

Reference SOP No.: SOP/QCD/GN/017



**THEMIS MEDICARE LTD. HARIDWAR**  
**QUALITY CONTROL DEPARTMENT**  
**CERTIFICATE OF ANALYSIS OF WORKING STANDARD**

Working Standard Name		Diclofenac Diethylamine	
Batch No.	DDA/14110035	WS No.	WS/DDA/01
Date of Mfg.	11/2014	Date of Exp.	10/2019
Source of Materials	Aarti Drugs Ltd.	Date of Standardization	27/05/2015
RS Lot No./B.No	3100	Validity of RS	Not Applicable
Quantity of Sample:	20.000 gm	Valid Up to	26/05/2016

S.No	Test	Specification	Results
1.	Description	A White to light beige, crystalline powder.	A white crystalline powder.
2.	Identification	(A) By IR: The IR spectrum of test should be concordant with the IR spectrum of reference spectrum of diclofenac diethylamine. (B) By TLC: The two principal spots in the chromatogram obtained with solution (1) are similar in position, colour and size to the corresponding spots in the chromatogram obtained with solution (2).	Complies  Complies
3.	Loss on drying/Water	Not more than 0.5%.	0.31%
4.	Assay (By HPLC)	Not less than 99.0 % and not more than 101.0% (On dried basis)	99.07% (On dried basis)

Remark: The above Working standard complies/ does not complies as per IP/BP/USP and H specification.

	PREPARED BY	CHECKED BY	APPROVED BY
Signature			
Name	Jyoti Shrivastava	Sampat Kumar	Naveen Tripathi
Date	27-05-2015	27-05-2015	27-05-2015

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