5000 ppm NMT 5000 ppm NMT 5000 ppm NMT 5000 ppm NMT 60 ppm NMT 320 ppm
WATER CONTENT	NMT 0.5%
RESIDUE ON IGNITION	NMT 0.1%
HEAVY METALS	NMT 20 ppm