

**ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS**

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ROMANIA

Hoogstraten, 12.01.2024

**ORIGINAL****Material**

C614100-001079-01 AMOXY-KEL 15% 100 ML

Pharmaceutical Form:

Sterile suspension

Batch 4017610 / Manufacturing Date 10.2023    Expiry date 10.2026

Inspection lot 40000075007 from 12.2023

**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:** Amoxicillin trihydrate eq.150 mg amoxicillin base excipients q.s.ad 1 ml

**Aspect:** white to pale yellow suspension

| Characteristic                | Unit  | Value    | Lower Limit | Upper Limit |
|-------------------------------|-------|----------|-------------|-------------|
| Aspect                        |       | Complies |             |             |
| Average volume (100 ml) (NLT) | %     | 101      | 100         |             |
| Resuspendability              | ROT   | 10       |             | 20          |
| Relative density              |       | 0,983    | 0,950       | 1,000       |
| Viscosity                     | mPa.s | 55       | 20          | 200         |
| Id: Amoxicillin trihydrate    |       | Complies |             |             |
| Id: Butylhydroxytoluene       |       | Complies |             |             |
| Assay: Amoxicillin            | %     | 99,5     | 95,0        | 105,0       |
| Assay: Butylhydroxytoluene    | %     | 99,7     | 90,0        | 110,0       |
| Sterility                     |       | Complies |             |             |