



AARTI INDUSTRIES LIMITED

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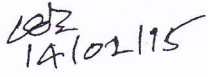
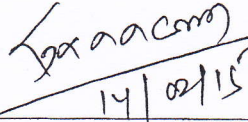
CERTIFICATE OF ANALYSIS

ADAPALENE Ph.Eur.

Batch No.	: AD-14002(JM-01)-001A	Date of Mfg.	: JUL-2014
AR. No.	: FG/044/15	Date of Exp.	: JUN-2019
Batch Qty.	: 1.36 Kg	Date of Release	: 04/02/15

Sr. #	TESTS	RESULTS	SPECIFICATION
1.	Description	White powder	White or almost white powder.
2.	Solubility	Complies	Sparingly soluble in Tetrahydrofuran, Practically insoluble in water and ethanol (96%)
3.	Identification A)By IR	Complies	The Infra Red spectrum of Sample should concordant with similar preparation of that of Adapalene WS.
	B)By HPLC	Complies	The retention time of the major peak of the sample solution corresponds to that of standard solution, as obtained in the assay
4.	Appearance of Solution	Complies	The solution is clear and not more intensely coloured than reference solution BY ₆
5.	Related substances (By HPLC)	Not detected	Impurity A : Not more than 0.3%
		Not detected	Impurity C : Not more than 0.15%
		Not detected	Impurity D : Not more than 0.2%
		Below Disregard Limit	Unspecified impurities : Not more than 0.10%
		Below Disregard Limit	Total impurities : Not more than 0.5%
6.	Heavy metals	Complies	Not more than 20 ppm
7.	Loss on drying (At 105°C for 4 hours)	0.25 %	Not more than 0.5 %
8.	Sulphated ash	0.06%	Not more than 0.1 %
9.	Assay (By HPLC)	100.59 %	Between 98.0 % to 102.0 % on dried substances
10.	Organic Volatile Impurities (Residual solvent) (By HSGC)	114 ppm	Dichloromethane : NMT 600 ppm
		68 ppm	Ethyl acetate : NMT 5000 ppm
		311 ppm	Tetrahydrofuran : NMT 720 ppm
		626 ppm	Toluene : NMT 890 ppm
		Not Detected	Diglyme : NMT 500 ppm
11.	Triethylamine content (By HSGC)	Not Detected	Not more than 80 ppm

Remark: The material complies as per Ph.Eur. and above specification.

Analyst	Checked By	Approved By
RS	 14/02/15	 14/02/15
	Head Quality Control	Head Quality Assurance

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