

CERTIFICATE OF ANALYSIS

Standard product specification

Venlafaxine EP Impurity D

Formulated product · EP Reference Standard Grade

1. PRODUCT IDENTITY

Product name	Venlafaxine EP Impurity D
C.A.S. number	Applicable to blend — on request
Grade / standard	EP Reference Standard Grade
Description	White to off-white powder
Product group	Pharma Reference Standard
Category	Laboratory & Analytical Reagents
Country of origin	India
Packing	Bags, drums, carboys, IBC or ISO tank as applicable — customer-specified packing available
Storage	Cool, dry, well-ventilated place in tightly closed original packing

2. ANALYTICAL SPECIFICATION

S. NO.	TEST PARAMETER	SPECIFICATION	TYPICAL RESULT	METHOD
1	Description	White to off-white powder	Complies	Visual
2	Identification (A) — Infrared absorption	Concordant with reference spectrum	Complies	IR Spectrophotometry
3	Identification (B) — Chemical / chromatographic	Positive for the substance	Complies	As per monograph
4	Solubility	As per specification	Complies	Visual / Monograph
5	Assay (on dried basis)	98.0 – 102.0 % w/w	99.47	HPLC / Titrimetry (Monograph)
6	Matter Insoluble in Water	Not more than 0.01 % w/w	0.0049	Gravimetry
7	pH (5 % aqueous solution)	As per specification	8.0	Potentiometry

8	Chloride (Cl)	Not more than 0.001 %	0.00041	Turbidimetry
9	Sulphate (SO ₄)	Not more than 0.002 %	0.00046	Turbidimetry
10	Iron (Fe)	Not more than 5 ppm	1.23 ppm	ICP-OES
11	Heavy Metals (as Pb)	Not more than 5 ppm	Less than 2 ppm	ICP-OES
12	Loss on Drying	Not more than 1.0 % w/w	0.31	Gravimetry (Monograph)
13	Sulphated Ash / Residue on Ignition	Not more than 0.1 % w/w	0.028	Gravimetry (Monograph)
14	Related Substances — any individual impurity	Not more than 0.10 %	0.030	HPLC
15	Related Substances — total impurities	Not more than 0.50 %	0.226	HPLC
16	Residual Solvents	Complies with ICH Q3C limits	Complies	Headspace GC

3. DECLARATION

This document sets out the standard specification for Venlafaxine EP Impurity D and applies to all consignments of this product and grade supplied by Scapex Exports Pvt. Ltd. It is not a lot-specific release document; a lot-specific certificate carrying the analysis of the material actually shipped is issued with, and travels with, each consignment. Scapex Exports supplies against customer-specified assay limits and pharmacopoeial standards — send your specification sheet and we confirm compliance in writing before the order is accepted.



Scapex Exports Pvt. Ltd. · Ahmedabad, Gujarat, India · info@scapexexports.com · +91 9925522674 — system-generated document, valid without physical signature.