Aarti Drugs Limited
Manufacturers of : Bulk Drugs & Chemicals

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QUALITY CONTROL
CERTIFICATE OF ANALYSIS

PRODUCT NAME		: **DICLOFENAC SODIUM USP 39**		
BATCH NO.		: **DFS/17050157**	Batch Size	: 1300.00 kg
MFG. DATE		: May '2017	A.R. NO.	: FP/17/1542
EXP. DATE		: April' 2022	RELEASE DATE	: 03/06/2017
SR. NO.	**TESTS**	**SPECIFICATION**		**RESULTS**
1	Description	White to off white, hygroscopic, crystalline powder.		White, hygroscopic, crystalline powder.
2	Melting point	Melts at about 284^{0}C		Melts at about 276.3 ^{0}C
3	Solubility	Freely soluble in methanol; soluble in ethanol; sparingly soluble in water; practically insoluble in chloroform and in ether		Freely soluble in methanol; soluble in ethanol; sparingly soluble in water; practically insoluble in chloroform and in ether
4	Identification • I. R Spectrum • By HPLC • Flame test for Sodium	The Infrared absorption spectrum of sample is concordant with Infrared absorption spectrum of diclofenac sodium WS. Retention time of the test substance is matches with the std substance in the chromatography test. Residue obtained by the ignition gives the test for sodium.		Concordant with IR absorption spectrum of diclofenac sodium WS. Retention time of test substance matches With the std. Gives test for sodium
5	Color of the solution	A 5% solution in methanol is Colorless to faintly yellow, and absorbance measured at 440 nm, is not more than 0.05.		Absorbance at 440 nm is 0.0269
6	Clarity of solution	Solution should be clear		5 % solution is clear
7	pH	Between 7.0 and 8.5, determined on a 1% w/v solution.		7.10
8	Loss on drying	Not more than 0.5 %, determined on 1.0 g by drying in an oven at 105 ^{0}C for 3 hrs.		0.26 %
9	Heavy metal (Method II)	Not more than 0.001 %		Less than 0.001%
10	Chromatographic purity • Related compound A • Individual Specified impurity. • Individual Unspecified impurity. • Total impurities	Not more than 0.2 % Not more than 0.2 % Not more than 0.1 % Not more than 0.5 %		Not Detected. Not Detected. Not Detected. Not Detected.
11	Assay by Potentiometrically	Not less than 99.0 % and not more than 101.0 % of $C_{14}H_{10}Cl_2NNaO_2$, calculated with reference to the dried basis		99.52 %
12	Total Aerobic Count	• Aerobic bacteria: less than 100 cfu/g • Yeast and Mould : NMT 10 cfu/g • Pathogen : E Coli, P. Aeruginos, S. Aureus, Salmonella: Should be absent		Not detected. Not detected. Absent
Opinion		: **The above material passes as per USP 39 Specification.**		

Analyzed By	: Amore	Checked By	: NMMutkule	Approved By	: [illegible]
QC Officer	: Arun	QC Dy. Manager	: Nitata	QC. Manager	: Tanaji
Date	03/06/2017	Date	03/06/2017	Date	03/06/2017