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CIN U46909GJ2025PTC164345

CERTIFICATE OF ANALYSIS Standard product specification

Tacrolimus (FK506)

CAS 104987-11-3 · USP/EP

1. PRODUCT IDENTITY

Product name	Tacrolimus (FK506)
C.A.S. number	104987-11-3
Grade / standard	USP/EP
Description	White crystalline powder
Product group	Immunosuppressant APIs
Category	Active Pharmaceutical Ingredients (APIs)
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 crystalline 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	100.30	HPLC / Titrimetry (Monograph)
6	Clarity & Colour of Solution	Clear; not more intensely coloured than reference	Complies	Visual (Monograph)

7	pH (1 % w/v aqueous solution)	As per monograph	6.2	Potentiometry
8	Water Content (Karl Fischer)	Not more than 0.5 % w/w	0.23	Karl Fischer titration
9	Melting Range / Point	As per monograph	Complies	Capillary method
10	Particle Size (d90)	As per specification	208 µm	Laser diffraction
11	Sulphated Ash / Residue on Ignition	Not more than 0.1 % w/w	0.040	Gravimetry (Monograph)
12	Heavy Metals	Not more than 20 ppm	Less than 10 ppm	ICP-OES / Limit test
13	Related Substances — any individual impurity	Not more than 0.10 %	0.012	HPLC
14	Related Substances — total impurities	Not more than 0.50 %	0.087	HPLC
15	Residual Solvents	Complies with ICH Q3C limits	Complies	Headspace GC

3. DECLARATION

This document sets out the standard specification for Tacrolimus (FK506) 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.

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