

	Batch Record	I-HAI-087_V002-F003
Product:	Rabitec	
Internal Batch No.:	0271019-B	

Product: Rabitec
Internal Batch No.: 0271019-B
SAP batch no.: 2001100002
Presentation: 4 x 200 doses

Manufacturer: IDT Biologika GmbH
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1. Manufacturing Record
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1. Manufacturing Record

A) Starting material

Seed lot	Internal batch no.:	Production date:	Release date:
Master seed virus MSV SPBN GASGAS/ID03_EU	011012	18.10.2012	24.02.2015
Working seed virus WSV SPBN GASGAS/ID03_EU	010417	07.04.2017	15.06.2018
Master cell seed MCS BHK BSR CL 13 GASGAS/ID03_EU	010212	15.02.2012	02.12.2014
Working cell seed WCS BHK BSR CL 13 GASGAS/ID03_EU	010312	29.03.2012	13.11.2015

B) Virus production

Cell culture		Virus harvest		Result [L]
SAP Batch No.	Date	SAP Batch No.	Date	
1808300035	05.09.18	1809040015	11.09.18	181.9
1808300035	05.09.18	1809040104	14.09.18	181.5
1808300035	05.09.18	1809060020	17.09.18	182.7

In process controls for virus production

Test material	Test	Start	End	Requirement	Result
Cell culture SAP Batch No.: 1808300035	Sterility	12.09.18	26.09.18	sterile	sterile
	Mycoplasma	18.09.18	16.10.18	free of mycoplasma	free of mycoplasma
Virus harvest SAP Batch No.: 1809040015	Sterility	19.09.18	04.10.18	sterile	sterile
	Virus content	24.09.18	26.09.18	min. 10 ^{6.0} FFU/ml	10 ^{7.4} FFU/ml
Virus harvest SAP Batch No.: 1809040104	Sterility	24.09.18	08.10.18	sterile	sterile
	Virus content	24.09.18	26.09.18	min. 10 ^{6.0} FFU/ml	10 ^{7.5} FFU/ml
Virus harvest SAP Batch No.: 1809060020	Sterility	25.09.18	09.10.18	sterile	sterile
	Virus content	24.09.18	26.09.18	min. 10 ^{6.0} FFU/ml	10 ^{7.5} FFU/ml

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C) Clarification

Virus harvest		Filtrate		Result [L]
SAP Batch No.	Date	SAP Batch No.	Date	
1809040015	11.09.18	1909300025	11.09.18	56.0
1809040104	14.09.18	1909300027	14.09.18	126.0
1809060020	17.09.18	1909300028	17.09.18	126.0

In process controls for virus clarification

Test material	Test	Start	End	Requirement	Result
filtrate SAP Batch No.: 1909300025	Sterility	19.09.18	04.10.18	sterile	sterile
	Virus content	24.09.18	26.09.18	min. $10^{6.0}$ FFU/ml	$10^{7.2}$ FFU/ml
filtrate SAP Batch No.: 1909300027	Sterility	24.09.18	08.10.18	sterile	sterile
	Virus content	24.09.18	26.09.18	min. $10^{6.0}$ FFU/ml	$10^{7.6}$ FFU/ml
filtrate SAP Batch No.: 1909300028	Sterility	28.09.18	12.10.18	sterile	sterile
	Virus content	24.09.18	26.09.18	min. $10^{6.0}$ FFU/ml	$10^{7.4}$ FFU/ml
Mixed virus bulk	Calculated virus content	-	-	$10^{7.5}$ FFU/ml	$10^{7.5}$ FFU/ml

D) Batch blending

Start date: 21.10.19 Start time: 06:53 h End date: 21.10.19 End time: 08:10 h

Component	Bulk/ SAP No.	Ratio [%]	Quantity Actual [L]
clarified Virus harvest	1909300025	69	56.0
	1909300027		126.0
	1909300028		126.0
GS 8-stabilizer	1905020003	30	133.9
0,5 % neomicinsulphate solution	1904110053	1	4.5
Total quantity	1910170032	100	446.4

Test material	Test	Start	End	Requirement	Result
Blended Batch SAP Batch No.: 1910170032	Sterility	24.10.19	07.11.19	sterile	sterile
	Virus content	23.10.19	25.10.19	N/A	$10^{7.0}$ FFU/ml

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E) Finishing / Filling

Start date: 21.10.19	Start time: 09:00 h	End date: 24.10.19	End time: 08:05 h
Filling machine	TM 2/160		
Foil material:	PVC deep draw foil / Aluminium cover foil, PVC coated		
Total filling quantity:	446.4 litre	SAP no. blended batch: 1910170032	
Weight/filled blister	Target: 1.89 – 2.52 g	Actual: 1.98 – 2.32 g	
Result:	252,744 blister	SAP no. blister: 1910170035	

F) Bait manufacturing

Starting materials for bait mixture

Components of bait mixture per 500 kg	SAP No.	Bait mixture	
		Target [kg]	Actual [kg]
Coconut fat, blocks	1908050001	100 ± 1.0	100.0
Paraffin 52/54	1904040014	50 ± 0.5	50.0
Berga fat F100	1910020033	150 ± 1.5	150.0
Fishmeal	1906110018	200 ± 2.0	200.0
Oxytetracycline-HCl (only used for purpose-build item)	1803160022	4.8 ± 0.1	4.8

Bait manufacturing

Batch/sub batch / SAP No. baits	Start	End	Result/dose
0271019-B / 2001100002	13.01.20	16.01.20	122,681

In-process control of packaging

Test material SAP No.	Test	Start	End	Requirement	Result
Blister 1910170035	Visual inspection	13.01.20	16.01.20	correct imprint	correct imprint
Bait 2001100002	Visual inspection	13.01.20	16.01.20	correct label	correct label

G) Summary

I hereby certify that this batch was produced in accordance with the currently valid GMP requirements and in accordance with the manufacturing specification.

Dessau-Rosslau, 18.03.2020

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Head of Manufacturing – Bait production

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