

19/11/2024

METAPHARMACEUTICAL

N DE LOTE:

0080124

Emcure



COPY-3



CERTIFICATE OF ANALYSIS

| | | | |
|------------------|--------------------------------|--------------|-------------|
| Name of Material | Mycophenolate Mofetil Ph.Eur. | | |
| Manufactured by | Emcure Pharmaceuticals Limited | | |
| A.R. No. | 40000903979 | Release Date | 20231229 |
| Batch No. | 10MN123137 | Quantity | 193.330 KG |
| Mfg. Date | 04.DEC.2023 | Exp. Date | 03.DEC.2028 |
| | | Page | 1 of 4 |

| Sr. No. | Tests | Specification | Results |
|---------|---|--|--|
| 1 | Appearance | White or almost white, crystalline powder. It melts about 96°C. | White crystalline powder. It melts at 95°C. |
| 2 | Solubility | Practically insoluble in water, freely soluble in acetone, sparingly soluble in anhydrous ethanol. | Practically insoluble in water, freely soluble in acetone, sparingly soluble in anhydrous ethanol. |
| 3 | Identification: | | |
| 4 | A) By Infrared absorption spectrophotometry | The infrared absorption spectrum of the Sample preparation should exhibit maxima at the same wavenumbers as that of similar preparation of corresponding standard. | Meets the requirement. |
| 5 | B) By HPLC | The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay by HPLC. | Meets the requirement. |
| 6 | Appearance of solution | The solution should be clear and colourless. | Meets the requirement. |
| 7 | Related substances by HPLC | | |
| | Impurity A | Not more than 0.1% | Below disregard limit. |
| | Impurity B | Not more than 0.2% | Not detected. |
| | Impurity D | Not more than 0.1% | Not detected. |

| | |
|----------------------------------|----------------------------|
| Prepared by : Kiran Phule | Approved by : Sanjay Thete |
| Date : 28.12.2023 | Date : 29.12.2023 |
| QC Personnel : ASSISTANT MANAGER | Head QA/Designee : MANAGER |

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Emcure Pharmaceuticals Limited

D - 24 & D - 24/1, M.I.D.C., Kurkumbh, Tal.Daund, Dist. Pune - 413 802

Phone Nos. : 02117 - 235742 / 350000 Telefax No. : 02117 - 235743

Registered Office : Emcure House, T-184, M.I.D.C., Bhosari, Pune 411 026. INDIA

Phone Nos. : +91 20 35010000, 40700000 Fax No. : 91 - 20 - 35010111 E.mail : corporate@emcure.co.in

CIN : U24231PN1981PLC024251, Website : www.emcure.com

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|---------|---|--|------------------------|
| | Impurity E | Not more than 0.1% | Not detected. |
| | Impurity F | Not more than 0.5% | 0.1% |
| | Impurity G | Not more than 0.1% | Not detected. |
| | Impurity H | Not more than 0.1% | Not detected. |
| | Any other impurity | Not more than 0.1% | Below disregard limit. |
| | Total impurities | Not more than 0.7% | 0.1% |
| 6 | Loss on drying | Maximum 0.5% w/w | 0.2%w/w |
| 18 | Sulfated ash | Maximum 0.1% w/w | 0.0% w/w (0.04% w/w) |
| 8 | Assay by HPLC | Not less than 98.0% w/w and not more than 102.0% w/w, calculated on the dried basis. | 99.2%w/w |
| 9 | Residual Solvents by GC-HS | | |
| | Ethyl acetate | Not more than 5000 ppm | 100ppm |
| | Toluene | Not more than 890 ppm | 49ppm |
| | n-Butyl acetate | Not more than 5000 ppm | Not detected. |
| 10 | Z-Mycophenolate mofetil content by UPLC | Not more than 0.10% | Not detected. |
| 25 | Microbiological examination | | |
| 26 | a) Microbial Enumeration Tests | | |
| 27 | i) Total aerobic microbial count | Not more than 10^3 cfu/g | <10cfu/gm |
| 28 | ii) Total combined yeasts and molds count | Not more than 10^2 cfu/g | <10cfu/gm |

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| Sr. No. | Tests | Specification | Results |
|---------|---------------------------------------|-----------------------------|----------|
| 29 | b) Test for Specified Microorganisms: | | |
| 30 | Escherichia Coli | Should be absent per g | Absent/g |
| 12 | Particle size by Malvern | d(0.9): Not more than 70 µm | 38µm |

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| Test Name | Impurity Name | LOQ (% w.r.t. sample) | LOD (% w.r.t. sample) | Disregard limit (% w.r.t. sample) |
|--|-------------------------|-----------------------|-----------------------|-----------------------------------|
| 1) Related substances by HPLC | Impurity-F | -- | -- | 0.05% |
| | Impurity-A | -- | -- | 0.05% |
| | Impurity-H | -- | -- | 0.05% |
| | Impurity-G | -- | -- | 0.05% |
| | Impurity-B | -- | -- | 0.05% |
| | Mycophenolate Mofetil | -- | -- | 0.05% |
| | Z-Mycophenolate Mofetil | | | 0.05% |
| | Impurity-D | | | 0.05% |
| 2) Residual Solvents by GC-MS | Impurity-E | -- | -- | 0.05% |
| | Ethyl acetate | 25 ppm | -- | -- |
| | Toluene | 18 ppm | -- | -- |
| | n-Butyl acetate | 50 ppm | -- | -- |
| 3) Z-Mycophenolate Mofetil content by UPLC | Z-Mycophenolate Mofetil | 0.04% | -- | -- |

Remark : The product complies as per specification number, SC-DS-322/03. The Product CAS Number is 128794-94-5, Certificate of suitability CEP #CEP R0-CEP 2019-089 - Rev 02.

| | |
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