

Quality Control Certificate of Analysis

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Product: **Dexafort , 50 ml**

SAP-UIN: **112069**

Manufact. Date: **09/2020**

Batch-No: **0176105**

Expiry Date: **08/2022**

Product-Code: **150000**

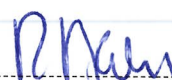
Specification: **150000 S-05-EZ Rev.00**

Test	Result	Limits
Description [Ph.Eur. 2.2.1] (White to off-white Suspension)	Complies	Complies
Color of solution [Ph.Eur. 2.2.2]	B8	<= B7
Volume in Container [Ph.Eur. 2.9.17]	51.0	50.0 - 52.0 ml
pH-Value [Ph.Eur. 2.2.3]	7.4	7.0 - 7.8
Identity Dexamethasone Phenylpropionate [04-FRI-1005-M-02]	Complies	Complies
Assay Dexamethasone Phenylpropionate [04-FRI-1005-M-02]	2.72	2.54 - 2.80 mg / ml
Identity Dexamethasone sodium phosphate [04-FRI-1004-M-02]	Complies	Complies
Identity Benzyl Alcohol [04-FRI-1004-M-02]	Complies	Complies
Assay Dexamethasone sodium phosphate [04-FRI-1004-M-02]	1.31	1.25 - 1.39 mg / ml
Assay Benzyl Alcohol [04-FRI-1004-M-02]	10.4	9.4 - 11.5 mg / ml
Determination of Benzaldehyde [04-FRI-1004-M-02]	1.0	<= 10.0 µg / ml
Free Dexamethasone [04-FRI-1006-M-03]	<0,82	<= 40.0 µg / ml
17-Ketodexamethasone [04-FRI-1006-M-03]	<1,20	<= 4.0 µg / ml
Individual Unknown [maximum] [04-FRI-1006-M-03]	0.0	<= 0.5 %
Total Impurities [04-FRI-1006-M-03]	0.1	<= 1.5 %
Resuspendability [04-FRI-1007-M-01]	5	<= 30 sec.
Syringeability [04-FRI-1007-M-01]	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]	>99	>= 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, 20.10.2020



R. Bareis (Qualified Person)