

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 08.03.202

ORIGINAL

Material

F824050-001079-01 DEXA-KEL 50 ML

Pharmaceutical Form:

Sterile solution

Batch 4017982 / Manufacturing Date 01.2024 Expiry date 01.2028

Inspection lot 40000075670 from 01.2024

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)	%	99	98	102
Relative density		1,014	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	%	99,8	95,0	105,0
Assay: Na methyl p-hydroxybenz	%	101,2	90,0	110,0
Sterility		Complies		