

PRODUCTO: TRAMADOL HCL

ITEMS	SPECIFICATIONS
APPEARANCE	White crystalline powder
SOLUBILITY	Freely soluble in water and methanol, practically insoluble in acetone
IDENTIFICATION	As per Ph. Eur.
APPEARANCE OF 5% AQ.SOLUTION	The solution should be clear
ACIDITY	As per Ph. Eur.
OPTICAL ROTATION	-10° ~ +10° (C=5, Water)
RELATED SUBSTANCES a) Mannich base (by TLC) b) Impurity A (by HPLC) c) Individual impurity (by HPLC) d) Total impurities (As tramadol hydrochloride)(by HPLC)	NMT 0.2% NMT 0.2% NMT 0.1% NMT 0.4%
WATER	NMT 0.5% w/w
SULPHATED ASH	NMT 0.1% w/w
HEAVY METALS	NMT 0.001% w/w
ASSAY BY CHEMICAL	99.0% w/w ~ 101.0% w/w (C ₁₅ H ₂₆ CLNO ₃ , on the dried basis)