

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

ORIGINAL

Hoogstraten, 27.11.2024

Material**L869050-001079-01 KELAPROFEN 100 MG/ML 50 ML****Pharmaceutical Form:****Sterile solution****Batch 4019664 / Manufacturing Date 08.2024 Expiry date 02.2027****Inspection lot 40000079220 from 10.2024**

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 Y5

Characteristic	Unit	Value	Lower Limit	Upper Limit
Autoclave cycle		A		
Aspect		Complies		
Aspect (colour)		Complies		
Extractable volume (50 ml) (NL	%	102	100	
Relative density		1,044	0,990	1,090
pH A		6,7	6,0	7,0
pH B		6,7	6,0	7,0
pH C		6,7	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	%	100,3	95,0	105,0
Assay: Ketoprofen B	%	100,9	95,0	105,0
Assay: Ketoprofen C	%	100,9	95,0	105,0
Assay: Ketoprofen D	%	100,9	95,0	105,0
Assay: Ketoprofen E	%		95,0	105,0
Assay: Benzyl alcohol A	%	99,9	95,0	105,0
Assay: Benzyl alcohol B	%	100,5	95,0	105,0
Assay: Benzyl alcohol C	%	100,2	95,0	105,0
Assay: Benzyl alcohol D	%	100,5	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				