



IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
Germany

Phone +49 34901 885 0
Fax +49 34901 885 5323

Certificate of Analysis

Product	Rabitec (bait) (finished product) ☒ Flying bait: 4 x 200 baits ☐ Tube bait: 1 x 800 baits ☐ Manual bait: 40 x 20 baits
Country	EE
SAP Material Number	0000104921
SAP Batch	2001100002
Customer / internal batch	0271019-B
Manufacturing Date	10/21/2019 (MM/DD/YYYY)
Expiry Date	10/21/2021 (MM/DD/YYYY)
Dosage form	suspension for oral application
Active Ingredients	living attenuated rabies virus, strain SPBN GASGAS
Strength	min. $10^{7.0}$ Focus Forming Units/ml max. $10^{7.9}$ Focus Forming Units/ml
Package Type	bait containing blister
Filling Volume	1.7 ml
Customer	CEVA Santé Animale SA
Manufacturer	IDT Biologika GmbH
Technical Quality Agreement:	Quality Agreement between Ceva (France) and Ceva (Hungary) and IDT Biologika (from 15 th July 2019)
Specification	Rabitec (baits)
Specification Number/ Version	RS-000195 V001

Test Parameter Test Method	Begin of Test End of Test	Acceptance Criteria	Test Result	Assessment
Virus content release titer (QOV-PM-045)	22.01.2020 – 28.01.2020	7.0 – 7.9 lg FFU/ml	7.3 lg FFU/ml	complies
Organoleptic Test (QOV-PM-013)				
Consistency	22.01.2020 – 22.01.2020	solid, little deformable, fatty	solid, little deformable, fatty	complies
Colour	22.01.2020 – 22.01.2020	brown	brown	complies



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Test Parameter Test Method	Begin of Test End of Test	Acceptance Criteria	Test Result	Assessment
Odor	22.01.2020 – 22.01.2020	intense, pleasant, fishy	intense, pleasant, fishy	complies
Bait stability	22.01.2020 – 22.01.2020	no deformation or slight deformation, no bursting	no deformation or slight deformation, no bursting	complies
Bait shape	22.01.2020 – 22.01.2020	edgy	edgy	complies
Melting point (QOC-PM-035)	24.01.2020 – 24.01.2020	≥ 35 °C	47 °C 47 °C 46 °C 47 °C 46 °C 47 °C MV: 47 °C	complies
Content determi- nation of biomarker (QOC-PM-416)	03.03.2020 – 06.03.2020	< 30% conversion of oxytetracycline into 4-epi oxytetracycline isomers	10% conversion of oxy- tetracycline into 4-epi oxytetracycline isomers	complies

Reference to Non-conformities: none

Remarks: V02: "Odor" test was supplemented

Statement of Compliance:

I hereby confirm that the testing stages indicated for this batch have been carried out in full compliance with the GMP requirements of the EU, with the requirements of the Marketing Authorizations of the destination countries, and the valid specification.

This batch

- ☒ Complies with given specifications.
☐ Does not comply with given specifications

Dr. Tobias Stahl

IDT Biologika GmbH
 Head of Quality Control

Dessau-Rosslau,

23. MRZ. 2020