METAPHARMACEUTICAL IND SL
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MICOFENOLATO MOFETIL (EUR. PH.)

PRODUCT CODE: 151294	CAS Nº: 128794-94-5	ANALYSIS Nº: 326/25	
MANUFACTURER BATCH:	MPM20250801	CERTIFICATE ID:	48.740
SUPPLIER BATCH:	----	MANUFACTURING DATE:	03/08/2025
METAPH BATCH:	0171025	EXPIRY DATE:	02/08/2029

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White fine crystalline powder
Solubility	Practically insoluble in water, freely soluble in acetone, sparingly soluble in anhydrous ethanol	Complies (*)
Melting point	About 96 ºC	96.9 ºC
Identification	Complies	Complies
Appearance of solution	Clear and colourless	Clear and colourless
Related substances		
Impurity F	=< 0.5 %	0.1 %
Impurity B	=< 0.2 %	< 0.05 %
Impurity A	=< 0.1 %	< 0.05 %
Impurity D	=< 0.1 %	Not Detected
Impurity E	=< 0.1 %	Not Detected
Impurity G	=< 0.1 %	Not Detected
Impurity H	=< 0.1 %	0.10 %
Any other impurity	=< 0.1 %	< 0.05 %
Total impurities	=< 0.7 %	0.2 %
Loss on drying	=< 0.5 %	0.02 %
Sulfated ash	=< 0.1 %	0.04 %
Assay	98.0 - 102.0 %	100.7 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliance with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Mycophenolate Mofetil is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

All data controlled by Metapharmaceutical Industrial SL.
(*) Data adapted from the manufacturer's certificate of analysis.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Store in tight container up to 25°C protected from light.

Analysis date: 22/10/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000349
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