

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

ORIGINAL

Hoogstraten, 08.07.2021

Material

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

Pharmaceutical Form:

Sterile solution

Batch 4011218 / Manufacturing Date 05.2021 Expiry date 11.2023

Inspection lot 40000059761 from 06.2021

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
Autoclave cycle		A		
Aspect		Complies		
Aspect (colour)		Complies		
Extractable volume (100 ml) (N	%	101	100	
Relative density		1,044	0,990	1,090
pH A		6,6	6,0	7,0
pH B		6,6	6,0	7,0
pH C		6,6	6,0	7,0
pH D		6,6	6,0	7,0
pH E		6,6	6,0	7,0
Visible particles		Absent		
Id: Ketoprofen		Complies		
Id: Benzyl alcohol		Complies		
Assay: Ketoprofen A	%	99,4	95,0	105,0
Assay: Ketoprofen B	%	100,0	95,0	105,0
Assay: Ketoprofen C	%	100,1	95,0	105,0
Assay: Ketoprofen D	%	100,1	95,0	105,0
Assay: Ketoprofen E	%		95,0	105,0
Assay: Benzyl alcohol A	%	101,4	95,0	105,0
Assay: Benzyl alcohol B	%	101,0	95,0	105,0
Assay: Benzyl alcohol C	%	101,4	95,0	105,0
Assay: Benzyl alcohol D	%	102,3	95,0	105,0
Assay: Benzyl alcohol E	%		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			167
Sterility A		Complies		
Sterility B		Complies		
Sterility C		Complies		
Sterility D		Complies		
Sterility E		Complies		

CERTIFICATE OF CONFORMITY / QUALITY

Date: 07/07/2021

KELAPROFEN 100MG/ML 100ML – batch 4011218– exp. 11-2023

The undersigned, KELA N.V., confirms that the product KELAPROFEN 100MG/ML 100ML 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 100ML has been manufactured according to the formula of KELAPROFEN which has been registered in Romania.

KELA N.V.



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