



Amoli Organics Pvt. Ltd.

Factory : BLOCK NO. 422, ECP CANAL ROAD, VILLAGE LUNA, TA : PADRA, DIST : VADODARA, INDIA, PIN CODE 391440
Phone : (91) (02662) 811200
E-mail Address : baroda@amoliindia.com

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
1.0	Appearance	White, slightly hygroscopic, crystalline powder.	White or almost white, slightly hygroscopic, crystalline powder.
2.0	Solubility	Slightly soluble in water and in methanol, practically insoluble in hexane.	Slightly soluble in water and in methanol, practically insoluble in hexane.
3.0	Identification by I.R.	IR spectrum of the test sample is concordant with that of standard.	IR spectrum of the test sample should be concordant with that of 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 (determine on 0.200gm)	1.7 %w/w	Not more than 2.5 % w/w
7.0	Sulphated ash (determine on 1.0 gm)	0.03 %w/w	Maximum 0.1% w/w
8.0	Assay by HPLC (On anhydrous basis)	99.4 %w/w	98.0 % to 102.0 % w/w

	Prepared by	Checked by	Date of Approval: 19/01/18
Sign / Date	<i>Ankur Sheth</i>	<i>Mahendra Ravalji</i>	<i>Manish Shah</i>
Name :	Ankur Sheth	Mahendra Ravalji	Manish Shah
Designation :	Executive (QC)	Sr.Executive (QC)	Manager (QC)

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



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@amolindia.com

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Sr. No.	Test name	Test result	Acceptance criteria
Additional 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 2θ 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.R.No. : IASE18010337 (XRD)

INDOCO ANALYTICAL SOLUTIONS A.R.No. : IASE18010417 (DSC)

Date of Approval: 19/01/18			
Sign / Date	Prepared by <i>Ankur Sheth</i> 15/02/18	Checked by <i>Mahendra Ravalji</i> 15/02/18	Approved by <i>Manish Shah</i> 15/02/18
Name :	Ankur Sheth	Mahendra Ravalji	Manish Shah
Designation :	Executive (QC)	Sr.Executive (QC)	Manager (QC)

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