



ZOETIS BELGIUM SA
RUE LAID BURNIAT,1
B-1348 LOUVAIN-NEUVE
BELGIUM
AUTHORIZATION NUMBER 419 V

MANUFACTURER RELEASE DOCUMENT / CERTIFICATE OF ANALYSIS

Product Name: Versifel FeLV

Country: HU

Presentation: 10 x 1 ds

**Finished Product Batch
Number:** 421279

Batch data:	Liquid fraction Lot number – Unlabeled	398483
	Total Number of Containers	7730

Expiry Data:	Potency date	16/12/2019
	Finished product expiry date	15/12/2021

After reviewing all manufacturing and testing data, I am satisfied that this batch has been manufactured and tested in accordance with Good Manufacturing Practice and is in conformity with the methods and standards, described in the application dossier with the following exception: N/A

Qualified Person

Date

Lot Release Electronic
Signature: Philippe Perz

Lot Release Local Timestamp: 10-Feb-2020



SFP Batch Number: 398483 Product Name: Versifel FeLV
Number of doses: 1

COMPOSITION

Active Ingredient Batch Number

391130	Product Name: AG FELV Kawakami-Theilen (MS lot number #28, tested Apr-99)
375380	Product Name: AG FELV Kawakami-Theilen (MS lot number #28, tested Apr-99)

Finished Product Production Data

Data	Result
Blending date	27/11/2019
Number of filled containers	174427
Blended volume (L)	200.0
Volume filled (ml)	1.17
Container type	Glass vial

QC Tests

Test	Result	Result Unit	Acceptance Criteria	Date In	Date Out
Description	Conform	N/A	The glass vial contains a slightly opaque suspension which could settle during storage. The deposit is easily resuspended by shaking.	09-Dec-2019	09-Dec-2019
pH	6.9	N/A	6.8<=x<=7.4	09-Dec-2019	09-Dec-2019



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Test	Result	Result Unit	Acceptance Criteria	Date In	Date Out
Sterility	No Growth	N/A	No growth	19-Dec-2019	13-Jan-2020
GMT mouse potency/identity	8.6	log2	$\geq 8.4\log_2$	16-Dec-2019	30-Dec-2019



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Active Ingredient Batch Number 391130

Product Name: AG FELV Kawakami-Theilen (MS lot number #28, tested Apr-99)

Production Data

Data	Result
Manufactured by	Zoetis, Lincoln
Working seed lot number	1607116
WS last testing date	NOV 2006
WS passage level (from MS)	108
Batch size (L)	75.5
Inoculation date	17/04/2019
First harvest date (harvest A)	23/04/2019
Inactivation start date (harvest A)	23/04/2019
Inactivation end date/Neutralization start date (harvest A)	25/04/2019
Neutralization end date (harvest A)	25/04/2019
Second harvest date (harvest B)	29/04/2019
Inactivation start date (harvest B)	29/04/2019
Inactivation end date/Neutralization start date (harvest B)	01/05/2019
Neutralization end date (harvest B)	01/05/2019
Concentration date (harvest A+harvest B)	03/05/2019
Conditioning for storage date (harvest A+harvest B)	06/05/2019

QC Tests



Test	Result	Result Unit	Acceptance Criteria	Date In	Date Out
Absence of Mycoplasma before inactivation (harvest A)	No Mycoplasma detected	N/A	No Mycoplasma detected	30-Apr-2019	28-May-2019
Absence of Mycoplasma before inactivation (harvest B)	No Mycoplasma detected	N/A	No Mycoplasma detected	30-Apr-2019	28-May-2019
Sterility before inactivation (harvest A)	No Growth	N/A	No growth	10-May-2019	24-May-2019
Sterility before inactivation (harvest B)	No Growth	N/A	No growth	23-May-2019	06-Jun-2019
FeLV antigen titre before inactivation (harvest A)	6.0	L10CCID/ml	<= 6.7	02-May-2019	09-May-2019
FeLV antigen titre before inactivation (harvest B)	6.0	L10CCID/ml	<= 6.7	02-May-2019	09-May-2019
Test for complete inactivation on pool antigen fluids (harvest A)	No Growth	N/A	No growth	07-May-2019	28-May-2019
Test for complete inactivation on pool antigen fluids (harvest B)	No Growth	N/A	No growth	07-May-2019	28-May-2019
Residual sodium thiosulfate on antigen fluid (harvest A)	Detected	N/A	Must be detected	26-Apr-2019	26-Apr-2019
Residual sodium thiosulfate on antigen fluid (harvest B)	Detected	N/A	Must be detected	21-May-2019	21-May-2019
FeLV antigen titre after inactivation (harvest A)	70	µg/mL	>= 7	03-May-2019	03-May-2019
FeLV antigen titre after inactivation (harvest B)	45	µg/mL	>= 7	03-May-2019	03-May-2019
Sterility test after inactivation (harvest A)	No Growth	N/A	No growth	21-May-2019	04-Jun-2019
Sterility test after inactivation (harvest B)	No Growth	N/A	No growth	16-May-2019	30-May-2019
Sterility test after concentration	No Growth	N/A	No growth	20-May-2019	03-Jun-2019
FeLV antigen titre after concentration	667	µg/mL	>= 36	09-May-2019	09-May-2019



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Active Ingredient Batch Number 375380

Product Name: AG FELV Kawakami-Theilen (MS lot number #28, tested Apr-99)

Production Data

Data	Result
Manufactured by	Zoetis, Lincoln
Working seed lot number	1607116
WS last testing date	NOV 2006
WS passage level (from MS)	108
Batch size (L)	73.5
Inoculation date	06/02/2019
First harvest date (harvest A)	12/02/2019
Inactivation start date (harvest A)	12/02/2019
Inactivation end date/Neutralization start date (harvest A)	14/02/2019
Neutralization end date (harvest A)	14/02/2019
Second harvest date (harvest B)	18/02/2019
Inactivation start date (harvest B)	18/02/2019
Inactivation end date/Neutralization start date (harvest B)	20/02/2019
Neutralization end date (harvest B)	20/02/2019
Concentration date (harvest A+harvest B)	25/03/2019
Conditioning for storage date (harvest A+harvest B)	26/03/2019

QC Tests

Test	Result	Result Unit	Acceptance Criteria	Date In	Date Out
Absence of Mycoplasma before inactivation (harvest A)	No Mycoplasma detected	N/A	No Mycoplasma detected	19-Feb-2019	19-Mar-2019
Absence of Mycoplasma before inactivation (harvest B)	No Mycoplasma detected	N/A	No Mycoplasma detected	26-Feb-2019	26-Mar-2019
Sterility before inactivation (harvest A)	No Growth	N/A	No growth	21-Feb-2019	07-Mar-2019
Sterility before inactivation (harvest B)	No Growth	N/A	No growth	21-Feb-2019	07-Mar-2019
FeLV antigen titre before inactivation (harvest A)	6.5	L10CCID/ml	<= 6.7	26-Feb-2019	05-Mar-2019
FeLV antigen titre before inactivation (harvest B)	6.6	L10CCID/ml	<= 6.7	26-Feb-2019	05-Mar-2019
Test for complete inactivation on pool antigen fluids (harvest A)	No Growth	N/A	No growth	05-Mar-2019	26-Mar-2019
Test for complete inactivation on pool antigen fluids (harvest B)	No Growth	N/A	No growth	05-Mar-2019	26-Mar-2019
Residual sodium thiosulfate on antigen fluid (harvest A)	Detected	N/A	Must be detected	19-Feb-2019	19-Feb-2019
Residual sodium thiosulfate on antigen fluid (harvest B)	Detected	N/A	Must be detected	04-Mar-2019	04-Mar-2019
FeLV antigen titre after inactivation (harvest A)	45	µg/mL	>= 7	22-Feb-2019	22-Feb-2019
FeLV antigen titre after inactivation (harvest B)	55	µg/mL	>= 7	22-Feb-2019	22-Feb-2019
Sterility test after inactivation (harvest A)	No Growth	N/A	No growth	21-Feb-2019	07-Mar-2019
Sterility test after inactivation (harvest B)	No Growth	N/A	No growth	25-Feb-2019	11-Mar-2019
Sterility test after concentration	No Growth	N/A	No growth	28-Mar-2019	11-Apr-2019
FeLV antigen titre after concentration	641	µg/mL	>= 36	02-Apr-2019	02-Apr-2019