

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

ORIGINAL

PRODUCT :	Sildenafil Citrate		
Standard For Release :	EP	Mfg.Lic no. :	G/1518

Batch No.:	SCC/1504B/0010	A.R. No. :	FP/15/00393/03
Batch size :	16.60 kg	Date of sampling :	18/04/15
Mfg. date :	APR-2015	Retest date :	MAR-2018

Sr. No.	Test name	Test result	Acceptance criteria
Additional Tests			
10.0	Residual solvent		
	a) Methanol	10 ppm	a) Not more than 3000ppm
	b) Methylene dichloride	Not detected	b) Not more than 600ppm
	c) Triethylamine	1 ppm	c) Not more than 320ppm
11.0	Melting point by DSC		
	Form - I (SCC)	194.1°C	DSC curve shows sharp onset at about 199° C
12.0	X- ray Diffraction for form - I	X-ray diffraction Pattern of test sample concordant with Sildenafil Citrate (SCC) polymorph form-I working standard.	X-ray diffraction Pattern of test sample concordant with Sildenafil Citrate (SCC) polymorph form-I working standard.
13.0	Particle size by Malvern*		
	D(0.5)	7.6 µm	For information
	D(0.9)	18.3 µm	Less than 100 µm
14.0	Bulk density*	0.37 g/mL	Minimum 0.25 g/mL

SO No.: 00155

Remarks: The product complies with EP and customer specification. (*Wings)

Approved / Rejected

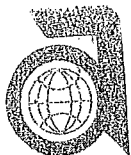
		Date of Approval: 07/02/16	
Sign / Date	Prepared by	Checked by	Approved by
	<i>[Signature]</i> 07/02/16	<i>[Signature]</i> 07/02/16	<i>[Signature]</i> 07/02/16
Name :	Gulshan Kumar	Mahendra Ravalji	Manish Shah
Designation :	Officer (QC)	Executive (QC)	Asst. Manager (QC)

Format No. QC/GEN/033/F1-01

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Corporate Office : 407, Dalamal House, Jamnalal Bajaj Road, Nariman Point, Mumbai-400045, INDIA
Phone : 91-22-22854715 / 16 / 17 * Fax : 22041400
E-mail Address : info@amoliindia.com



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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 more than 0.1%
5.0	Related substances (By HPLC)		
	a) Impurity A	Below disregarded limit	a) Not more than 0.3%
	b) Unspecified impurity	0.06 %	b) Not more than 0.10%
	c) Sum of unspecified impurities	0.06 %	c) Not more than 0.3%
	d) Total impurities	0.06 %	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	0.96 %w/w	Not more than 2.5% w/w
8.0	Sulphated ash	0.06%w/w	Not more than 0.1% w/w
9.0	Assay by HPLC (On anhydrous basis)	99.1 %w/w	98.0% to 102.0% w/w

Sign / Date	Prepared by <i>[Signature]</i> 07/02/16	Checked by <i>[Signature]</i> 07/02/16	Date of Approval: 07/02/16 Approved by <i>[Signature]</i> 07/02/16
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