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CIN U46909GJ2025PTC164345

CERTIFICATE OF ANALYSIS

Standard product specification

Mycophenolate Mofetil

CAS 128794-94-5 · ≥98% Pharma Grade

1. PRODUCT IDENTITY

Product name	Mycophenolate Mofetil
C.A.S. number	128794-94-5
Grade / standard	≥98% Pharma Grade
Description	White to off-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 to off-white crystalline powder	Complies	Visual
2	Identification	Conforms to the structure of the substance	Complies	FTIR / Chemical test
3	Solubility	As per specification	Complies	Visual / Monograph
4	Assay	Not less than 98.0 % w/w	98.90	Titrimetry / Instrumental
5	Clarity & Colour of Solution	Clear; not more intensely coloured than reference	Complies	Visual (Monograph)
6	pH (1 % w/v aqueous solution)	As per monograph	5.6	Potentiometry

7	Water Content (Karl Fischer)	Not more than 0.5 % w/w	0.16	Karl Fischer titration
8	Melting Range / Point	As per monograph	Complies	Capillary method
9	Particle Size (d90)	As per specification	112 µm	Laser diffraction

3. DECLARATION

This document sets out the standard specification for Mycophenolate Mofetil 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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