

**CERTIFICATE OF CONFORMITY / QUALITY**

Date: 02/10/2019

**KELAPROFEN 100MG/ML 50 ML – batch 4005858– exp. 02-2022**

The undersigned, KELA N.V., confirms that the product KELAPROFEN 100MG/ML 50 ML has been manufactured according to the methods of "Good Manufacturing Practices" at our factory in Hoogstraten and that they are for 100% C.E.E. origin.

The product KELAPROFEN 100MG/ML 50 ML has been manufactured according to the formula of KELAPROFEN which has been registered in Romania.

KELA N.V.



**kela**  
focus on health  
Sint Lenaartseweg 48  
2320 Hoogstraten  
Belgium

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

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

Hoogstraten, 02.10.2019

ORIGINAL

**Material**

L869050-001079-01 KELAPROFEN 100MG/ML 50 ML

**Pharmaceutical Form:**

Sterile solution

Batch 4005858 / Manufacturing Date 08.2019    Expiry date 02.2022

Inspection lot 40000046250 from 08.2019

**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         |       | A        |             |             |
| Aspect                  |       | Complies |             |             |
| Aspect (colour)         |       | Complies |             |             |
| Average volume (50 ml)  | %     | 101,08   | 100,00      | 102,00      |
| Relative density        |       | 1,044    | 0,990       | 1,090       |
| pH A                    |       | 6,71     | 6,00        | 7,00        |
| pH B                    |       | 6,70     | 6,00        | 7,00        |
| pH C                    |       | 6,70     | 6,00        | 7,00        |
| pH D                    |       | 6,69     | 6,00        | 7,00        |
| pH E                    |       | 6,70     | 6,00        | 7,00        |
| Visible particles       |       | Absent   |             |             |
| Id: Ketoprofen          |       | Complies |             |             |
| Id: Benzyl alcohol      |       | Complies |             |             |
| Assay: Ketoprofen A     | %     | 98,67    | 95,00       | 105,00      |
| Assay: Ketoprofen B     | %     | 98,72    | 95,00       | 105,00      |
| Assay: Ketoprofen C     | %     | 98,53    | 95,00       | 105,00      |
| Assay: Ketoprofen D     | %     | 98,50    | 95,00       | 105,00      |
| Assay: Ketoprofen E     | %     | 98,75    | 95,00       | 105,00      |
| Assay: Benzyl alcohol A | %     | 100,10   | 95,00       | 105,00      |
| Assay: Benzyl alcohol B | %     | 100,13   | 95,00       | 105,00      |
| Assay: Benzyl alcohol C | %     | 100,09   | 95,00       | 105,00      |
| Assay: Benzyl alcohol D | %     | 100,04   | 95,00       | 105,00      |
| Assay: Benzyl alcohol E | %     | 100,09   | 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 | < 5      |             | 167         |
| Sterility A             |       | Complies |             |             |
| Sterility B             |       | Complies |             |             |
| Sterility C             |       | Complies |             |             |
| Sterility D             |       | Complies |             |             |
| Sterility E             |       | Complies |             |             |