

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 12.01.2024

ORIGINAL

Material

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

Pharmaceutical Form:

Sterile solution

Batch 4017465 / Manufacturing Date 10.2023 Expiry date 04.2026

Inspection lot 40000074875 from 11.2023

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

Dig. Sign.: Van Buggenhout Kris
04.01.2024 10:55:20

Qualified Person

Conclusion:
Quality test complied

Characteristic	Unit	Value	Lower Limit	Upper Limit
Autoclave cycle		A		
Aspect		Complies		
Aspect (colour)		Complies		
Extractable volume (50 ml) (NL)	%	103	100	
Relative density		1,044	0,990	1,090
pH A		6,6	6,0	7,0
pH B		6,7	6,0	7,0
pH C		6,6	6,0	7,0
pH D		6,6	6,0	7,0
pH E			6,0	7,0
Visible particles		Absent		
Id: Ketoprofen		Complies		
Id: Benzyl alcohol		Complies		
Assay: Ketoprofen A	%	101,3	95,0	105,0
Assay: Ketoprofen B	%	100,4	95,0	105,0
Assay: Ketoprofen C	%	100,3	95,0	105,0
Assay: Ketoprofen D	%	100,6	95,0	105,0
Assay: Ketoprofen E	%		95,0	105,0
Assay: Benzyl alcohol A	%	100,5	95,0	105,0
Assay: Benzyl alcohol B	%	100,8	95,0	105,0
Assay: Benzyl alcohol C	%	101,1	95,0	105,0
Assay: Benzyl alcohol D	%	100,9	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				