

Certificate of Compliance



Latina S.r.l.

Product: SYNULOX 50MGX100 TABS CZ/SK/H

Lot number: 46961405

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Inspiring Partner for Efficient Solutions

S.S. 156 Km 47,600 - 04100 Borgo San Michele (Latina) Italy
Phone +39 0773 4251 Fax +39 0773 250920
www.haupt-pharma.com

Product SYNULOX 50MGX100 TABS CZ/SK/H

Lot number 46961405

Manufacturing date 09/2014

Expiration date 09/2016

Test	Specifications	Results	Methods
Disintegration	Meets Test	PASS	EP 2.9.1
Friability	5% max	0 %	EP 2.9.7
Id. Amoxicillin	Positive (HPLC)	PASS	SAM A 569
Id. Clavulanate	Positive (HPLC)	PASS	
Amoxyc.Content	38 to 42 mg/tabs (HPLC)	40 mg/tab	SAM A 569
Clavulan.Conten	10.0 to 11.0 mg/tabs (HPLC)	10.6 mg/tab	SAM A 569
Appearance	Specklet pink flat circul.Tabs	PASS	A 28.03
Moisture	6% max	5 %	EP 2.5.12
Uniform. Weight	Meets test	PASS	EP 2.9.5

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.

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

Batch Released

Date : Oct 28, 2014

Haupt Pharma Latina S.r.l. was formerly known as Pfizer Italia S.r.l.

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User	Reason	Date (CET)
Rossi Vincenzo (Quality Control Manager & QP)	Approve final document	10/29/14 11:49 AM