



Aarti Drugs Limited

Manufacturers of : Bulk Drugs & Chemicals

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QUALITY CONTROL CERTIFICATE OF ANALYSIS

Product	DICLOFENAC SODIUM EP	Batch Size	780.0 Kg
Batch Number	DCS/14080010	CAS Number	15307-79-6
Manufacturing Date	AUG. 2024	A. R. No.	FG/24/0464
Expiry Date	JULY. 2029	Analysis Date	30/08/2024
Sr. No.	TESTS	LIMIT	RESULTS
1	Appearance	White or slightly yellowish, slightly hygroscopic, crystalline powder.	Complies
2	Solubility	Sparingly soluble in water, freely soluble in methanol, soluble in ethanol (96%), slightly soluble in acetone.	Complies.
3	Melting Point	About 280° C, with decomposition.	281.0°C
4	Identification A. By Infra Red	The IR absorption spectra of test substance concordant with spectrum obtained with diclofenac sodium CRS or WS.	Complies.
	B. By TLC	The principle spot in the chromatogram obtained with the test solution is similar in position and size to the principle spot in the chromatogram obtained with ref solution (a).	Complies.
	C. As per EP	A blue colour develops and a precipitate is formed.	Complies.
	D. Reaction (b) of sodium	No precipitate is formed with ammonium carbonate solution R.	Complies.
5	Appearance of solution	The solution is clear and its absorbance measured at 440 nm is not greater than 0.05.	Complies.
6	Related substances	Impurity A : Maximum 0.2 %	0.028%
		Impurity F : Maximum 0.15 %	0.025%
		Unspecified impurities : Maximum 0.10 %	0.034%
		Total : Maximum 0.4 %	0.144%
7	Loss on drying	Maximum 0.5%, determined on 1.000 g by drying in an oven at 105 ° C for 3 hrs.	0.28%
8	Assay by Potentiometrically	Not less than 99.0% and Not more than 101.0% with reference to dried substance.	99.45%
9	Particle size	100% passing through 175 um	6.31 µm

OPINION : The above material is complying as per EP specification. CEP 2021-246-Rev 00

Prepared By		Checked By		Approved By	
QC Officer	Vedika Patil	QC Officer	Somnath ghule	QC Head	Harshad Mandekar
Date	17/06/2025	Date	17/06/2025	Date	17/06/2025

COA is re-issued on Date 17/06/2025

Factory Address: Plot No. W-60 (B), 61(B), 62 (B), 71(B), 72 (B), 73 (B), M.I.D.C., Tarapur,
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