



Amoli Organics Pvt. Ltd.

Factory : BLOCK NO. 422, ECP CANAL ROAD, VILLAGE LUNA, TA : PADRA, DIST : VADODARA, INDIA. PIN CODE 391440
Phone : (91) (02662) 300200 * Fax : (91) (02662) 300201
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/1706B/0005 ✓	A.R. No. :	FP/17/01294/03
Batch size :	17.00 kg	Date of sampling :	09/06/17
Mfg. date :	JUN - 2017	Retest date :	MAY - 2021 ✓

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	a) Not more than 0.3 %
	b) Unspecified impurity	Below disregarded limit	b) Not more than 0.10 %
	c) Sum of unspecified impurities	Below disregarded limit	c) Not more than 0.3 %
	d) Total impurities	Below disregarded limit	d) Not more than 0.5 %
6.0	Heavy metal	Less than 20 ppm	Not more than 20 ppm
7.0	Water content by KF	2.0 % w/w	Not more than 2.5 % w/w
8.0	Sulphated ash	0.03 % w/w	Not more than 0.1 % w/w
9.0	Assay by HPLC (On anhydrous basis)	99.6 % w/w	98.0 % to 102.0 % w/w

Date of Approval : 24/06/17

	Prepared by	Checked by	Approved by
Sign / Date	<i>Ankur Sheth</i> 26/06/17	<i>Urvashi Mahida</i> 26/06/17	<i>Manish Shah</i> 26/06/17
Name :	Ankur Sheth	Urvashi Mahida	Manish Shah
Designation :	Executive (QC)	Asst. Manager (QC)	Manager (QC)

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



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10.0	Residual solvent by GC		
	a) Methanol	19 ppm	Not more than 3000 ppm
	b) Methylene dichloride	Not detected	Not more than 600 ppm
11.0	Triethylamine	Not detected	Not more than 320 ppm
Additional tests			
12.0	X- ray Diffraction #	Complies	X-ray diffraction Pattern of test sample should be match with 2 θ value - 8.08, 10.29, 14.40, 19.87, 22.66 $\pm$ 0.2.
13.0	Melting point by DSC #		
	Form - I (SCC)	195.7°C	DSC curve shows sharp onset at about 199° C
14.0	Particle size by Malvern		
	D(0.5)	8.1 μ m	For information
	D(0.9)	36.9 μ m	Less than 100 μ m
15.0	Bulk density	0.26 g/mL	Minimum 0.25 g/mL

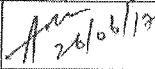
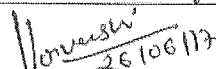
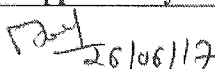
SO No.: 00023

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

Approved / Rejected

INDOCO ANALYTICAL SOLUTIONS A.R.No. : IASE17060302 (XRD & DSC)

Date of Approval : 24/06/17

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Sign / Date	 26/06/17	 26/06/17	 26/06/17
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