

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 27.11.2024

ORIGINAL

Material

F869250-001079-01 COMBI-KEL 40 250 ML

Pharmaceutical Form:

Sterile suspension

Batch 4019876 / Manufacturing Date 10.2024 Expiry date 10.2027

Inspection lot 40000079229 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: Penicilline G Procaine 1aqua 200.000 IU -

Dihydrostreptomycinesulphate equivalent with 200 mg Dihydrostreptomycine base - excipients q.s. ad 1 ml

Aspect: white to yellow-white suspension

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (250 ml)	%	100	98	102
pH		6,4	5,5	7,0
Relative density		1,160	1,100	1,200
Needling time	s	7		30
Resuspendability		Complies		
Sedimentation (F24)	%	91	50	
Id: Benzylpenicillin procaine		Complies		
Id: Dihydrostreptomycin Sulph		Complies		
Id: Na Methyl p-hydroxybenz		Complies		
Id: Na Formaldehyde sulf		Complies		
Assay: Benzylpenicillin	%	100,4	95,0	105,0
Assay: Dihydrostreptomycin	%	97,3	90,0	110,0
Assay: Na methyl p-hydroxybenz	%	98,0	90,0	110,0
Sterility		Complies		

Characteristic	ORIGINAL	Unit	Value	Lower Limit	Upper Limit
Autoclave cycle			A		
Aspect			Complies		
Aspect (colour)			Complies		
Extractable volume (250 ml) (N	%		100	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	%		101,2	95,0	105,0
Assay: Ketoprofen B	%		100,8	95,0	105,0
Assay: Ketoprofen C	%		100,9	95,0	105,0
Assay: Ketoprofen D	%		101,8	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	%		100,1	95,0	105,0
Assay: Benzyl alcohol C	%		100,3	95,0	105,0
Assay: Benzyl alcohol D	%		100,0	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		