

CERTIFICATE OF CONFORMITY / QUALITY

Date: 27/03/2019

COMBI-KEL 40 100 ML– batch 4004570– exp. 02-2022

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 that they are for 100% C.E.E. origin.

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

KELA N.V.

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 27.03.2019

ORIGINAL

Material

F869100-001079-01 COMBI-KEL 40 100 ML

Pharmaceutical Form:

Sterile suspension

Batch 4004570 / Manufacturing Date 02.2019 Expiry date 02.2022

Inspection lot 40000041560 from 02.2019

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)	%	101,37	98,00	102,00
pH		6,77	5,50	7,00
Relative density		1,161	1,100	1,200
Needling time	s	9		30
Resuspendability	ROT	8		10
Sedimentation (F24)	%	90,00	50,00	
Id: Benzylpenicillin procaine		Complies		
Id: Dihydrostreptomycin Sulph		Complies		
Id: Na Methyl p-hydroxybenz		Complies		
Id: Na formaldehyde sulf		Complies		
Assay: Benzylpenicillin	%	99,53	95,00	105,00
Assay: Dihydrostreptomycin	%	100,00	90,00	110,00
Assay: Na methyl p-hydroxybenz	%	100,14	90,00	105,00
Sterility		Complies		

Dig. Sign.: Van Buggenhout Kris
14.03.2019 15:22:57

Qualified Person