B7/10820

TEVA CZECH INDUSTRIES S.R.O., Ostravska 29/305, 747 70 OPAVA - KOMAROV, CZECH REPUBLIC

PRODUCT SPECIFICATIONS AND CERTIFICATE OF ANALYSIS

Product Name: MYCOPHENOLATE MOFETIL

Control No.: 74402007917 **Order No.:** JU70042901

Client Packing Order: 160827

Customer Name: TEVA PHARMACEUTICAL WORKS-DEBRECEN

Quantity: 322.700 KG **Quality Market:** EUR

Manufacturing Site: Opava. Czech Republic **Original Analysis Date:** May 2017

Manufacturing Date: May 2017 **Re Test date:** May 2022

Packaging and storage: Preserve in tight container and store at room temperature.

TESTS AND METHODS	SPECIFICATIONS	RESULTS*
	SV-744020-01, rev.3 TESTS	
Apperance *Visual*	A white to off-white crystalline powder.	Complies
Identity (IR) *EP, 2.2.24*	The IR spectrum of the tested substance exhibits maxima at the same wavelengths as that of the reference standard obtained under the same conditions.	Complies
Identity (HPLC) *AM-AQC-LC1067*	Retention time of the principal peak in the chromatogram of the tested substance corresponds to the retention time of the peak in chromatogram of the reference standard.	Complies
Related substances *EP, 2.2.29, AM-AQC-LC1067*		
Mycophenolic acid (MPA)	NMT 0.30 %	0.04%
Lactone of MPA	NMT 0.10 %	Less than 0.02%
Methylester of MPA	NMT 0.10 %	Less than 0.02%
Other impurities individually	NMT 0.10 %	0.04%
Total impurities	NMT 0.70 %	0.12%
Loss on drying *EP, 2.2.32*	NMT 0.5 %	0.1%
Clarity of solution *EP, 2.2.1*	Clear	Complies

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TESTS AND METHODS	SPECIFICATIONS	RESULTS*
SV-744020-01, rev.3 TESTS		
Colour of solution *EP, 2.2.2, method II*	Colourless	Complies
Organic residual solvents *AM-AQC-GC1050* Butyl acetate Dibutylether	 NMT 5000 ppm NMT 500 ppm	 205ppm Less than 25ppm
Assay (TITR) *EP, 2.2.20, AM-RD-TI011*	98.0 to 102.0 % recalculated on dried basis	99.7%
Sulphated ash *EP (2.4.14) or* *AM-AQC-OT1176*	NMT 0.1 %	Less than 0.1%
Heavy metals *EP, 2.4.8, Method C or* *AM-AQC-OT1193*	NMT 20 ppm	Less than 20ppm
CS05, rev.5 TESTS		
Particle size *ARD- 41464* 10 % 50 % 90 %	 NMT 30 um NMT 80 um NMT 140 um	 17um 46um 86um
Bulk density *EP, (2.9.34 met.1)*	NMT 0.70 g/ml	0.50g/ml

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TESTS AND METHODS	SPECIFICATIONS	RESULTS*
	CS05, rev.5 TESTS	
Tapped density *EP, (2.9.34 met.1)*	NMT 0.90 g/ml	0.77g/ml

Remarks:

1. Conforms to the requirements of the SV-744020-01, rev.3 and CS05, rev.5 Specifications.
2. Conforms to the current EP monograph and the In house tests.
3. The following residual solvents Class 1, as defined in the ICH Q3C, benzene, carbon tetrachloride, 1,2-Dichloroethane, 1,1-Dichloroethene and 1,1,1- Trichloroethane are not present in the Active Pharmaceutical ingredient.
4. The product meets the requirements for residual solvents USP <467>, EP 5.4 and ICH guide Q3C.
5. The product has been produced and controlled in compliance with GMP rules and valid documentation. Tested parameters comply with the approved specification.
6. We declare that the batch was produced according to the currently valid R1-CEP 2005-239-Rev 01.

Released by Quality Control Manager: **Bohumir Biba**	**Signature**:** PP\ Vitezslav Branda 29 May 2017 9:42:23
	Print Date: 29 May 2017
	QA Approval: Marek Dominik

(*) Upon completion of the 'Results' column this document becomes a certificate of analysis **End of C.O.A.**

(**) This document was signed electronically and this is the manifestation of the electronic signature.