

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 06.08.2025

ORIGINAL

Material

F824050-001079-01 DEXA-KEL 50 ML

Pharmaceutical Form:

Sterile solution

Batch 4021616 / Manufacturing Date 03.2025 Expiry date 03.2029

Inspection lot 40000082367 from 06.2025

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		7,7	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	%	103,6	95,0	105,0
Assay: Na methyl p-hydroxybenz	%	98,7	90,0	110,0
Sterility		Complies		