

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 11.07.2022

ORIGINAL

Material

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

Pharmaceutical Form:

Sterile solution

Batch 4013410 / Manufacturing Date 10.2021 Expiry date 10.2025

Inspection lot 40000065946 from 04.2022

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)	%	101	98	102
Relative density		1,015	1,010	1,050
pH		7,8	6,5	8,5
Refractive index		1,350	1,330	1,370
Id: Dexamethasone Na phosphate		Complies		
Id: Na methyl p-hydroxybenz		Complies		
Assay: Dexamethasone na phosph	%	99,4	95,0	105,0
Assay: Na methyl p-hydroxybenz	%	101,8	90,0	110,0
Sterility		Complies		

CERTIFICATE OF CONFORMITY / QUALITY

Date: 07/07/2022

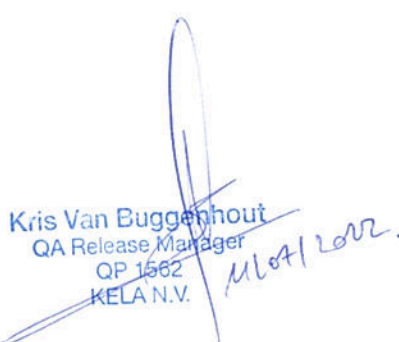
DEXA-KEL 0,2 % 50 ML – batch 4013410– exp. 10.2025

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 0,2 % which has been registered in Romania.

KELA N.V.

 **kela** Sint Lenaartseweg 48
2320 Hoogstraten
Belgium


Kris Van Buggenhout
QA Release Manager
QP 1562
KELA N.V. 07/07/2022

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