

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 16.03.2023

ORIGINAL

Material

F869100-001079-01 COMBI-KEL 40 100 ML

Pharmaceutical Form:

Sterile suspension

Batch 4015007 / Manufacturing Date 04.2022 Expiry date 04.2025

Inspection lot 40000070498 from 02.2023

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 laqua 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 (100 ml)	%	101	98	102
pH		6,5	5,5	7,0
Relative density		1,160	1,100	1,200
Needling time	s	9		30
Resuspendability	ROT	9		10
Sedimentation (F24)	%	97	50	
Id: Benzylpenicillin procaine		Complies		
Id: Dihydrostreptomycin Sulph		Complies		
Id: Na Methyl p-hydroxybenz		Complies		
Id: Na Formaldehyde sulf		Complies		
Assay: Benzylpenicillin	%	100,8	95,0	105,0
Assay: Dihydrostreptomycin	%	99,0	90,0	110,0
Assay: Na methyl p-hydroxybenz	%	98,7	90,0	110,0
Sterility		Complies		

Dig. Sign.: Van Buggenhout Kris
03.03.2023 15:37:41

Qualified Person

Conclusion:
Quality test complied

CERTIFICATE OF CONFORMITY / QUALITY

Date: 15/03/2023

COMBI-KEL 40 100 ML – batch 4015007 – exp. 04-2025

The undersigned, KELA N.V., confirms that the product COMBI-KEL 40 100 ML has been manufactured according to the methods of "Good Manufacturing Practices" at our factory in Hoogstraten and is of EU origin.

The product COMBI-KEL 40 100 ML has been manufactured according to the formula of COMBI-KEL which has been registered in Romania.

KELA N.V.

 Sint Lenaartseweg 48
2320 Hoogstraten
Belgium

Kris Van Euggenhout
QA Release Manager
QP 1562
KELA N.V.

Kela nv
Sint Lenaartseweg 48
2320 Hoogstraten
Belgium

BTW BE 0403.835.645
RPR Turnhout
IBAN BE36 4134 5145 0181

T +32 3 340 04 11
E info@kela.health
www.kela.health