

Specification

Diclofenac Sodium Ph. Eur.

Appearance	A white or slightly yellowish slightly hygroscopic, crystalline powder.
Solubility	Sparingly soluble in water, freely soluble in methanol, soluble in ethanol 96%, slightly soluble in acetone
Melting Point	It melts at about 280°C, with decomposition
Identification	The infrared absorption spectrum of the sample must be concordant with that of Diclofenac sodium reference/working standard spectrum.
(A) By IR spectrophotometer	
(D) Reaction of sodium (b)	No precipitate is formed
Appearance of solution	The solution is clear
Ab.5% In MeOH/440nm/1cm	Not more than 0.05
Related substances (By HPLC)	
Impurity-A	Not more than 0.2 %
Impurity-F	Not more than 0.15 %
Unspecified Impurity	Not more than 0.10 %
Total impurities	Not more than 0.4 %
Heavy metals	Not more than 10 ppm
Loss on drying (At 105°C for 3 hrs)	Not more than 0.5 % (w/w)
Assay	Not less than 99.0 % and Not more than 101.0 % (w/w)
(Calculated on dried basis)	
Additional In-House test	
Particle size (By Sieve)	100 % passing through 20 mesh
EDTA Content	Not more than 10 ppm
Residual solvents	
2- Propanol	Not more than 1000 ppm
Toluene	Not more than 100 ppm
Conclusion	Complies as per Ph. Eur., Additional In-house Test & Customer Test Specification
Manufacturing site:	Amoli Organics Pvt. Ltd., Plot No.322/4, 40 Shed Area, G.I.D.C., Vapi-396 195. Gujarat – India.