

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 04.12.2

ORIGINAL

Material

F869250-001079-01 COMBI-KEL 40 250 ML

Pharmaceutical Form:

Sterile suspension

Batch 4017143 / Manufacturing Date 03.2023 Expiry date 03.2026

Inspection lot 40000074575 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: 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)	%	101	98	102
pH		6,5	5,5	7,0
Relative density		1,160	1,100	1,200
Needling time	s	12		30
Resuspendability		Complies		
Sedimentation (F24)	%	94	50	
Id: Benzylpenicillin procaine		Complies		
Id: Dihydrostreptomycin Sulph		Complies		
Id: Na Methyl p-hydroxybenz		Complies		
Id: Na Formaldehyde sulf				
Assay: Benzylpenicillin	%	99,7	95,0	105,0
Assay: Dihydrostreptomycin	%	100,0	90,0	110,0
Assay: Na methyl p-hydroxybenz	%	100,2	90,0	110,0
Sterility		Complies		