

# Certificate of Compliance/Analysis



Product: SYNULOX 250MGX10TABS ALT.S RUS

Lot number: A1956200

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Haupt Pharma Latina S.r.L.  
S.S. 156 Km 47,600 - 04100 Borgo San Michele (Latina) Italy  
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**Product: SYNULOX 250MGX10TABS ALT.S RUS**  
**Lot number: A1956200 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  |
|-------------------------------------------------------|-------------------|----------|
| <b>Specifications</b>                                 |                   |          |
| <b>Disintegr. Time</b><br>Max 15 min.                 | PASS              | EP 2.9.1 |
| <b>M.T.I.</b><br>5 % max                              | 1 %               | M 20.2   |
| <b>Polymer Clavul.</b><br>2.5% max                    | 1.5 %             | C 107.4  |
| <b>Identif of Dye</b><br>Positive                     | PASS              | I 1.98   |
| <b>Amoxycillin Con</b><br>190 - 210 mg/tabs (HPLC)    | 199 mg/tab        | A 107.0  |
| <b>Clavulan. Conten</b><br>50.0 - 55.0 mg/tabs (HPLC) | 53.6 mg/tab       | A 107.0  |
| <b>Uniform. Weight</b><br>Meets Test                  | PASS              | EP 2.9.5 |
| <b>Id. Amoxycillin</b><br>Positive HPLC               | PASS              | A 107.0  |
| <b>Id. Clavulanate</b><br>Positive HPLC               | PASS              | A 107.0  |
| <b>Appearance</b><br>Specklet pink flat circul.Tabs   | PASS              | A 28.03  |
| <b>Moisture (KF)</b><br>6 % maximum                   | 5 %               | W 1.0    |
| <b>Friability</b><br>5 % max                          | 0 %               | EP 2.9.7 |
| <b>Bacteria</b><br><= 1000 CFU/g or ml                | NOT PERFORMED (1) | EP 5.1.4 |

|                                                          |                                      |                              |
|----------------------------------------------------------|--------------------------------------|------------------------------|
| <b>Manufacturing/Quality site</b><br>HAUPT-PHARMA LATINA | <b>Address</b><br>S.S. 156 KM 47.600 | <b>Auth. Nr</b><br>26/2018/V |
|----------------------------------------------------------|--------------------------------------|------------------------------|

|                                                          |                                                       |            |
|----------------------------------------------------------|-------------------------------------------------------|------------|
| <b>Manufacturing/Quality site</b><br>HAUPT-PHARMA LATINA | <b>Certificate of GMP compliance</b><br>NBF/47/2018/V | (EudraGMP) |
|----------------------------------------------------------|-------------------------------------------------------|------------|

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 8:01 PM |

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