

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

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

Hoogstraten, 12.05.2020

ORIGINAL

Material  
L869100-001079-01 KELAPROFEN 100MG/ML 100 ML  
Pharmaceutical Form:  
Sterile solution  
Batch 4007612 / Manufacturing Date 01.2020    Expiry date 07.2022

Inspection lot 40000049968 from 02.2020

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: Ketoprofen 100 mg - Excipients q.s. ad 1 ml

Aspect: clear solution, not more intensely coloured than reference solution Y5

## ORIGINAL

| Characteristic          | Unit  | Value    | Lower Limit | Upper Limit |
|-------------------------|-------|----------|-------------|-------------|
| Autoclave cycle         |       | B        |             |             |
| Aspect                  |       | Complies |             |             |
| Aspect (colour)         |       | Complies |             |             |
| Average volume (100 ml) | %     | 100,61   | 100,00      | 102,00      |
| Relative density        |       | 1,044    | 0,990       | 1,090       |
| pH A                    |       | 6,68     | 6,00        | 7,00        |
| pH B                    |       | 6,65     | 6,00        | 7,00        |
| pH C                    |       | 6,64     | 6,00        | 7,00        |
| pH D                    |       | 6,64     | 6,00        | 7,00        |
| pH E                    |       |          | 6,00        | 7,00        |
| Visible particles       |       | Absent   |             |             |
| Id: Ketoprofen          |       | Complies |             |             |
| Id: Benzyl alcohol      |       | Complies |             |             |
| Assay: Ketoprofen A     | %     | 98,07    | 95,00       | 105,00      |
| Assay: Ketoprofen B     | %     | 97,59    | 95,00       | 105,00      |
| Assay: Ketoprofen C     | %     | 99,29    | 95,00       | 105,00      |
| Assay: Ketoprofen D     | %     | 98,00    | 95,00       | 105,00      |
| Assay: Ketoprofen E     | %     |          | 95,00       | 105,00      |
| Assay: Benzyl alcohol A | %     | 99,33    | 95,00       | 105,00      |
| Assay: Benzyl alcohol B | %     | 97,56    | 95,00       | 105,00      |
| Assay: Benzyl alcohol C | %     | 98,96    | 95,00       | 105,00      |
| Assay: Benzyl alcohol D | %     | 98,62    | 95,00       | 105,00      |
| Assay: Benzyl alcohol E | %     |          | 95,00       | 105,00      |
| Bacterial endotoxins A  | IU/ML | < 5      |             | 167         |
| Bacterial endotoxins B  | IU/ML | < 5      |             | 167         |
| Bacterial endotoxins C  | IU/ML | < 5      |             | 167         |
| Bacterial endotoxins D  | IU/ML | < 5      |             | 167         |
| Bacterial endotoxins E  | IU/ML |          |             | 167         |
| Sterility A             |       | Complies |             |             |
| Sterility B             |       | Complies |             |             |
| Sterility C             |       | Complies |             |             |
| Sterility D             |       | Complies |             |             |
| Sterility E             |       |          |             |             |

## CERTIFICATE OF CONFORMITY / QUALITY

Date: 12/05/2020

### **KELAPROFEN 100MG/ML 100 ML – batch 4007612– exp. 07.2022**

The undersigned, KELA N.V., confirms that the product KELAPROFEN 100MG/ML 100 ML has been manufactured according to the methods of "Good Manufacturing Practices" at our factory in Hoogstraten and is of EU origin.

The product KELAPROFEN 100MG/ML 100 ML has been manufactured according to the formula of KELAPROFEN 100MG/ML which has been registered in Romania.

KELA N.V.



**kela**  
focus on health  
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