

CERTIFICATE OF CONFORMITY / QUALITY

Date: 02/10/2019

KELAPROFEN 100MG/ML 250 ML – batch 4006051– exp. 02-2022

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

KELA N.V.

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

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

Pharmaceutical Form:

Sterile solution

Batch 4006051 / Manufacturing Date 08.2019 Expiry date 02.2022

Inspection lot 40000046244 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

Characteristic	ORIGINAL	Unit	Value	Lower Limit	Upper Limit
Autoclave cycle			D		
Aspect			Complies		
Aspect (colour)			Complies		
Average volume (250 ml)		%	100,59	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		