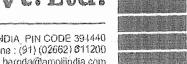


Fecha Entrada: 05-03-2018 8548

## Amoli Organics Pvt. Ltd.



Factory: BLOCK NO, 422, ECP CANAL ROAD, VILLAGE LUNA, TA: PADRA, DIST: VADODARA, INDIA, PIN CODE 391440
Phone: (91) (02662) 611200

E-mail Address : baroda@amoliindia.com

## QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

Sildenafil Citrate (SCC)	1	
Ph.Eur	Mfg.Lic no.:	G/1518
	<i>y</i>	
SCC/1801B/7002	A.R. No. :	FP/18/00069/08
160.69 Kg	Date of sampling:	11/01/18
JAN - 2018	Retest date:	DEC - 2022
	Ph.Eur SCC/1801B/7002 160.69 Kg	Ph.Eur Mfg.Lic no. :  SCC/1801B/7002 A.R. No. :  160.69 Kg Date of sampling :

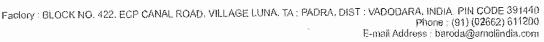
Sr. No.	Test name	Test result	Acceptance criteria
1.0	Appearance	White, slightly hygroscopic,	White or almost white, slightly
		crystalline powder.	hygroscopic, crystalline powder.
2.0	Solubility	Slightly soluble in water and	Slightly soluble in water and in
		in methanol, practically	methanol, practically insoluble in
		insoluble in hexane.	hexane.
3.0	Identification by I.R.	IR spectrum of the test sample	IR spectrum of the test sample
		is concordant with that of	should be concordant with that of
		standard.	standard.
4.0	Impurity E by TLC	Less than 0.1 %	Not mote than 0.1 %
5.0	Related substances (By HPLC)		
	a) Impurity A	Not detected	Not more than 0.15%
	b) Impurity D	Below detection limit	Not more than 0.15%
	c) Unspecified Impurity	Below detection limit	Not more than 0.10%
	d) Total impurities	Below limit of Quantification	Not more than 0.5%
6.0	Water content by KF	1.7 %w/w	Not more than 2.5 % w/w
	(determine on 0.200gm)		
7.0	Sulphated ash	0.03 %w/w	Maximum 0.1% w/w
	(determine on 1.0 gm)		
8.0	Assay by HPLC	99.4 %w/w	98.0 % to 102.0 % w/w
	(On anhydrous basis)		

			Date of Approval: 19/01/18
	Prepared by	Checked by	Approved by
Sign / Date	A1502/18	1502113	( July 18/03/18
Name:	Ankur Sheth	Mahendra Ravalji	Manish Shah
Designation:	Executive (QC)	Sr.Executive (QC)	Manager (QC)
		Forms	+ No OCD/GEN/033/FL-01

Page 1 of 2



## Amoli Organics Pvt. Ltd.





QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

PRODUCT:	Sildenafil Citrate (SCC)		**************************************
Standard For Release:	Ph.Eur	Mfg.Lic no. :	G/1518
Batch No.:	SCC/1801B/7002	A.R. No. :	FP/18/00069/08
Batch size:	160.69 Kg	Date of sampling:	11/01/18
Mfg. date:	JAN - 2018	Retest date:	DEC - 2022

Sr. No.	Test name	Test result	Acceptance criteria	
Addition	ial tests			
9.0	Residual solvent by GC			
	a) Methanol	Not detected	Not more than 3000 ppm	
	b) Methylene dichloride	Not detected	Not more than 600 ppm	
10.0	Triethylamine	Not detected	Not more than 320 ppm	
11.0	Polymorphism # (By XRD)	Complies	X-ray diffraction pattern of test sample should be match with 20 value - 8.08, 10.29, 14.40, 19.87, 22.66 ±0.2	
12.0	Melting point by DSC #			
	Form - I (SCC)	197.1°C	DSC curve shows sharp onset at about 199° C	
13.0	Particle size By Malvern			
	D(0.5)	12.7 µm	For information	
	D(0.9)	28.3 µm	Less than 100 µm	
14.0	Bulk density	0.38 g/mL	Minimum 0.25 g/mL	

SO No.: 00302

Remarks: The product complies with Ph.Eur - 9.0 and customer specification (Wings).

Approved / Rejected

# INDOCO ANALYTICAL SOLUTIONS A

A.R.No.: IASE18010337 (XRD)

# INDOCO ANALYTICAL SOLUTIONS

A.R.No.: IASE18010417 (DSC)

Date of Approval: 19/01/18

		Date of Approval, 19701710
Prepared by	Checked by	Approved by
A15/02/18	15/00/18	(Jee 15/02/18
Ankur Sheth	Mahendra Ravalji	Manish Shah
Executive (QC)	Sr.Executive (QC)	Manager (QC)
	Arkur Sheth	Ankur Sheth  Executive (QC)  Mahendra Ravalji  Sr. Executive (QC)

Format No.:QCD/GEN/033/F1-01