

	SIONC PHARMACEUTICALS PVT. LTD.		
	Factory: Plot No. 34A, Road No. 1, JN Pharma City, IDA Parawada, Thanam(v), Visakhapatnam-531021, Andhra Pradesh, India, Ph: +91-8924-236117/236118, Fax: +91-8924-236119, E-mail: info@sioncpharma.co.in		

CERTIFICATE OF ANALYSIS

Name of the Product	:	TRETINOIN	Page No.	:	1 of 3
Batch Number	:	2010/3/001/17	A.R.No	:	FP/0048/17
Manufacturing Date	:	13/03/2017	Expiry/Re test Date	:	12/03/2021
Batch Quantity	:	5.200 Kg	Sample Quantity	:	---
Customer Name	:	---	Date of Analysis	:	24/03/2017

S. No.	Test Parameter	Specification	Result
1.	Description	Yellow to light orange crystalline powder.	Yellow crystalline powder
2.	Solubility	Slightly soluble in Alcohol, in Chloroform & in Methanol and practically insoluble in Water.	Complies
3.	Identification		
	a) By IR	The IR spectrum of the sample should match with that of standard spectrum.	Complies
	b) By UV absorbance at 352nm (On dried basis)	Not differ more than 3.0%	1.67 %
	c) By HPLC	The retention time of the major peak in the chromatogram of the test solution should correspond to that of the standard solution.	Complies
4.	Loss on drying (at Room temperature for 16 hours under vacuum)	Not more than 0.5 %w/w	0.20 %w/w
5.	Residue on Ignition	Not more than 0.1 %w/w	0.06 %w/w
6.	Heavy Metals	Not more than 0.002%	Less than 0.002%
7.	Limit of Isotretinoin	Not more than 2.0 %w/w	0.04 %w/w

Compiled by	Checked by	Approved by
 24/03/17	 24/03/2017	 24/03/2017
B. Raminaidu Sr. Executive-QC	G. Ravi Kumar Asst. Manager-QC	M. Nagababu Dy. Manager-QA

Office Address: Regd. Off: #43-11-56, Subbalakshmi Nagar, Railway New Colony, Visakhapatnam-530016, Andhra Pradesh, India, Ph: +91-891-2712885, Fax: +91-891-2712875.

FM01/QA035/02-01/01/2017



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S. No.	Test Parameter	Specification	Result
8.	Chemical Assay by Titrimetry (On dried basis)	Not less than 97.0 %w/w and Not more than 103.0 %w/w	98.1 %w/w
9.	Related Substances by HPLC		
	a) Alitretinoin	Not more than 0.15 %w/w	0.01 %w/w
	b) 11,13 di cis retinoic acid	Not more than 0.15 %w/w	BDL
	c) 5,6-Epoxy all trans retinoic acid	Not more than 0.15 %w/w	0.01 %w/w
	d) Any single unknown impurity	Not more than 0.10 %w/w	0.004 %w/w
	e) Total impurities (Excluding Isotretinoin)	Not more than 0.5 %w/w	0.03 %w/w
10.	Assay by HPLC (On dried basis)	Not less than 98.0 %w/w and Not more than 102.0 %w/w	100.1 %w/w
11.	Residual solvents by GC		
	a) Acetone	Not more than 5000 ppm	53 ppm
	b) Hexanes	Not more than 290 ppm	BDL
	c) Methanol	Not more than 3000 ppm	BDL
	d) Methylene chloride	Not more than 600 ppm	BDL
	e) n-Heptane	Not more than 5000 ppm	BDL

Compiled by	Checked by	Approved by
<i>Raw</i> 24/03/17 B. Raminaidu Sr. Executive-QC	GR 24/03/2017 G. Ravi Kumar Asst. Manager-QC	<i>my</i> 24/03/2017 M. Nagababu Dy. Manager-QA

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Batch Quantity	: 5.200 Kg	Sample Quantity	: ---
Customer Name	: ---	Date of Analysis	: 24/03/2017

S. No.	Test Parameter	Specification	Result
	f) Tetrahydrofuran	Not more than 720 ppm	BDL
	g) Ethyl acetate	Not more than 5000 ppm	BDL

BDL: Below Detection limit

REMARKS: The material complies as per the USP/In-house specification.

Compiled by	Checked by	Approved by
<i>Ran</i> 24/03/17	<i>ER</i> 24/03/2017	<i>mb</i> 24/03/2017
B.Raminaidu	G.Ravi Kumar	M.Nagababu
Sr.Executive-QC	Asst.Manager-QC	Dy.Manager-QA

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