

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

ORIGINAL

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

Hoogstraten, 04.02.2020

Material

L869100-001079-01 KELAPROFEN 100MG/ML 100 ML

Pharmaceutical Form:

Sterile solution

Batch 4006546 / Manufacturing Date 10.2019 Expiry date 04.2022

Inspection lot 40000048455 from 11.2019

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

Characteristic	Unit	Value	Lower Limit	Upper Limit
ORIGINAL				
Autoclave cycle		B		
Aspect		Complies		
Aspect (colour)		Complies		
Average volume (100 ml)	%	100,68	100,00	102,00
Relative density		1,044	0,990	1,090
pH A		6,65	6,00	7,00
pH B		6,64	6,00	7,00
pH C		6,63	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	%	98,17	95,00	105,00
Assay: Ketoprofen B	%	98,82	95,00	105,00
Assay: Ketoprofen C	%	99,20	95,00	105,00
Assay: Ketoprofen D	%	98,93	95,00	105,00
Assay: Ketoprofen E	%		95,00	105,00
Assay: Benzyl alcohol A	%	97,96	95,00	105,00
Assay: Benzyl alcohol B	%	99,43	95,00	105,00
Assay: Benzyl alcohol C	%	99,07	95,00	105,00
Assay: Benzyl alcohol D	%	98,92	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: 04/02/2020

KELAPROFEN 100MG/ML 100 ML – batch 4006546– exp. 04-2022

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.



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Belgium