

Amoli Organics Pvt. Ltd.

Amoli Organics Pvt. Ltd. (A.O.P.) is a leading manufacturer and exporter of various pharmaceuticals and chemicals. The company is located at Amoli, District - Amli, Gujarat - 388 120. The company is registered with the Ministry of Health, Government of India, and is a member of the Indian Pharmaceutical Association (IPA).

QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

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

Batch No.:	SCC/1501B/001B ✓	A.R. No. :	FP/15/00116/03
Batch size :	66.10 kg	Date of sampling :	24/01/15
Mfg. date :	JAN-2015	Retest date :	DEC-2017 ✓

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	Not detected	a) Not more than 0.3%
	b) Unspecified impurity	0.05 %	b) Not more than 0.10%
	c) Sum of unspecified impurities	0.05 %	c) Not more than 0.3%
	d) Total impurities	0.05 %	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)	98.7 %w/w	98.0% to 102.0% w/w

Date of Approval: 31/01/15

Sign / Date	Prepared by	Checked by	Approved by
	KP 27/03/15	KK 27/03/15	BK 27/03/15
Name :	Krishna Patel	Ketul Kaka	Bhavesh Kharva
Designation :	Officer (QC)	Sr.Executive (QC)	Asst.Manager (QC)

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

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Additional Tests			
10.0	Residual solvent		
	a) Methanol	52 ppm	a) Not more than 3000ppm
	b) Methylene dichloride	Not detected	b) Not more than 600ppm
	c) Triethylamine	2 ppm	c) Not more than 320ppm
11.0	Melting point by DSC		
	Form - I (SCC)	194.4°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)	7.05 µm	For information
	D(0.9)	26.78 µm	Less than 100 µm
14.0	Bulk density*	0.32 g/mL	Minimum 0.25 g/mL

SO No.: 00177

Remarks: The product complies with EP and customer specification.

Approved / Rejected

Date of Approval: 31/01/15

Sign / Date	Prepared by	Checked by	Approved by
	Kt. 29/03/15	Kt. 29/03/15	Bh. 29/03/15
Name :	Krishna Patel	Ketul Kaka	Bhavesht Kharva
Designation :	Officer (QC)	Sr.Executive (QC)	Asst.Manager (QC)

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