

CERTIFICATE OF ANALYSIS

Product: Metrovis flavour 100mg 100tab
RO
Dosage form: tablets
Batch No.: S460.106
Manufac. Date: 09/2019

Testing Instruction: SFP00307-01
Expiry Date: 08/2021

Parameter	Specification	Result
Appearance	Beige coloured, round tablets with double indentation	conforms
Identity A: metronidazole (HPLC)	Retention times of standard and sample must correspond	conforms
Identity B: metronidazole (UV)	The spectra of reference and sample must correspond	conforms
Loss on drying	max. 5,0%	2,1%
Uniformity of dosage by mass variation	AV (10un) $\leq$ 15,0, if AV (10un) $>$ 15,0 then AV (30un) $\leq$ 15,0; $0,75 \times M \leq X_i \leq 1,25 \times M$	conforms
Assay metronidazole	95,0 – 105,0 mg/Tabl.	98,1 mg/Tabl.
Dissolution test (T=15min.)	Q= 85%	100%
Hardness	15 – 30 N	17 N
Related substances		
Impurity A	max. 0.3%	<0.1%
Unspecified individual impurity	max. 0.3%	<0.1%
Total impurities	max. 0.6%	<0.1%
Microbiological impurity		
TAMC	< 1000 CFU/g	10 CFU/g
TYMC	< 100 CFU/g	10 CFU/g
Escherichia coli	absent/g	absent/g

"I hereby certify that the above information is authentic and accurate. This batch of product has been fabricated/ manufactured, including packaging 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 as layed down in the manufacturing and quality control instructions which have been approved by the Marketing Authorisation holder or Contract giver.
The batch processing, packaging and analysis records were reviewed and found to be in compliance in GMP."

Date of issue: 2020-03-26

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HRB-Nr. 10339
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