



TECHNICAL DATA SHEET

151294-TDS-ENG-2024

MICOFENOLATO MOFETIL (EUR. PH.)		
DESCRIPTION DCI: MYCOPHENOLATE MOFETIL		DESCRIPTION DOE: MICOFENOLATO DE MOFETILO
CAS Nº: 128794-94-5	EC Nº: 627-027-6	AEMPS CODE: 7330LM
MOL. WEIGHT: 433,49	MOL. FORMULA: C ₂₃ H ₃₁ NO ₇	ARTICLE CODE: 151294

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Practically insoluble in water, freely soluble in acetone, sparingly soluble in anhydrous ethanol
Melting point	About 96 °C
Identification	Complies
Appearance of solution	Clear and colourless
Related substances	
Impurity F	=< 0.5 %
Impurity B	=< 0.2 %
Impurity A	=< 0.1 %
Impurity D	=< 0.1 %
Impurity E	=< 0.1 %
Impurity G	=< 0.1 %
Impurity H	=< 0.1 %
Any other impurity	=< 0.1 %
Total impurities	=< 0.7 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.0 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

REMARKS

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

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.