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CERTIFICATE OF ANALYSIS

Product Name : DICLOFENAC SODIUM USP		Sampling Date : 27/09/2021
Batch No. : A21450F021	Mfg. Date: Sep-2021	Released Date : 30/09/2021
Batch Size : 1053.59 Kgs.	Exp. Date : Aug-2026	A.R. No. : 80000000848
TEST	**OBSERVATION**	**SPECIFICATION**
Description	White hygroscopic crystalline powder,	A white to off white hygroscopic crystalline powder.
	282.5°C	Melts at about 284°C
Solubility	Complies	Freely soluble in methanol, soluble in ethanol, sparingly soluble in water, practically insoluble in chloroform & in ether.
Identification (A) By IR Spectroscopy	Complies	The Infrared absorption spectrum of the sample must be concordant with that of Diclofenac sodium reference/working standard spectrum.
(B) By HPLC	Complies	The retention time of the Diclofenac peak in the chromatogram of the test solution corresponds to that of the system suitability solution as obtained in the test for organic impurities.
(C) By Flame test	Complies	A dense precipitate is formed. Sodium compound impart an intense yellow color to a non luminous flame.
Colour of solution Ab.5% In MeOH/440nm/1cm	Complies 0.017	The solution should be colorless to faintly yellow Not more than 0.05
Clarity of solution	Complies	The solution prepared as directed under colour of solution is not significantly less clear than an equal volume of methanol contained in a similar vessel and examined similarly.
pH (1% solution in water)	7.76	Between 7.0 to 8.5
Loss on drying (At 105°C to 110°C for 3 hrs)	0.26 % (w/w)	Not more than 0.5 % (w/w)
Organic Impurities (By HPLC)	0.001 % 0.05 % 0.07 %	Related compound-A Not more than 0.2 % Individual impurity Not more than 0.10 % Total impurities Not more than 0.5 %
Assay (Calculated on dry basis)	100.1 % (w/w)	Not less than 99.0 % and Not more than 101.0 %
Additional In-house Test		
Residual solvent 2- Propanol Toluene	 Below Detection Limit Below Detection Limit	 Not more than 1000 ppm Not more than 100 ppm
Conclusion : The Sample Complies as per USP 43 & Additional In-house Test.		

	Prepared By	**Checked By**	**Released for Dispatch**
Sign & Date **Name & Designation**	10/03/22 D.D.Tandel, Sr. Exe.-QC	10/03/22 R.D.Mehta, Sr. Mgr.-QC	10/03/22 A.N.Nehate, Mgr.-QA

SOP No. : VQC/O/006 Format No. : VQC/F/089-00

DS-LGM Pharma, USA-EXP 1211030768-300

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