

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 16.11.2021

ORIGINAL

Material

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

Pharmaceutical Form:

Sterile solution

Batch 4011832 / Manufacturing Date 08.2021 Expiry date 08.2025

Inspection lot 40000060989 from 08.2021

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		7,9	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	%	98,4	95,0	105,0
Assay: Na methyl p-hydroxybenz	%	97,7	90,0	110,0
Sterility		Complies		

CERTIFICATE OF CONFORMITY / QUALITY

Date: 15/11/2021

DEXA-KEL 0,2% 50 ML – batch 4011832 – exp. 08.2025

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.



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focus on health

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