

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

S.C. BISTRI-VET SRL  
LIBERTATII STR. 13  
420155 BISTRITA (JUD. BISTRITA-NASAUD)  
ROMANIA

Hoogstraten, 23.04.2025

**ORIGINAL**

**Material**

L076100-001079-01 CEFOKEL 50 MG/ML 100 ML

Pharmaceutical Form:

Sterile suspension

Batch 4020819 / Manufacturing Date 11.2024 Expiry date 11.2027

Inspection lot 40000081187 from 03.2025

**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: Ceftiofur HCl equivalent with 50 mg Ceftiofur - excipients q.s. ad 1 ml

Aspect: white to off-white, beige suspension

| Characteristic                | Unit          | Value    | Lower Limit | Upper Limit |
|-------------------------------|---------------|----------|-------------|-------------|
| Aspect                        |               | Complies |             |             |
| Extractable volume (100 ml)   | %             | 102      | 100         | 110         |
| Relative density              |               | 0,894    | 0,860       | 0,960       |
| Water content                 | %             | 0,1      |             | 0,2         |
| Particle size: x90            | $\mu\text{m}$ | 5        |             | 10          |
| Resuspendability              | s             | < 20     |             | 20          |
| Id: Ceftiofur HCL             |               | Complies |             |             |
| Assay: Ceftiofur              | %             | 98,2     | 95,0        | 105,0       |
| Rls: D3- anti oxime ceftiofur | %             | < 0,3    |             | 1,0         |
| Rls: any other imp            | %             | < 0,3    |             | 1,0         |
| Rls: sum of imp               | %             | 0,0      |             | 3,0         |
| Sterility                     |               | Complies |             |             |