

**ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS**

LLC GLOBAL-VET  
ST. FRYAZEVSKAYA, 10  
FLOOR 2, APT. III ROOM 1  
111396 MOSCOW  
RUSSIAN FEDERATION

Hoogstraten, 09.11.2020

**ORIGINAL**

**Material**

F382100-001216-03 KOMBIKEL 40 LA 72H 100 ML

Pharmaceutical Form:

Sterile suspension

Batch 4009635 / Manufacturing Date 10.2020 Expiry date 10.2023

Inspection lot 40000055079 from 10.2020

**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: Procaine benzylpenicilline 120.000 IU - Benzathine benzylpenicilline 80.000 IU - dihydrostreptomycinsulfate eq. with 200 mg base - excipients q.s. ad 1 ml

Aspect: homogeneous white to yellow suspension

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (100 ml)	%	101,10	98,00	102,00
pH		6,73	5,00	7,00
Relative density		1,208	1,180	1,280
Needling time	s	20		30
Id: Benzylpenicillin		Complies		
Id: Benzathine		Complies		
Id: Procaine		Complies		
Id: Dihydrostreptomycin Sulph		Complies		
Id: Na methyl p-hydroxybenz		Complies		
Assay: Benzylpenicillin	%	100,55	95,00	105,00
Assay: Dihydrostreptomycin	%	99,27	90,00	110,00
Assay: Na methyl p-hydroxybenz	%	91,60	90,00	105,00
Sterility		Complies		

*C.O.*  
Michiel Janssens  
Quality Manager / QP 2296  
KELA N.V.  
*0202/11/09/2020*