ZOETIS BELGIUM SA
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: 100131

Batch data:

Freeze-dried fraction Lot Number - Unlabeled:	T42080
Liquid fraction Lot Number - Unlabeled:	T42146
Total number of containers the release is applied for:	4600

Expiry data:

Removal from freezer date (FD fraction)	10/10/2014
Expiry date (FD fraction)	09/10/2016
Manufacturing date (Liquid fraction)	13/05/2014
Expiry date (Liquid fraction)	05/2019
Finished product expiry date	09/10/2016

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: 20/10/14

Luc Giorgi
Qualified Person

Philippe PERZ
Quality Operations Director/TL
Zoetis Belgium SA

BATCHES PROTOCOL

SFP Batch Number: T42080
Number of Doses: 1

Product Name: CVR

COMPOSITION

Active Ingredient Batch Number	Active Ingredient Name
1057152/A	AG FPV (MS lot number WS/288, tested Jan-76)
1166100/A	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	09/05/2014
Blended volume (L)	96.4
Number of filled containers	182203
Volume filled (ml)	0.47
Freeze-drying start date	09/05/2014
Freeze-drying end date	11/05/2014
Container type	Glass vial

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SFP Batch Number: T42080
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	28-MAY-2014	
Residual humidity	1	%	<=3	28-MAY-2014	
Sterility	No growth	N/A	No growth	16-MAY-2014	30-MAY-2014
Identification FCV	Positive	N/A	Positive for FCV (SN)	21-MAY-2014	28-MAY-2014
Identification FPV	Positive	N/A	Positive for FPV (IF)	21-MAY-2014	26-MAY-2014
Identification FVRm	Positive	N/A	Positive for FVRm (SN)	21-MAY-2014	28-MAY-2014
Titration FCV	6.7	log10 CCID50/ds	5.8<=x<=7.5	21-MAY-2014	28-MAY-2014
Titration FPV	4.9	log10 CCID50/ds	3.4<=x<=5.2	21-MAY-2014	26-MAY-2014
Titration FVRm	6.3	log10 CCID50/ds	5.7<=x<=7.3	21-MAY-2014	28-MAY-2014

SFP Batch Number: T42146
Number of Doses: 1

Product Name: DILUANT H20 1ML

Finished Product Production Data

Data	Result
Filling date	14/05/2014
Number of filled containers	285719
Sterilization date	14/05/2014
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	04-JUN-2014	
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	04-JUN-2014	
Oxidisable substances	Conform	N/A	The solution remains faintly pink	04-JUN-2014	
Chlorides (limit test)	Conform	N/A	Not more than 0.5 ppm	04-JUN-2014	
Nitrates	Conform	N/A	Not more than 0.2 ppm	04-JUN-2014	
Residue on evaporation (mg/100ml)	2	mg/100ml	<= 8 mg/100ml	05-JUN-2014	
Sulfates	Conform	N/A	The solution shows no change in appearance for at feast one hour.	04-JUN-2014	
Ammonium	Conform	N/A	Not more than 0.6 ppm	04-JUN-2014	
Calcium and magnesium	Conform	N/A	Production of a pure blue colour	04-JUN-2014	
Extractable volume (Mean)	1.2	ml	1.1-1.3 ml	05-JUN-2014	

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SFP Batch Number: T42146
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.)	1.2	ml	1.1-1.3 ml	05-JUN-2014	
Extractable volume (Max.)	1.2	ml	1.1-1.3 ml	05-JUN-2014	
Particulate contamination	43	N/A	Not more than 6000/vial for particles >= 10 microm	05-JUN-2014	
Particulate contamination	1	N/A	Not more than 600/vial for particles >= 25 microm	05-JUN-2014	
Conductivity (microS/cm)	6	microS/cm	Not more than 25 microS/cm	05-JUN-2014	
Sterility	No growth	N/A	No growth	23-MAY-2014	06-JUN-2014
Bacterial endotoxins	< 0.05	IU/ml	Less than 0.25 IU/ml	10-JUN-2014	

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

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: 1166100/A	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)	4
Batch size (L)	181.5
Inoculation date	21 MAR 2011
Harvest date	25 MAR 2011
Conditioning for storage date	25 MAR 2011

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	29-MAR-2011	26-APR-2011
Sterility	No growth	N/A	No growth	30-MAR-2011	13-APR-2011
FVRm antigen titre	8.8	log10 CCID50/ml	Titre sufficient to allow formulation	06-APR-2011	15-APR-2011
Absence of extraneous agents (on NL-FK cells)	No live extraneous virus detected	N/A	No live extraneous virus detected	05-APR-2011	19-APR-2011
Absence of extraneous agents (on Vero cells)	No live extraneous virus detected	N/A	No live extraneous virus detected	28-APR-2011	12-MAY-2011