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PREVIOUSLY NAMED
PFIZER ANIMAL HEALTH SA
RUE LAID BURNIAT, 1
B-1348 LOUVAIN-LA-NEUVE
BELGIUM
AUTHORIZATION NUMBER 419 V

MANUFACTURERS RELEASE DOCUMENT / CERTIFICATE OF ANALYSIS

Product Name: VERSIFEL CVR
Country: HU
Product Description: 10 x 1 ds

Finished Product Batch Number: 129758

Batch data:

Freeze-dried fraction Lot Number - Unlabeled:	124246
Liquid fraction Lot Number - Unlabeled:	115510
Total number of containers the release is applied for:	4800

Expiry data:

Removal from freezer date (FD fraction)	20/11/2015
Expiry date (FD fraction)	19/11/2017
Manufacturing date (Liquid fraction)	07/09/2015
Expiry date (Liquid fraction)	09/2020
Finished product expiry date	19/11/2017

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: NA

Date: 07/01/2016

Luc Giorgi
Qualified Person

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BATCHES PROTOCOL

SFP Batch Number: 124246
Product Name: CVR
Number of Doses: 1

COMPOSITION

Active Ingredient Batch Number	Active Ingredient Name
1057152/A	AG FPV (MS lot number WS/288, tested Jan-76)
1303482	AG FVR FVRM (MS lot number A, p12, tested Oct-79)
1303489	AG FCV F-9 (MS lot number F-9, R+3, tested Apr-78)

Finished Product Production Data

Data	Result
Blending date	21/10/2015
Blended volume (L)	98.2
Number of filled containers	184615
Volume filled (ml)	0.47
Freeze-drying start date	21/10/2015
Freeze-drying end date	23/10/2015
Container type	Glass vial

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SFP Batch Number: 124246 Product Name: CVR
Number of Doses: 1

QC Tests on Finished Product

Test	Result	Result Unit	Acceptance Criteria	Date In	Date Out
Description	Conform	N/A	Slightly coloured freeze-dried pellet	05-NOV-2015	
Residual humidity	1	%	<=3	05-NOV-2015	
Sterility	No growth	N/A	No growth	28-OCT-2015	12-NOV-2015
Identification FCV	Positive	N/A	Positive for FCV (SN)	05-NOV-2015	12-NOV-2015
Identification FPV	Positive	N/A	Positive for FPV (IF)	05-NOV-2015	10-NOV-2015
Identification FVRm	Positive	N/A	Positive for FVRm (SN)	05-NOV-2015	12-NOV-2015
Titration FCV	6.5	log10 CCID50/ds	5.8<=x<=7.5	05-NOV-2015	12-NOV-2015
Titration FPV	4.8	log10 CCID50/ds	3.4<=x<=5.2	05-NOV-2015	10-NOV-2015
Titration FVRm	6.4	log10 CCID50/ds	5.7<=x<=7.3	05-NOV-2015	12-NOV-2015

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SFP Batch Number: 115510
Number of Doses: 1

Product Name: DILUANT H20 1ML

Finished Product Production Data

Data	Result
Filling date	08/09/2015
Number of filled containers	283397
Sterilization date	10/09/2015
Volume filled (ml)	1.2

QC Tests on Finished Product

Test	Result	Result Unit	Acceptance Criteria	Date In	Date Out
Characters	Conform	N/A	Clear, colourless liquid, no visible impurities	23-SEP-2015	
Acidity or Alcalinity	Conform	N/A	If the solution is yellow, it becomes red on the addition of 0.1 ml of 0.01M NaOH; if red it becomes yellow on the addition of 0.15 ml of 0.01 M HCl	23-SEP-2015	
Oxidisable substances	Conform	N/A	The solution remains faintly pink	23-SEP-2015	
Chlorides (limit test)	Conform	N/A	Not more than 0.5 ppm	23-SEP-2015	
Nitrates	Conform	N/A	Not more than 0.2 ppm	23-SEP-2015	
Residue on evaporation (mg/100ml)	1	mg/100ml	<= 8 mg/100ml	24-SEP-2015	
Sulfates	Conform	N/A	The solution shows no change in appearance for at least one hour.	23-SEP-2015	
Ammonium	Conform	N/A	Not more than 0.6 ppm	23-SEP-2015	
Calcium and magnesium	Conform	N/A	Production of a pure blue colour	23-SEP-2015	
Extractable volume (Mean)	1.2	ml	1.1-1.3 ml	23-SEP-2015	

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SFP Batch Number: 115510
Number of Doses: 1

Product Name: DILUANT H20 1ML

QC Tests on Finished Product

Test	Result	Result Unit	Acceptance Criteria	Date In	Date Out
Extractable volume (Min.)	1.1	ml	1.1-1.3 ml	23-SEP-2015	
Extractable volume (Max.)	1.2	ml	1.1-1.3 ml	23-SEP-2015	
Particulate contamination	74	N/A	Not more than 6000/vial for particles >= 10 microm	23-SEP-2015	
Particulate contamination	1	N/A	Not more than 600/vial for particles >= 25 microm	23-SEP-2015	
Conductivity (microS/cm)	10	microS/cm	Not more than 25 microS/cm	23-SEP-2015	
Sterility	No growth	N/A	No growth	22-SEP-2015	06-OCT-2015
Bacterial endotoxins	< 0.05	IU/ml	Less than 0.25 IU/ml	23-SEP-2015	

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Active Ingredient Batch Number: 1303489	Active Ingredient Name: AG FCV F-9 (MS lot number F-9, R+3, tested Apr-78)

Active Ingredient Production Data

Data	Result
Manufactured by	Pfizer, Lincoln
Working seed lot number	1256
WS last testing date	APR 2002
WS passage level (from MS)	4
Batch size (L)	171
Inoculation date	16 APR 2013
Harvest date	17 APR 2013
Conditioning for storage date	17 APR 2013

QC Tests on Active Ingredient

Test	Result	Result Unit	Acceptance Criteria	Date In	Date Out
Absence of Mycoplasma	No Mycoplasma detected	N/A	No Mycoplasma detected	23-APR-2013	21-MAY-2013
Sterility	No growth	N/A	No growth	22-APR-2013	06-MAY-2013
FCV antigen titre	8.4	log10 CCID50/ml	Titre sufficient to allow formulation	26-APR-2013	02-MAY-2013
Absence of extraneous agents (on NL-FK cells)	No live extraneous virus detected	N/A	No live extraneous virus detected	24-APR-2013	08-MAY-2013
Absence of extraneous agents (on Vero cells)	No live extraneous virus detected	N/A	No live extraneous virus detected	24-APR-2013	08-MAY-2013

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Active Ingredient Batch Number: 1057152/A	Active Ingredient Name: AG FPV (MS lot number WS/288, tested Jan-76)

Active Ingredient Production Data

Data	Result
Manufactured by	Pfizer, Lincoln
Working seed lot number	6250
WS last testing date	AUG 1999
WS passage level (from MS)	3
Batch size (L)	159
Inoculation date	29 JUN 2010
Harvest date	06 JUL 2010
Conditioning for storage date	06 JUL 2010

QC Tests on Active Ingredient

Test	Result	Result Unit	Acceptance Criteria	Date In	Date Out
Absence of Mycoplasma	No Mycoplasma detected	N/A	No Mycoplasma detected	13-JUL-2010	10-AUG-2010
Sterility	No growth	N/A	No growth	14-JUL-2010	28-JUL-2010
Absence of extraneous agents (on NL-FK cells)	No live extraneous virus detected	N/A	No live extraneous virus detected	13-JUL-2010	27-JUL-2010
Absence of extraneous agents (on Vero cells)	No live extraneous virus detected	N/A	No live extraneous virus detected	14-JUL-2010	28-JUL-2010
FPV antigen titre	6.9	log10 CCID50/ml	Titre sufficient to allow formulation	14-JUL-2010	21-JUL-2010

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Active Ingredient Batch Number: 1303482	Active Ingredient Name: AG FVR FVRM (MS lot number A, p12, tested Oct-79)

Active Ingredient Production Data

Data	Result
Manufactured by	Pfizer, Lincoln
Working seed lot number	2753
WS last testing date	JUN 1999
WS passage level (from MS)	3
Batch size (L)	176
Inoculation date	08 APR 2013
Harvest date	12 APR 2013
Conditioning for storage date	12 APR 2013

QC Tests on Active Ingredient

Test	Result	Result Unit	Acceptance Criteria	Date In	Date Out
Absence of Mycoplasma	No Mycoplasma detected	N/A	No Mycoplasma detected	16-APR-2013	14-MAY-2013
Sterility	No growth	N/A	No growth	22-APR-2013	06-MAY-2013
FVRm antigen titre	8.5	log10 CCID50/ml	Titre sufficient to allow formulation	19-APR-2013	29-APR-2013
Absence of extraneous agents (on NL-FK cells)	No live extraneous virus detected	N/A	No live extraneous virus detected	24-APR-2013	08-MAY-2013
Absence of extraneous agents (on Vero cells)	No live extraneous virus detected	N/A	No live extraneous virus detected	26-APR-2013	08-MAY-2013

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