

SPECIFICATION SHEET

Diclofenac Sodium

SR NO.	TEST	SPECIFICATION
1	Description	A white or slightly yellowish crystalline powder, slightly hydroscopic
2	Solubility	Freely soluble in methano;, soluble in ethano;(95%), sparingly soluble in water and in glacial acetic acid, partially insoluble in ether, in chloroform, and in toluene
3	Identification (A) By I.R	The infrared spectrum of the test concordant with the reference spectrum of diclofenac sodium CRS or Diclofenac Sodium WS
	(B) Chemical test	To meet the test
	(C) By HPLC	The principal in the chromatograph obtained with the test solution corresponds to the peak in the chromatograph obtained the reference solution
	(D) Chemical test	To meet the chemical test
4	Appearance of solution (5.0% w/v)	Comply
5.	pH(1% w/v)	6.5 to 8.5
6.	Light absorption	NMT 0.005
7.	Related substance by HPCL	Individual impurity NMT: 0.2% Total impurity NMT:0.5%
8.	Heavy metals	NMT 10 PPM
9.	Loss on drying	NMT 0.50%
10.	Assay (on dried basis)	98.50% to 101.5%