

Certificate of Analysis

Product: NOBIVAC DHPPI, 10X1 D
Batch: 0129040A01

Country	Romania
Sales Order Number	1110882911 / 10
Delivery number	1214709516 / 900002

Material Number: 017242	
Product type: Live Vaccines	Dosage per Container: 1 Dose
Start date of Shelf Life: 20-May-2022	Expiry Date: May-2024
Storage Conditions: 2-8°C	

CERTIFICATION BY THE MANUFACTURER

I herewith certify that the presented information is authentic and accurate. All measures have been taken to demonstrate compliance with Regulation (EU) 2019/6. This batch has been manufactured /fabricated (incl. APIs and intermediates if applicable) including packaging and quality control, in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Dr. S.A. v.d. Geer-v.d. Klei

Name:
Function:
Date:
Signature:



09 SEP 2022

Qualified Person



Certificate of Analysis

Product: **NOBIVAC DHPPI, 10X1 D**
 Batch: **0129040A01**

Final Batch Testing Finished Product

<u>Date on</u>	<u>Date off</u>	<u>Test Results</u>
01-Jun-2022	15-Jun-2022	<u>Sterility</u> Tested according to Ph. Eur. 0062 / Ph. Eur. 2.6.1 Result: No growth Threshold: No growth Conclusion: Passed
01-Jun-2022	15-Jun-2022	<u>Mycoplasmas</u> Tested according to Ph. Eur. 2.6.7 Result: No live mycoplasma present Threshold: No live mycoplasma present Conclusion: Passed
16-Jun-2022	23-Jun-2022	<u>Virus content CDV (TCID50)</u> Result: 5.1 Log10/VL Threshold: 4.0 – 6.0 Log 10/dose Conclusion: Passed
03-Jun-2022	10-Jun-2022	<u>Virus content CAV (TCID50)</u> Result: 5.8 Log 10/VL Threshold: 4.0 – 6.5 Log 10/dose Conclusion: Passed
30-Jun-2022	07-Jul-2022	<u>Virus content CPI (TCID50)</u> Result: 6.1 Log10/VL Threshold: 5.5 – 7.0 Log 10/dose Conclusion: Passed
		<u>Identity CPI</u> Result: Identity conform Threshold: Identity conform Conclusion: Passed
20-May-2022	30-May-2022	<u>Virus content CPV (TCID50)</u> Result: 7.6 Log10/VL Threshold: 7.0 – 8.4 Log 10/dose Conclusion: Passed

Certificate of Analysis

Product: **NOBIVAC DHPPI, 10X1 D**

Batch: **0129040A01**

Final Batch Testing Finished Product

<u>Date on</u>	<u>Date off</u>	<u>Test Results</u>
08-Jun-2022	22-Jun-2022	<u>Extraneous viruses using cells</u>
		Tested according to Ph. Eur. 0964
		Result: No extraneous agents detected Threshold: No extraneous agents detected Conclusion: Passed
		<u>Identity CDV</u>
		Result: Identity conform
		Threshold: Identity conform Conclusion: Passed
		<u>Identity CAV</u>
		Result: Identity conform
		Threshold: Identity conform Conclusion: Passed
10-Jun-2022	15-Jun-2022	<u>Identity CPV</u>
		Result: Identity conform
		Threshold: Identity conform Conclusion: Passed
24-May-2022	24-May-2022	<u>Residual moisture</u>
		Tested according to Ph. Eur. 2.5.32
		Result: 1 % Threshold: <= 4 % Conclusion: Passed