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:	**Venlafaxine Hydrochloride**		
Standard For Release:	USP	Mfg.Lic no.:	G/1518

Batch No.:	VLF/1606B/0080J1	A.R. No.:	FP/16/01246/01
Batch size:	160.10 kg	Date of sampling:	27/06/16
Mfg. date:	JUN-2016	Exp date:	MAY-2021

Sr. No.	Test name	Test result	Acceptance criteria
1.0	Description	White crystalline powder	Off white to white crystalline powder.
2.0	Solubility	Soluble in methanol and in water	Soluble in methanol and in water
3.0	Identification		
	A. I.R.	A. IR spectrum of the test sample is concordant with that of standard.	A. IR spectrum of the test sample should be concordant with that of standard.
	B. By HPLC	B. Retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay	B. The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay
	C. Chloride	C.White, curdy precipitate is formed	C.A white, curdy precipitate should be formed
4.0	Assay (By HPLC) (On dried basis)	99.2 %w/w	Not less than 98.0% and Not more than 102.0% w/w
5.0	Residue on ignition	0.04 %w/w	Not more than 0.1%w/w
6.0	Heavy metals	Less than 20 ppm	Not more than 20 ppm

05/07/16
Date of Approval: 30/06/16

	Prepared by	Checked by	Approved by
Sign / Date	30/06/16	30/06/16	30/06/16
Name	Ankur Sheth	Mahendra Ravalji	Manish Shah
Designation	Sr.Officer (QC)	Executive (QC)	Dy.Manager (QC)

Format No.:QCD/GEN/03?/F1-01

Corporate Office : 407, Dalamal House, Jamnalal Bajaj Road, Nariman Point, Mumbai-400 021. 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
7.0	Organic impurities (By HPLC)		
	a) Descyclohexanol venlafaxine	Not detected	a) Not more than 0.15%
	b) Didesmethyl venlafaxine	Not detected	b) Not more than 0.15%
	c) Venlafaxine related compound A	Below Disregarded Limit	c) Not more than 0.15%
	d) Deoxy venlafaxine	Not detected	d) Not more than 0.15%
	e) Any unknown individual impurity	Below Disregarded Limit	e) Not more than 0.10%
	f) Total Impurities	Below Disregarded Limit	f) Not more than 0.5%
8.0	Loss on drying (Under vacuum at 105°C for 3 Hrs.)	0.25 %w/w	Not more than 0.5%w/w
Additional Test			
9.0	Residual solvent		
	a) Methanol	Not detected	a) Not more than 1000ppm
	b) Ethanol	Not detected	b) Not more than 1000ppm
	c) Isopropyl Alcohol	59 ppm	c) Not more than 3000ppm
	d) Ethyl Acetate	Not detected	d) Not more than 1000ppm
	e) Isopropyl acetate	Not detected	e) Not more than 300ppm
	f) Toluene	1 ppm	f) Not more than 500ppm
10.0	Particles size	13.5 µm	100% Less than 75 µm

SO No.: 00290

Remarks: **The product complies with USP and customer Specification (*Umedica).**

Approved / ~~Rejected~~

Date of Approval: 30/06/16

	Prepared by	Checked by	Approved by
Sign / Date	30/06/16	30/06/16	30/06/16
Name	Ankur Sheth	Mahendra Ravalji	Manish Shah
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