

NA: 200900080

Certificate of Analysis

Micofenolato Mofetilo 500 mg film-coated tablets 50x, Chile

Batch Number:	3450120	Item Code:	80032010
Bulk Batch Number:	0A45EK		
Date of Manufacture:	January-2020	Expiry Date:	January-2023
Date of Analysis:	28-Jan-2020		
Reference:	SIDR002753/2		

Test	Specification	Result
Description	Pale purple, oval shaped film-coated tablet, debossed with "M500" on one side and plain on the other side.	Conforms
Identification of Mycophenolate Mofetil (HPLC)	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that of the standard preparation as obtained in the Assay.	Conforms
Identification of Mycophenolate Mofetil (UV)	The UV spectra of the test and standard solutions, as obtained in the identification test, exhibit maxima and minima of the same wavelengths.	Conforms
Identification of Titanium dioxide	An orange red colour must be produced.	Performed Periodically
Identification of Iron oxide	A blue colour must be produced.	Performed Periodically
Identification of Indigocarmine (HPLC)	The retention time of the indigocarmine peaks in the chromatogram of the Sample solution corresponds to that of the major peaks in the chromatogram of the Standard solution.	Performed Periodically
Uniformity of Dosage Units by Mass Variation	Conforms to the current Ph. Eur. 2.9.40.	Conforms
Uniformity of Dosage Units by Mass Variation AV	NMT 15.0	2.9
Dissolution (UV) (within 30 minutes) (labelled amount)	Not less than 80 % (Q) of the labelled amount is dissolved in 30 minutes. (Acceptance criteria: current Ph. Eur. 2.9.3.)	96 - 97 %
Range		
Stage Passed		1
Mean		97 %
Assay (HPLC) (labelled amount)	NLT 95.0 & NMT 105.0 %	100.3 %
Impurities/Degradation Products (HPLC)		
Mycophenolic acid	NMT 1.0 %	0.09 %

TEVA Pharmaceutical Works Private Limited Company H-4042, Hungary, Debrecen, Pallagi út 13

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Date of Manufacture:	January-2020	Expiry Date:	January-2023
Date of Analysis:	28-Jan-2020		
Reference:	SDIR002753/2		

Test	Specification	Result
Any unknown	NMT 0.10 %	0.03 %
Total impurities	NMT 1.5 %	0.13 %
Microbiological quality		
Total aerobic microbial count	Not more than 10^3 CFU/g	Performed Periodically
Total yeasts and moulds count	Not more than 10^2 CFU/g	Performed Periodically
Escherichia coli	Absence in 1 g	Performed Periodically

It is hereby certified that the above material has been checked in accordance with the principles of Good Manufacturing Practice and complies with the requirements of the registration file.

Lot Approved By:	Dr. Kéri Vilmosné
Title:	QC Supervisor
Issued by:	Rácskai Erika
	QA Assistant
Date of Issue:	11/Feb/2020 11:07:40

As this document has been generated in a validated laboratory information management system, this document has been electronically signed.



Manufacturer's Batch Certificate for
Medicinal Products Exported

1. Name of product.

Micofenolato mofetilo 500 mg filmtablets 50x

2. Importing Country.

Chile

3. Marketing Authorisation Number / Procedure Number.

F-18229/10 / national

4. Strength/Potency.

Mycophenolate mofetil 500 mg

5. Dosage form (pharmaceutical form).

film-coated tablets

6. Package size (contents of container) and type (e.g. vials, bottles, blisters).

5 x 10 tablets in blister/box, total quantity: 7550 boxes

7. Lot/batch number.

3450120

8. Date of fabrication/manufacture.

01. 2020

Packaging date.

01. 2020

9. Expiry date.

01. 2023

10. Name, address and authorisation number.

TEVA Pharmaceutical Works Private Limited Company
Pallagi str. 13.
H-4042 Debrecen
Hungary
HU-M-TEVA

Manufacturing	☒
Packaging	☒
QC	☒
Release	☒



11. Number of GMP Compliance of all sites listed under 10.

OGYÉI/53191-6/2017

12. Results of analysis.

Attached

Reference No.: 704,381

13. Comments/remarks.

- ☒ No deviation occurred during production, packaging or testing.
☐ Occurred deviation was appropriately investigated and resolved.
Record ID :
☐ Product was reworked
☐ It was the validation batch
☒ Change Control Procedure ID : 1336203

API Manufacturing site

Name: Teva Czech Industries S.R.O.,

Address: Ostravska 29/305, 747 70, Opava-Komarov, Czech Republic

Authorization number: N/A

Eudra GMP reference number or certificate of GMP Compliance: suks197490/2016

Artwork reference number:

PIL: 20078330 0419
Label: N/A
Blister: M557
Box: 20078330 0918

Finished product storage condition: Do not store above 25°C.

Release date: 06/02/2020

Technical Agreement number : N/A

14. Certification statement.

"I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP".

15. Name and position/title of person authorising the batch release.

Magdolna Molnár Bőjtös Pharm.D.

Qualified Person

Quality Assurance Division

16. Signature:

17. Date: 11 February 2020

EUVA 197490/2016
Teva Pharmaceutical Works
Limited
Quality Assurance Division
Debrecen, Hungary

Teva Pharmaceuticals Ltd.
Quality Assurance Division

Authorisation Number HU-M-TEVA

Number of GMP Compliance: OGYÉI/53191-6/2017

H-4042 Debrecen, Pallagi út 13. | Tel: +36 52 515 100 | Fax: +36 52 515 119

Item code: 80032010



Commercial Invoice

Invoice No.: 12088100311

Invoice Date: 12.02.2020

Supplier:TEVA PHARMACEUTICAL WORKS PRIVATE LIMITED
COMPANY

Debrecen, Pallagi, út, 13. Hungary 4042

Tel.: Fax:

Bank: CITI BANK ZRT.**SWIFT:** CITIHHX**IBAN:** HU47108000072100105100000000**Acc.No.:** 10800007-21001051-00000000**VAT No.:** HU10318353**Tax No.:** 10318353-2-09**Payment Terms:** Net Due in 90 Days**Buyer:**

LABORATORIO CHILE S.A.

Chile

9978 SANTIAGO

Av. Maratón 1315,

Mean of transport: OCEAN**At the disposal of:** BUYER**Insurance covered by:** us**Consignee:**

LABORATORIO CHILE S.A.

Chile

9978 SANTIAGO

Av. Maratón 1315,

Place of dispatch:

Debrecen, Hungary

Place of destination:

SANTIAGO, Chile

Currency	Payment Method	Delivery Date	Delivery Terms				
USD	WIREHU	12.02.2020	CIF				
Number and kind of packages, description of goods							
Customer Itemno	Quantity	U/M	Unit Price	Net Unit Price	Discount Per Unit	VAT %	Net Amount
Rimox 1mg film-coated tablet 30x, Chile 120-10-80451	10.080,00	EA	3,51000	3,51000	0,00	0	35.380,80
Micofenolato Mofetilo 250 mg capsules 100x, Chile 120-10-76775	5.950,00	EA	6,75000	6,75000	0,00	0	40.162,50
Citalopram 20mg tablet 30x, Chile 120-10-80690	31.990,00	EA	1,36000	1,36000	0,00	0	43.506,40
Micofenolato Mofetilo 500 mg film-coated tablets 50x, Chile 120-10-76783	13.555,00	EA	6,67000	6,67000	0,00	0	90.411,85
TACNI XR 5mg capsule 50x, Chile 120-10-80545	366,00	EA	281,88000	281,88000	0,00	0	103.168,08
Tax Total				VAT %	VAT Amount	Net Amount	Gross Amount
				0	0,00	312.629,63	312.629,63
Totals					VAT Amount	Net Amount	Total Payable
					0,00	312.629,63	312.629,63

VAT exemption is granted based on article 98. of Act on VAT No. 127 of 2007. Buyer is obliged to pay the VAT.

Gross Weight (kg): 3022.31

Measurement (m3): 25.2336

Net Weight (kg): 2145.51

LABORATORIO CHILE S.A.
AV. MARATÓN 1315
THE BOROUGH OF NUNOA
9978 SANTIAGO
CHILE

The exporter of the products covered by this document (customs authorisation No. HU711000N5001831987) declares that, except where otherwise clearly indicated, these products are of EU preferential origin.

B-NO:1-29



TEVA PHARMACEUTICAL WORKS PRIVATE LIMITED
Packing List for Invoice No: 12088100311 For Delivery: 13704044



Customer Product # : 120-10-76783 Micofenolato Mofetilo 500 mg film-coated tablets 50x, Chile

Manufacturer Item# : 80032010

Plant : TPW DEBRECEN MFG

Order : 1183655

Customer Ref: 242453

<u>Pallet No.</u>	<u>Packages</u>	<u>Quantity</u>	<u>Weight(Kg)</u>		<u>Lot No.</u>	<u>Expiry Date</u>	<u>Measures(m)</u>
			<u>Gross</u>	<u>Net</u>			
8	24 Cartons (24*70)	1,680.00	144.79	112.56	3440120	31-JAN-2023	0.8 X 1.2 X 1.03
9	12 Cartons (11*70+55)	825.00	81.89	55.28	3440120	31-JAN-2023	0.8 X 1.2 X 0.59
10	24 Cartons (24*70)	1,680.00	144.79	112.56	3450120	31-JAN-2023	0.8 X 1.2 X 1.03
11	24 Cartons (24*70)	1,680.00	144.79	112.56	3450120	31-JAN-2023	0.8 X 1.2 X 1.03
12	24 Cartons (24*70)	1,680.00	144.79	112.56	3450120	31-JAN-2023	0.8 X 1.2 X 1.03
13	24 Cartons (24*70)	1,680.00	144.79	112.56	3450120	31-JAN-2023	0.8 X 1.2 X 1.03
14	12 Cartons (11*70+60)	830.00	82.23	55.61	3450120	31-JAN-2023	0.8 X 1.2 X 0.59
15	24 Cartons (24*70)	1,680.00	144.79	112.56	3460120	31-JAN-2023	0.8 X 1.2 X 1.03
16	24 Cartons (24*70)	1,680.00	144.79	112.56	3460120	31-JAN-2023	0.8 X 1.2 X 1.03
17	2 Cartons (2*70)	140.00	31.32	9.38	3460120	31-JAN-2023	0.8 X 1.2 X 0.37
Total: 10 Pallets 194 Cartons		13,555.00 EA	1,209.0 Kg	908.2 Kg			8.41 m³

LOT Summary:

<u>Lot</u>	<u>Quantity</u>
3440120	2,505.00 EA
3450120	7,550.00 EA
3460120	3,500.00 EA

Customer Product # : 120-10-80451 Rimox 1mg film-coated tablet 30x, Chile

Manufacturer Item# : 84002425

Plant : TPW DEBRECEN MFG

Order : 1183654

Customer Ref: 242026

<u>Pallet No.</u>	<u>Packages</u>	<u>Quantity</u>	<u>Weight(Kg)</u>		<u>Lot No.</u>	<u>Expiry Date</u>	<u>Measures(m)</u>
			<u>Gross</u>	<u>Net</u>			
18	36 Cartons (36*120)	4,320.00	121.76	88.56	1491219	31-DEC-2021	0.8 X 1.2 X 1.07
19	36 Cartons (36*120)	4,320.00	121.76	88.56	1491219	31-DEC-2021	0.8 X 1.2 X 1.07
20	12 Cartons (12*120)	1,440.00	54.59	29.52	1491219	31-DEC-2021	0.8 X 1.2 X 0.61
Total: 3 Pallets 84 Cartons		10,080.00 EA	298.1 Kg	206.6 Kg			2.64 m³

LOT Summary:

<u>Lot</u>	<u>Quantity</u>
1491219	10,080.00 EA