

# Certificate of Compliance



Latina S.r.l.

Product: SYNULOX 250MGX100 TABS CZ/SK/H

Lot number: 46955401

Page 1 of 2

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 250MGX100 TABS CZ/SK/H

**Lot number** 46955401

**Manufacturing date** 08/2014

**Expiration date** 08/2016

Test	Specifications	Results	Methods
Disintegr. Time	Meets Test	PASS	EP 2.9.1
Amoxicillin Con	190 - 210 mg/tabs (HPLC)	198 mg/tab	A 107.0
Clavulan.Conten	50.0 - 55.0 mg/tabs (HPLC)	52.8 mg/tab	
Uniform. Weight	Meets Test	PASS	EP 2.9.5
Id. Amoxicillin	Positive HPLC	PASS	A 107.0
Id. Clavulanate	Positive HPLC	PASS	
Appearance	Specklet pink flat circul.Tabs	PASS	A 28.03
Bacteria	1000cfu/g max	0 cfu/g	EP 2.6.12
Fungi	100cfu/g max	0 cfu/g	
Bacteria	1000cfu/g max	NOT PERFORMED (1)	
Fungi	100cfu/g max	NOT PERFORMED (1)	
E. Coli	absent/1g or mL	NOT PERFORMED (1)	EP 2.6.13
Moisture (KF)	6 % maximum	4.6 %	EP WATER (KF)
Friability	5 % max	0 %	EP 2.9.7

(1) NOT PERFORMED: as this test is performed on a random basis.

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 : Sep 25, 2014**

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

printed by Daniela Salvini on Thu Oct 02 13:35:18 CEST 2014

Deutsche Bank SpA  
Acc1 No. 820911  
ABI 03104  
CAB 03207

IBAN:  
IT89N03104032070000000820911  
BIC:  
DEUTITM1599

Commercial Register Latina 174220  
VAT: IT06385930960

An enterprise of the  
Haupt Pharma Group

Diszpó: PN-ZX14001023 Vevő: TolnAgro Kft 7100 File név: PN00008089 Egyedi sorszám: PN000007294 2 másolat  
Szállító: Zoetis Hungary Kft. Oldal/Lap 2 / 1 Anyaglap: PN0428/14  
Az eredetivel megegyező elektronikus másolat a(z): Nyomtatás dátuma: 2014.10.30 CertEx v 3.03  
Dr. Nagy Edith min.bizt.gyógyszerész által küldve.

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User	Reason	Date (CET)
Francesca Spinelli (Head of Quality Operations & QP)	Approve final document	9/26/14 1:01 PM

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