



**Aarti Drugs Limited**

Manufacturers of : Bulk Drugs & Chemicals

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**QUALITY CONTROL  
CERTIFICATE OF ANALYSIS**

PRODUCT NAME		: DICLOFENAC SODIUM BP WORKING STANDARD	
SOURCE BATCH NO.		: DFS/13020035	
EVALUATED WITH		: BPCRS 2926	
EVALUATION DATE		: Feb' 2013	A.R. NO. : FG/10330,10331,10332
VALID UPTO		: Jan' 2016	WORKING STD NO : WS/13-16/D-1
SR. NO.	TESTS	SPECIFICATION	RESULTS
1	Appearance	A white or slightly yellowish, crystalline powder, Hygroscopic.	A white, crystalline powder, slightly hygroscopic.
2	Solubility	slightly hygroscopic, sparingly soluble in water, freely soluble in methanol, soluble in alcohol, slightly soluble in acetone	Sparingly soluble in water, freely soluble in methanol, soluble in alcohol, slightly soluble in acetone.
3	Melting Point	It melts at about 280°C, with decomposition	It melts at about 280°C, with decomposition
4	Identification A. I. R Spectrum  B. TLC  C. As per BP  D. Reaction of sodium	The infrared absorption spectrum of sample is concordant with infrared absorption spectrum of diclofenac sodium CRS.  The principal spot obtained in test solution is similar in position and size to the principal spot obtained with reference solution (a).  A blue color develops and a precipitate is form  Gives reaction for sodium	Concordant with IR absorption spectrum of diclofenac sodium CRS.  The principal spot in the test matches with reference solution (a).  A blue color develops and a precipitate is form  Gives reaction for sodium
5	Appearance of solution	The solution is clear and absorbance measured at 440 nm is not greater than 0.05	Solution is clear and absorbance is 0.0140 A°
6	Related substances Impurity A,B,C,D,E Total Impurities	Not more than 0.2 % Not more than 0.5 %	Not Detected Not Detected
7	Heavy metals	Not more than 10 ppm, determined on 2.0 g.	Less than 10 ppm
8	Loss on drying	Not more than 0.5 %, determined on 1.0 g by drying in an oven at 105 °C for 3 hrs.	0.27 %
9	Assay	Not less than 99 % and not more than 101 % of $C_{14}H_{10}Cl_2NNaO_2$ , calculated with reference to the dried substance	99.65 %
10	pH *	Between 6.5 to 8.5 of 1 % solution in water	7.28
Opinion		: WS No WS/13-16/D-1 is suitable as a substitute for working standard BP	
Analyzed By	: <i>ABRwade</i>	Checked By	: <i>QJ</i>
Date	: 22/02/2013	Date	: 22/02/2013
Approved By	: <i>QJ</i>	Date	: 22/02/2013

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