

Certificate of Analysis



Customer: SLA Pharma AG
Product: Metronidazole Ointment 10%
Batch: HC6207
FDAS Number: S1805138
Work Order: 13674
Purchase Order: TBD

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RESULTS

| Tests | Specifications | | Results | Date Tested | Reference |
|--|------------------------------------|--------------|------------------|-------------|-----------|
| Appearance (visual) | Pale white to pale yellow ointment | | Meets test | 14/08/18 | 001233/ml |
| Identification of Metronidazole (HPLC) | Positive by Retention Time | | Positive | 13/07/18 | IPN 482 |
| Metronidazole Assay | 95 – 105% Label Claim | | 102% Label Claim | 13/07/18 | IPN 482 |
| Related substances (HPLC) | 2-methyl-5-nitroimidazole | NMT 0.2% | <0.05% | 13/07/18 | IPN 482 |
| | Individual unknowns | NMT 0.2% | <0.05% | | |
| | Total | NMT 0.5% | <0.5% | | |
| Microbial Limits | TAMC | ≤ 100 cfu/g | <10 cfu/g | 14/08/18 | 001233/ml |
| | TYMC | ≤ 10 cfu/g | <10 cfu/g | | |
| | <i>Ps. aeruginosa</i> | Absent in 1g | Absent | | |
| | <i>S. aureus</i> | Absent in 1g | Absent | | |

The above product has been tested by FDAS in accordance with the requirements of directive 2004/27/EC and 2001/83/EC.

Test method validation status: Assay and Related Validation Ongoing, Micro Validation WO13674.

MATTHEW HARDMAN
Quality Assurance Technician

DATE: 21 August 2018

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Version 1
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