

PRODUCTO: KETOROLACO TROMETAMINA

ITEMS	SPECIFICATIONS
DESCRIPTION	White to off white crystalline powder
SOLUBILITY	<p>Freely soluble in water, methanol. Slightly soluble in alcohol, in dehydrated alcohol, in tetrahydrofuran. Practically insoluble in acetone, in dichloromethane, in toluene, in ethyl acetate, in dioxane, in hexane, in butyl alcohol and in acetonitrile</p>
MELTING POINT	165°C~170°C with descomposition
IDENTIFICATION a) Infrared absorption b) Ultraviolet absorption c) Tromethamine test (by TLC)	<p>The IR absorption spectrum of the preparation of the test specimen, exhibits maxima only at the same wave lengths as that of a similar preparation of the corresponding Ketorolac Tromethamine working/reference standard</p> <p>The UV absorption spectra of the test solution and the standard solution exhibit maxima and minima at the same wave lengths</p> <p>The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with Ketorolac Tromethamine working reference standard</p>
PH	5.7~6.7

LOSS ON DRYING	NMT 0.5% w/w
RESIDUE ON IGNITION	NMT 0.1% w/w
HEAVY METALS	NMT 0.002%
CHROMATOGRAPHIC PURITY BY HPLC <ul style="list-style-type: none"> ➤ Ketorolac 1- Keto analog ➤ Ketorolac 1-Hydroxyanalog ➤ Impurity at RRT 0.54 ➤ Impurity at RRT 0.66 ➤ Any other impurity ➤ Total impurities 	NMT 0.1% NMT 0.1% NMT 0.5% NMT 0.5% NMT 0.5% NMT 1.0%
ASSAY BY HPLC (on dried basis)	98.5% w/w ~ 101.5% w/w
ADDITIONAL TEST <ul style="list-style-type: none"> a) 1,2-Dichloroethane b) Methanol c) Ethylene acetate d) Acetone e) Toluene 	NMT 5 ppm NMT 3000 ppm NMT 5000 ppm NMT 5000 ppm NMT 890 ppm