

PRODUCTO: RANITIDINA HCL

ITEMS	SPECIFICATIONS
DESCRIPTION	White to pale yellow practically odourless, crystalline powder
SOLUBILITY	Very soluble in water, sparingly soluble in alcohol
IDENTIFICATION	IR, UV and Chlorides
PH (1 in 100)	4.5 ~ 6.0
CHROMATOGRAPHIC PURITY (By HPLC) <ul style="list-style-type: none"> a) Ranitidine bis-compound (Imp-B) NMT 0.3% b) Ranitidine simple nitroacetamide NMT 0.1% c) Ranitidine oxime NMT 0.1% d) Ranitidine amino alcohol hemifumarate NMT 0.1% e) Ranitidine diamine hemifumarate (Imp-A) NMT 0.1% f) Ranitidine S-oxide (Imp-C) NMT 0.1% g) Ranitidine N-oxide NMT 0.1% h) Ranitidine complex nitroacetamide NMT 0.1% i) Ranitidine formaldehyde adduct NMT 0.1% j) Major/ Largest single unknown impurity NMT 0.1% k) Total impurities NMT 0.5% 	
LOSS ON DRYING	NMT 0.75%

RESIDUE ON IGNITION	NMT 0.10%
ASSAY (dry basis)	97.5% ~ 102.0%
RESIDUAL SOLVENTS a) Chloroform b) Isopropanol c) Methanol d) M.I.B.K. e) Toluene	NMT 60 ppm NMT 5000 ppm Not used Not used Not used
MELTING RANGE	About 140°C
HEAVY METALS	NMT 20 ppm
CLARITY: 10% SOLN: 430nm absorbance	NMT 0.20