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 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: VANGUARD PLUS 7
 Country: HU
 Product Description: 25 x 1 ds

Finished Product Batch Number: 110564

Batch data:

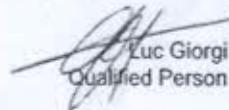
Freeze-dried fraction Lot Number - Unlabeled:	107821
Liquid fraction Lot Number - Unlabeled:	101533
Total number of containers the release is applied for:	11750

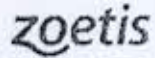
Expiry data:

Removal from freezer date (FD fraction)	19/06/2015
Expiry date (FD fraction)	18/06/2017
Potency date (Liquid fraction)	12/02/2015
Expiry date (Liquid fraction)	11/02/2019
Finished product expiry date	18/06/2017

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: 31/7/2015


 Luc Giorgi
 Qualified Person



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BATCHES PROTOCOL

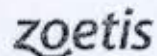
SFP Batch Number: 107821
Number of Doses: 1

Product Name: DA2P

COMPOSITION

Active Ingredient Batch Number	Active Ingredient Name
1400160	AG CAV2 MANHATTAN (MS lot number 1, tested Dec-91)
1400161	AG CPI5 NL-CPI5 (MS lot number 12, tested Dec-91)
1400162	AG CPI5 NL-CPI5 (MS lot number 12, tested Dec-91)
1400163	AG CPI5 NL-CPI5 (MS lot number 12, tested Dec-91)
1402059	AG CDV N-CDV (MS lot number L15, tested Dec-91)
1403279	AG CPI5 NL-CPI5 (MS lot number 12, tested Dec-91)
1403280	AG CPI5 NL-CPI5 (MS lot number 12, tested Dec-91)
1403281	AG CPI5 NL-CPI5 (MS lot number 12, tested Dec-91)
1404014	AG CPI5 NL-CPI5 (MS lot number 12, tested Dec-91)
1405485	AG CDV N-CDV (MS lot number L15, tested Dec-91)
1406215	AG CDV N-CDV (MS lot number L15, tested Dec-91)
1406860	AG CDV N-CDV (MS lot number L15, tested Dec-91)

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SFP Batch Number: 107821	Product Name: DA2P
Number of Doses: 1	

Finished Product Production Data

Data	Result
Blending date	01/06/2015
Blended volume (L)	137.5
Number of filled containers	184407
Volume filled (ml)	0.7
Freeze-drying start date	01/06/2015
Freeze-drying end date	04/06/2015
Container type	Glass vial

QC Tests on Finished Product

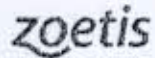
Test	Result	Result Unit	Acceptance Criteria	Date In	Date Out
Description	Conform	N/A	Slightly coloured freeze-dried pellet	18-JUN-2015	
Residual humidity	1.6	%	<=3%	18-JUN-2015	
Sterility	No growth	N/A	No growth	15-JUN-2015	29-JUN-2015
Identification CDV	Positive	N/A	Positive for CDV	18-JUN-2015	29-JUN-2015
Identification CAV2	Positive	N/A	Positive for CAV2	18-JUN-2015	25-JUN-2015
Identification CPI5	Positive	N/A	Positive for CPI5	18-JUN-2015	26-JUN-2015
CDV titre	4.9	log10 CCID50/ids	3.9<=CDV<=5.5	18-JUN-2015	29-JUN-2015
CAV2 titre	4.8	log10 CCID50/ids	3.4<=CAV2<=5.2	18-JUN-2015	25-JUN-2015
CPI5 titre	7.6	log10 CCID50/ids	6.9<=CPI5<=8.0	18-JUN-2015	26-JUN-2015

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Diszpó: PN-2A15002497 Vevő: Alpha-Vet 8000
Szállító: Zoetis Hungary Kft.
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Kizárólag a két tintával szignált másolat tekinthető hitelesnek!

File név: PN00008505 Egyedi sorszám: PN0000075549 3 másolat
Oldal/Lap 22 / 3 Anyaglap: PN0343/15
Nyomtatás dátuma: 2015.10.08
CertEx v3.03a



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SFP Batch Number: 101533 Product Name: VANGUARD CPV-L
Number of Doses: 1

COMPOSITION	
Active Ingredient Batch Number	Active Ingredient Name
1308302	AG LEPTO CANICOLA (MS lot number 10003, tested Dec-74)
1401302	AG CPV37 (MS lot number 1-D(P35-D), tested May-93)
1402707	AG CPV37 (MS lot number 1-D(P35-D), tested May-93)
1403290	AG CPV37 (MS lot number 1-D(P35-D), tested May-93)
1403552	AG LEPTO CANICOLA (MS lot number 10003, tested Dec-74)

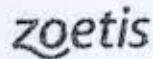
Finished Product Production Data	
Data	Result
Blending date	03/02/2015
Blended volume (L)	339.4
Number of filled containers	282130
Volume filled (ml)	1.18
Container type	Glass vial

QC Tests on Finished Product					
Test	Result	Result Unit	Acceptance Criteria	Date In	Date Out
Description	Conform	N/A	Clear to slightly turbid pinkish liquid	10-FEB-2015	
Individual volume (min.)	1.12	ml	1.10<=x<=1.30 ml	11-FEB-2015	

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SFP Batch Number: 101533
Number of Doses: 1

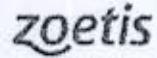
Product Name: VANGUARD CPV-L

QC Tests on Finished Product

Test	Result	Result Unit	Acceptance Criteria	Date In	Date Out
Individual volume (max.)	1.15	ml	1.10<=x<=1.30 ml	11-FEB-2015	
Individual volume (average)	1.14	ml	1.10<=x<=1.30 ml	11-FEB-2015	
pH	7.4	N/A	7.0<=x<=7.8	10-FEB-2015	
Sterility	No growth	N/A	No growth	10-MAR-2015	24-MAR-2015
Identification CPV	Positive	N/A	Positive for CPV37	20-FEB-2015	24-FEB-2015
Titration CPV37	7.6	log10 CCID50/ds	7.4<=x<=8.5	20-FEB-2015	24-FEB-2015
Viridial activity CDV-CPE	0.2	log10 CCID50/ds	<= 0.7 log/ds on CDV reference	13-FEB-2015	23-FEB-2015
Identification Lepto canicola&icterohaemorrhagiae	See potency test	N/A	See potency test	12-FEB-2015	19-MAR-2015
Lepto canicola potency test (vaccinates/5)	5	N/A	>= 4/5 vaccinates protected	12-FEB-2015	19-MAR-2015
Lepto icterohaemorrhagiae potency (vaccinates/5)	5	N/A	>= 4/5 vaccinates protected	12-FEB-2015	19-MAR-2015
Lepto canicola potency test (ctrl/5)	5	N/A	>=4/5 ctrl died	12-FEB-2015	19-MAR-2015
Lepto icterohaemorrhagiae potency (ctrl/5)	4	N/A	>=4/5 ctrl died	12-FEB-2015	19-MAR-2015

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Active Ingredient Batch Number: 1400160 Active Ingredient Name: AG CAV2 MANHATTAN (MS lot number 1, tested Dec-91)

Active Ingredient Production Data

Data	Result
Manufactured by	Pfizer, Lincoln
Working seed lot number	1750
WS last testing date	08/04/96
WS passage level (from MS)	4
Batch size (L)	91.75
Inoculation date	10/01/14
Harvest date	14/01/14
Conditioning for storage date	14/01/14

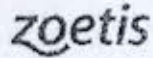
QC Tests on Active Ingredient

Test	Result	Result Unit	Acceptance Criteria	Date In	Date Out
Absence of Mycoplasma	No Mycoplasma detected	N/A	No Mycoplasma detected	21-JAN-2014	18-FEB-2014
Sterility	No growth	N/A	No growth	23-JAN-2014	06-FEB-2014
CAV2 antigen titre	7.6	log10 CCID50/ml	Titre sufficient to allow formulation	20-JAN-2014	27-JAN-2014
Absence of extraneous agents (on NL-DK cells)	No live extraneous virus detected	N/A	No live extraneous virus detected	29-JAN-2014	12-FEB-2014
Absence of extraneous agents (on Vero cells)	No live extraneous virus detected	N/A	No live extraneous virus detected	22-JAN-2014	05-FEB-2014

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Active Ingredient Batch Number: 1402059 Active Ingredient Name: AG CDV N-CDV (MS lot number L15, tested Dec-91)

Active Ingredient Production Data

Data	Result
Manufactured by	Zoetis, Lincoln
Working seed lot number	2502
WS last testing date	FEB 2002
WS passage level (from MS)	4
Batch size (L)	186
Inoculation date	28 FEB 2014
Harvest date	07 MAR 2014
Conditioning for storage date	07 MAR 2014

QC Tests on Active Ingredient

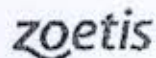
Test	Result	Result Unit	Acceptance Criteria	Date In	Date Out
Absence of Mycoplasma	No Mycoplasma detected	N/A	No Mycoplasma detected	11-MAR-2014	08-APR-2014
Sterility	No growth	N/A	No growth	10-MAR-2014	24-MAR-2014
CDV antigen titre	6.6	log10 CCID50/ml	Titre sufficient to allow formulation	13-MAR-2014	19-MAR-2014
Absence of extraneous agents (on NL-DK cells)	No live extraneous virus detected	N/A	No live extraneous virus detected	19-MAR-2014	02-APR-2014
Absence of extraneous agents (on Vero cells)	No live extraneous virus detected	N/A	No live extraneous virus detected	19-MAR-2014	02-APR-2014

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Active Ingredient Batch Number: 1405485 Active Ingredient Name: AG CDV N-CDV (MS lot number L15, tested Dec-91)

Active Ingredient Production Data

Data	Result
Manufactured by	Zoetis, Lincoln
Working seed lot number	2502
WS last testing date	FEB 2002
WS passage level (from MS)	4
Batch size (L)	176
Inoculation date	09 MAY 2014
Harvest date	16 MAY 2014
Conditioning for storage date	16 MAY 2014

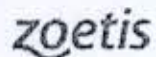
QC Tests on Active Ingredient

Test	Result	Result Unit	Acceptance Criteria	Date In	Date Out
Absence of Mycoplasma	No Mycoplasma detected	N/A	No Mycoplasma detected	17-JUN-2014	15-JUL-2014
Sterility	No growth	N/A	No growth	22-MAY-2014	05-JUN-2014
CDV antigen titre	6.8	log10 CCID50/ml	Titre sufficient to allow formulation	22-MAY-2014	28-MAY-2014
Absence of extraneous agents (on NL-DK cells)	No live extraneous virus detected	N/A	No live extraneous virus detected	21-MAY-2014	04-JUN-2014
Absence of extraneous agents (on Vero cells)	No live extraneous virus detected	N/A	No live extraneous virus detected	28-MAY-2014	11-JUN-2014

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Active Ingredient Batch Number: 1406215

Active Ingredient Name: AG CDV N-CDV (MS lot number L15, tested Dec-91)

Active Ingredient Production Data

Data	Result
Manufactured by	Zoetis, Lincoln
Working seed lot number	2502
WS last testing date	FEB 2002
WS passage level (from MS)	4
Batch size (L)	180
Inoculation date	02 JUN 2014
Harvest date	06 JUN 2014
Conditioning for storage date	06 JUN 2014

QC Tests on Active Ingredient

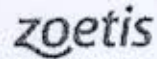
Test	Result	Result Unit	Acceptance Criteria	Date In	Date Out
Absence of Mycoplasma	No Mycoplasma detected	N/A	No Mycoplasma detected	10-JUN-2014	08-JUL-2014
Sterility	No growth	N/A	No growth	11-JUN-2014	25-JUN-2014
CDV antigen titre	7.0	log ₁₀ CCID ₅₀ /ml	Titre sufficient to allow formulation	12-JUN-2014	18-JUN-2014
Absence of extraneous agents (on NL-DK cells)	No live extraneous virus detected	N/A	No live extraneous virus detected	18-JUN-2014	02-JUL-2014
Absence of extraneous agents (on Vero cells)	No live extraneous virus detected	N/A	No live extraneous virus detected	11-JUN-2014	25-JUN-2014

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File név: PN00008505 Egyedi sorszám: PN0000075549 3 másolat
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Active Ingredient Batch Number: 1406860 Active Ingredient Name: AG CDV N-CDV (MS lot number L15, tested Dec-91)

Active Ingredient Production Data

Data	Result
Manufactured by	Zoetis, Lincoln
Working seed lot number	2502
WS last testing date	FEB 2002
WS passage level (from MS)	4
Batch size (L)	192
Inoculation date	06 JUN 2014
Harvest date	13 JUN 2014
Conditioning for storage date	13 JUN 2014

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	17-JUN-2014	15-JUL-2014
Sterility	No growth	N/A	No growth	18-JUN-2014	02-JUL-2014
CDV antigen titre	6.7	log10 CCID50/ml	Titre sufficient to allow formulation	19-JUN-2014	25-JUN-2014
Absence of extraneous agents (on NIL-DK cells)	No live extraneous virus detected	N/A	No live extraneous virus detected	18-JUN-2014	02-JUL-2014
Absence of extraneous agents (on Vero cells)	No live extraneous virus detected	N/A	No live extraneous virus detected	25-JUN-2014	09-JUL-2014

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