



# 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		
Standard For Release :	EP	Mfg. Lic no. :	G/1518

Batch No.:	SCC/1505B/0013	A.R. No. :	FP/15/00637/05
Batch size :	16.90 kg	Date of sampling :	18/05/15
Mfg. date :	MAY-2015	Retest date :	APR-2019

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	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	1.04%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)	99.2 %w/w	98.0% to 102.0% w/w

SILDENAFIL CITRATO

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Lot: 0057511

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QC-0072527

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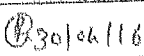
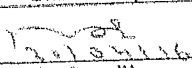

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Amoli Organics Pvt. Ltd. is a ISO 9001:2008 certified company. The product is manufactured under strict quality control. The product is free from any harmful impurities. The product is stable and does not require any special storage conditions. The product is suitable for use in the treatment of erectile dysfunction. The product is available in various strengths. The product is manufactured in India. The product is exported to various countries. The product is sold through various channels. The product is available at a competitive price. The product is of high quality. The product is safe for use. The product is effective. The product is reliable. The product is of good value for money. The product is of good quality. The product is safe for use. The product is effective. The product is reliable. The product is of good value for money.

Date of Approval: 30/04/16

	Prepared by	Checked by	Approved by
Sign / Date			
Name :	Ravi Patel	Mahendra Ruvalji	Manish Shah
Designation :	Officer (QC)	Executive (QC)	Asst. Manager (QC)

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

Page 1 of 2

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# Amoli Organics Pvt. Ltd.

Factory BLOCK NO. 422, EGP CANAL ROAD, VILLAGE LUNA, TA. PAJRA, DIST. VAUGHDA, INDIA PIN CODE 381440  
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E-mail Address : amolindia@gmail.com

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<b>Additional Tests</b>			
10.0	Residual solvent		
	a) Methanol	95 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)	194.7°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)	9.8 µm	For information
	D(0.9)	24.6 µm	Less than 100 µm
14.0	Bulk density*	0.26 g/mL	Minimum 0.25 g/mL

SO No.: 00019

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

Approved / Rejected

	Prepared by	Checked by	Date of Approval: 30/04/16 Approved by
Sign / Date	<i>Ravi Patel</i> 30/04/16	<i>Manish Shah</i> 30/04/16	
Name :	Ravi Patel	Manish Shah	
Designation :	Officer (QC)	Executive (QC)	Asst. Manager (QC)

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

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