

PRODUCTO: GABAPENTIN

ITEMS	SPECIFICATIONS
APPEARANCE	White to off white crystalline powder
SOLUBILITY	Freely soluble in water and in alkaline and acidic solution
IDENTIFICATION a) IR b) HPLC	The IR spectrum of the sample in potassium bromide dispersion exhibits maxima only at the same wavelength as that of GABAPENTIN form-II WS The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation, as obtained in the assay
PH IN SOLUTION (1gm in 50 ml water)	6.5~8.0
WATER BY K.F.	NMT 0.5% w/w
RESIDUE ON IGNITION	NMT 0.1% w/w
HEAVY METALS	NMT 20 ppm
RELATED COMPOUNDS BY HPLC ➤ Early eluting impurities <ul style="list-style-type: none"> • Gabapentin related compound A • Gabapentin related compound B • Gabapentin related compound E • Individual unknown impurity ➤ Late eluting impurities <ul style="list-style-type: none"> • Any individual impurity ➤ Total impurities	NMT 0.10% NMT 0.06% NMT 0.10% NMT 0.10% NMT 0.10% NMT 0.5%
ASSAY BY HPLC (on anhydrous basis)	98.0%~102.0%