

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 11.10.2018

ORIGINAL

Material

F869250-001079-01 COMBI-KEL 40 250 ML

Pharmaceutical Form:

Sterile suspension

Batch 4002588 / Manufacturing Date 09.2018 Expiry date 09.2021

Inspection lot 40000037805 from 09.2018

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)	%	100,51	98,00	102,00
pH		6,60	5,50	7,00
Relative density		1,159	1,100	1,200
Needling time	s	12		30
Resuspendability	ROT	6		10
Sedimentation (F24)	%	91,00	50,00	
Id: Benzylpenicillin procaine		Complies		
Id: Dihydrostreptomycin Sulph		Complies		
Id: Na Methyl p-hydroxybenz		Complies		
Id: Na formaldehyde sulf		Complies		
Assay: Benzylpenicillin	%	100,34	95,00	105,00
Assay: Dihydrostreptomycin	%	100,70	90,00	110,00
Assay: Na methyl p-hydroxybenz	%	98,06	90,00	105,00
Sterility		Complies		