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SOP 426
Page 1/ 1

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

NEWCO PHARM HUNGARIA KFT
RÁKÓCZI U. 142 - 146.
7100 SZEKSZÁRD
HUNGARY

Hoogstraten, 22.11.2017

Material

S888998-006994-01 AMOXYCILLINE 70% 1 KG

Pharmaceutical Form:

Non sterile powder

Batch 27723A10 / Manufacturing Date 10.2017 Expiry date 10.2020

Inspection lot 40000029271 from 10.2017

CERTIFICATION STATEMENT: I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements

of the Marketing Authorisation of the destination country.

Formula: Amoxicillinetrihydrate equivalent with 700 mg Amoxicilline - excipients q.s. ad 1 g

Aspect: white to almost white powder free from conglomerates

| Characteristic | Unit | Value | Lower Limit | Upper Limit |
|-------------------------|------|----------|-------------|-------------|
| Aspect | | Complies | | |
| Average mass (1 kg) | % | 100,00 | 95,00 | 105,00 |
| pH of solution | | 7,96 | 7,00 | 8,00 |
| Water content (between) | % | 12,88 | 11,00 | 15,50 |
| Id: Amoxicillin | | Complies | | |
| Assay: Amoxicillin | % | 100,76 | 95,00 | 105,00 |

Dig. Sign.: Van Buggenhout Kris
07.11.2017 16:20:13

Qualified Person

Conclusion:
Quality test complied