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CERTIFICATE OF ANALYSIS

Product Name : DICLOFENAC SODIUM USP		Sampling Date : 26/08/2017
Batch No. : DS/1708/0223B	Mfg. Date : Aug. 2017	Released Date : 30/08/2017
Batch Size : 100.12 Kgs.	Exp. Date : Jul. 2022	A.R. No. : ADS/17/0272
TEST	**OBSERVATION**	**SPECIFICATION**
Description	White crystalline powder, slightly hygroscopic	A white to off white hygroscopic crystalline powder.
	279.2°C to 280.4°C	Melts at about 234°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	Conformed	The Infrared absorption spectrum of the sample must be concordant with that of Diclofenac sodium reference/working standard spectrum.
(B) By HPLC	Conformed	The retention time of the Diclofenac peak in the chromatogram of the test solution corresponds to that of the Resolution solution as obtained in the test for Chromatographic purity.
(C) By Flame test	Conformed	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)	7.21	Between 7.0 to 8.5
Loss on drying (At 105°C to 110°C for 3 hrs)	0.22 % (w/w)	Not more than 0.5 % (w/w)
Chromatographic purity (By HPLC)	Below Detection Limit 0.01 % 0.01 %	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)	100.7 % (w/w)	Not less than 99.0 % and Not more than 101.0 %
Additional In-House Test / Customer Requirement		
Particle size (By Malvern wet method)	12.5 µm 1.38 %	90 % < 20 micron 10 % between 20 to 40 micron
Bacterial endotoxin Total aerobic microbial count Total yeast & Fungi Escherichia Coli	Less than 4.67 EU/mg < 10 cfu/g < 10 cfu/g Absent	Not more than 4.67 EU/mg Not more than 100 cfu/g Not more than 10 cfu/g Should be absent
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 , Additional In-house Test & Customer Test Specification.		

	Prepared By	Checked By	Released for Dispatch
Sign & Date Name & Designation	26/08/17 M.R.Bhandari, Exe. -QC	26/08/17 A.M.Intwala, Asst.Mgr.-QC	26/08/17 A.N.Nehate, Asst. Mgr.-QA

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

DS-Laboratorio Chile S.A,Chile-EXP C167-100

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