

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 29.04.2019

ORIGINAL

Material

L869250-001079-01 KELAPROFEN 100MG/ML 250 ML

Pharmaceutical Form:

Sterile solution

Batch 4004470 / Manufacturing Date 03.2019 Expiry date 09.2021

Inspection lot 40000042063 from 03.2019

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 Y7)

Characteristic	Unit	Value	Lower Limit	Upper Limit
Autoclave cycle		C		
Aspect		Complies		
Aspect (colour)		Complies		
Average volume (250 ml)	%	100,60	100,00	102,00
Relative density		1,044	0,990	1,090
pH A		6,60	6,00	7,00
pH B		6,59	6,00	7,00
pH C		6,59	6,00	7,00
pH D		6,59	6,00	7,00
pH E			6,00	7,00
Visible particles		Absent		
Id: Ketoprofen		Complies		
Id: Benzyl alcohol		Complies		
Assay: Ketoprofen A	%	99,92	95,00	105,00
Assay: Ketoprofen B	%	99,06	95,00	105,00
Assay: Ketoprofen C	%	99,40	95,00	105,00
Assay: Ketoprofen D	%	98,77	95,00	105,00
Assay: Ketoprofen E	%		95,00	105,00
Assay: Benzyl alcohol A	%	100,81	95,00	105,00
Assay: Benzyl alcohol B	%	101,81	95,00	105,00
Assay: Benzyl alcohol C	%	100,80	95,00	105,00
Assay: Benzyl alcohol D	%	100,41	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: 02/05/2019

KELAPROFEN 100MG/ML 250ML – batch 4004470– exp. 09-2021

The undersigned, KELA N.V., confirms that the product KELAPROFEN 100MG/ML 250ML 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 250ML has been manufactured according to the formula of KELAPROFEN which has been registered in Romania.

KELA N.V.



Sint Lenaartseweg 48
2320 Hoogstraten
Belgium

Kela nv

Sint Lenaartseweg 48
2320 Hoogstraten
Belgium

BTW BE 0403.835.645
RPR Turnhout
IBAN BE36 4134 5145 0181

T +32 3 340 04 11
E info@kela.health
www.kela.health