Vet Pharma Friesoythe GmbH
Sedelsberger Straße 2-4, 26169 Friesoythe, Germany

Quality Control
Certificate of Analysis

Product: **Dexafort , 50 ml**

SAP-UIN: **112069**
Batch-No: **0066103**
Product-Code: **150000**

Manufact. Date: **02/2020**
Expiry Date: **01/2022**
Specification: **150000 S-04 Rev.00 EZ**

Test	Result	Limits
Description [Ph.Eur. 2.2.1] (White to off-white Suspension)	Complies	Complies
Color of solution [Ph.Eur. 2.2.2]	B7	<= B7
Volume in Container [Ph.Eur. 2.9.17]	50	50 - 52 ml
Average filling volume [Ph.Eur. 2.9.17]	50.8	>= 50.0 ml
pH-Value [Ph.Eur. 2.2.3]	7.4	7.0 - 7.8
Identity Dexamethasone Phenylpropionate	Complies	Complies
Assay Dexamethasone Phenylpropionate	2.74	2.54 - 2.80 mg / ml
Identity Dexamethasone sodium phosphate	Complies	Complies
Identity Benzyl Alcohol	Complies	Complies
Assay Dexamethasone sodium phosphate	1.34	1.25 - 1.39 mg / ml
Assay Benzyl Alcohol	10.4	9.4 - 11.5 mg / ml
Determination of Benzaldehyde	1	<= 10 µg / ml
Free Dexamethasone	<0,82	<= 40.0 µg / ml
17-Ketodexamethasone	<1,20	<= 4.0 µg / ml
Individual Unknowns [µg/ml]	0.56	no limit fixed µg / ml
Individual Unknown [maximum]	0.0	<= 0.5 %
Total Impurities	0.1	<= 1.5 %
Resuspendability	<30	<= 30 sec.
Syringeability	Complies	Complies
Sterility (no microbial growth) [Ph.Eur. 2.6.1]	Complies	Complies
Particle <= 5 µm [Ph.Eur. 2.9.37]	>90	>= 90 %
Particle <= 30 µm [Ph.Eur. 2.9.37]	100	>= 99 %

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(s) of the destination country/countries .

The batch is released for sale!

Friesoythe, 08.06.2020

09.06.2020 R. Bareis

R. Bareis (Qualified Person)