



KRISHNA SOLVECHEM LTD.

CHEMISTRY WITH COMMITMENT

STANDARD SPECIFICATIONS			
PRODUCT	Diclofenac Sodium BP		
CAS NO	15307-79-6	Mol. Formula	C ₁₄ H ₁₀ Cl ₂ NNaO ₂
Effective Date	05/06/2019	Revision Period	3 Years

Sr No.	TEST	SPECIFICATIONS
1	Appearance	White or slightly yellowish , slightly hygroscopic , Crystalline Powder
2	Solubility	Sparingly soluble in water, freely soluble in methanol, soluble in ethanol (96%1, slightly soluble in acetone.
3	Second Identification A. TLC B. Chemical Test C. Reaction of Sodium	The Principle spot in the chromatogram obtained with the test solution is similar in position, colour and size the principle spot in the chromatogram obtained with the working standard solution Dissolve about 10mg in 10ml of ethanol {96%} R to 1ml of this solution add 0.2ml of a mixture, prepared immediately before use of equal volumes of a 69/l solution of potassium ferricyanide R and a 9g/l solution of ferricchloride R allow to stand protected from light for 5 min. add 3ml of a 10g/l solution of hcl R Allow to stand protected from light for 15 min. A blue color develops and precipitate is formed. Dissolve 60mg in 0.5ml of methanol R and add 0.5ml of water R. The solution gives reaction (b) of sodium (2.3.1)
4	Ph	6.5 To 8.5
5	Light absorption (5.0% w/v in methanol, 440nm) (2.2.2S)	Not more than 0.05%
6	Related substances by HPLC(2.2.29] Unknown Individual Imp Total Impurities	NMT 0.2% NMT 0.4%
7	Heavy Metals	NMT 10ppm
8	Loss on Drying	NMT 0.5%
9	Assay	NLT 99.0% and NMT 101.0%

Note: This is a Computer - generated Specification. No signature is required.

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