

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 11.07.2022

ORIGINAL

Material

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

Pharmaceutical Form:

Sterile solution

Batch 4013482 / Manufacturing Date 02.2022 Expiry date 08.2024

Inspection lot 40000065944 from 04.2022

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 coloured than Y5

Characteristic	Unit	Value	Lower Limit	Upper Limit
Autoclave cycle		A		
Aspect		Complies		
Aspect (colour)		Complies		
Extractable volume (50 ml) (NL)	%	102	100	
Relative density		1,044	0,990	1,090
pH A		6,7	6,0	7,0
pH B		6,7	6,0	7,0
pH C		6,7	6,0	7,0
pH D		6,7	6,0	7,0
pH E		6,7	6,0	7,0
Visible particles		Absent		
Id: Ketoprofen		Complies		
Id: Benzyl alcohol		Complies		
Assay: Ketoprofen A	%	98,2	95,0	105,0
Assay: Ketoprofen B	%	97,8	95,0	105,0
Assay: Ketoprofen C	%	97,3	95,0	105,0
Assay: Ketoprofen D	%	97,2	95,0	105,0
Assay: Ketoprofen E	%	97,3	95,0	105,0
Assay: Benzyl alcohol A	%	99,7	95,0	105,0
Assay: Benzyl alcohol B	%	99,1	95,0	105,0
Assay: Benzyl alcohol C	%	99,7	95,0	105,0
Assay: Benzyl alcohol D	%	99,9	95,0	105,0
Assay: Benzyl alcohol E	%	99,5	95,0	105,0
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		

CERTIFICATE OF CONFORMITY / QUALITY

Date: 07/07/2022

KELAPROFEN 100MG/ML 50 ML – batch 4013482– exp. 08.2024

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 is of EU origin.

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

KELA N.V.

 Sint Lenaartseweg 48
2320 Hoogstraten
Belgium

Kris Van Buggenhout
QA Release Manager
QP 1562
KELA N.V.
07/07/2022