

Certificate of Compliance/Analysis



Product: SYNULOX 250MGX10TABS ALT.S RUS

Lot number: A1956100

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Haupt Pharma Latina S.r.L.
S.S. 156 Km 47,600 - 04100 Borgo San Michele (Latina) Italy
Phone +39 0773 4251 Fax +39 0773 250920

Product: SYNULOX 250MGX10TABS ALT.S RUS
Lot number: A1956100 MFG: 08/2020 EXP: 08/2022
Package: 10 tabs Blister UNCOATED TABLET
Strength/Potency: Amoxicillin: 200mg, Clavulanate: 50mg

Destination country Russian Fed.
Aut.nr 840-3-32.13-4185N°PVI-3-1.3/01344

Test	Results	Methods
Specifications		
Disintegr. Time Max 15 min.	PASS	EP 2.9.1
M.T.I. 5 % max	1 %	M 20.2
Polymer Clavul. 2.5% max	1.5 %	C 107.4
Identif of Dye Positive	PASS	I 1.98
Amoxycillin Con 190 - 210 mg/tabs (HPLC)	198 mg/tab	A 107.0
Clavulan. Conten 50.0 - 55.0 mg/tabs (HPLC)	53.2 mg/tab	A 107.0
Uniform. Weight Meets Test	PASS	EP 2.9.5
Id. Amoxycillin Positive HPLC	PASS	A 107.0
Id. Clavulanate Positive HPLC	PASS	A 107.0
Appearance Specklet pink flat circul.Tabs	PASS	A 28.03
Moisture (KF) 6 % maximum	5 %	W 1.0
Friability 5 % max	0 %	EP 2.9.7
Bacteria <= 1000 CFU/g or ml	NOT PERFORMED (1)	EP 5.1.4

Manufacturing/Quality site HAUPT-PHARMA LATINA	Address S.S. 156 KM 47.600	Auth. Nr 26/2018/V
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Manufacturing/Quality site HAUPT-PHARMA LATINA	Certificate of GMP compliance NBF/47/2018/V	(EudraGMP)
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I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging and quality control at the above mentioned site 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 EU-GMP.

Deviations, when occurred, have been investigated and resolved successfully.

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Batch Released

Date : Aug 31, 2020

User	Reason	Date (CET)
Rosi Michela (Head of Quality Operations and Qualified Person)	Approve final document	9/3/20 8:00 PM

This certificate was created by a validated system and is valid without manual signature