

CERTIFICATE OF CONFORMITY / QUALITY

Date: 02/10/2019

DEXA-KEL 0,2% 50 ML – batch 4006026 – exp. 09-2023

The undersigned, KELA N.V., confirms that the product DEXA-KEL 0,2% 50 ML has been manufactured according to the methods of "Good Manufacturing Practices" at our factory in Hoogstraten and is of EU origin.

The product DEXA-KEL 0,2% 50 ML has been manufactured according to the formula of DEXA-KEL which has been registered in Romania.

KELA N.V.



Sint Lenaartseweg 48
2320 Hoogstraten
Belgium

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

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 03.10.2019

ORIGINAL
Material

F824050-001079-01 DEXA-KEL 0,2 % 50 ML

Pharmaceutical Form:

Sterile solution

Batch 4006026 / Manufacturing Date 09.2019 Expiry date 09.2023

Inspection lot 40000046467 from 08.2019

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: Dexamethasone sodium phosphate eq. 2 mg dexamethasone -
 Excipient to 1 ml

Aspect: clear, colourless solution

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (50 ml)	%	98,76	98,00	102,00
Relative density		1,015	1,010	1,050
pH		7,46	6,50	8,50
Refractive index		1,350	1,330	1,370
Id: Dexamethasone Na phosphate		Complies		
Id: Na methyl p-hydroxybenz		Complies		
Assay: Dexamethasone na phosph	%	99,85	95,00	105,00
Assay: Na methyl p-hydroxybenz	%	96,55	90,00	110,00
Sterility		Complies		