NA: 1901000192

TEVA Pharmaceuticals Ltd.

# Certificate of Analysis

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

| | | | |
|---|---|---|---|
| **Batch Number:** | 3160918 | **Item Code:** | 80032010 |
| **Bulk Batch Number:** | 8L16EK | | |
| **Date of Manufacture:** | September-2018 | **Expiry Date:** | September-2021 |
| **Date of Analysis:** | 05-Oct-2018 | | |
| **Reference:** | SDIR002753/2 | | |

| 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<br>AV | NMT 15.0 | 2.4 |
| Dissolution (UV) (within 30 minutes) (labelled amount)<br>Range | Not less than 80 % (Q) of the labelled amount is dissolved in 30 minutes. (Acceptance criteria: current Ph. Eur. 2.9.3.) | 93 - 102 % |
| Stage Passed | | 1 |
| Mean | | 98 % |
| Assay (HPLC) (labelled amount) | NLT 95.0 & NMT 105.0 % | 99.6 % |
| Impurities/Degradation Products (HPLC)<br>Mycophenolic acid | NMT 1.0 % | 0.08 % |

*TEVA Pharmaceutical Works Private Limited Company H-4042, Hungary, Debrecen, Pallagi str. 13*



*Report: 642 211 90 SONE from LIMS PROD*

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| **Reference:** | SDIR0027532 | | |

| Test | Specification | Result |
|---|---|---|
| Any unknown | NMT 0.10 % | 0.03 % |
| Total impurities | NMT 1.5 % | 0.11 % |
| 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:** 05/Jan/2019 10:27:33

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