

MANUFACTURERS RELEASE DOCUMENT / CERTIFICATE OF ANALYSIS

Product Name: RISPOVAL 3

Country: HU-EE

Product Description: 5 ds

Finished Product Batch Number: 102064

Batch data:


Freeze-dried fraction Lot Number - Unlabeled:	100351
Liquid fraction Lot Number - Unlabeled:	100563
Total number of containers the release is applied for:	1920

Expiry data:

Removal from freezer date (FD fraction)	2003/2015
Expiry date (FD fraction)	2003/2017
Potency date (Liquid fraction)	10/11/2014
Expiry date (Liquid fraction)	2003/2017
Finished product expiry date	2003/2017

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

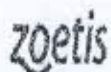
Date: 31/03/15


 Quality Director/TL
 Luc Giorgi
 Qualified Person
 Zoetis Belgium SA

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Note: emadca60

Instance Name: UCRBETP



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AUTHORIZATION NUMBER 419 V

Page: 2 of 16

BATCHES PROTOCOL

SFP Batch Number: 100563 Product Name: RISPOVAL 3 LIQUIDE
Number of Doses: 5

COMPOSITION

Active Ingredient Batch Number	Active Ingredient Name
1400608	AG BVD-K 5980 (MS lot number 51383, tested May-85)
1400657	AG BVD-K 5960 (MS lot number 51383, tested May-85)
1400958	AG BVD-K 5980 (MS lot number 51383, tested May-85)
1404425	AG BVD-K 6309 (MS lot number 112383, tested Mar-85)
1406213	AG BVD-K 6309 (MS lot number 112383, tested Mar-85)
1406881	AG BVD-K 6309 (MS lot number 112383, tested Mar-85)

Finished Product Production Data

Data	Result
Blending date	23/10/2014
Blended volume (L)	979.6
Number of filled containers	43913
Volume filled (ml)	22
Container type	Glass vial

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Code: 419023/00

Instance Name: LICR8E7P

Diszpó: PN-ZA15002330 Vevő: Alpha-Vet 8000 File név: PN00008346 Egyedi sorszám: PN0000075303 1 másolat
Szállító: Zoetis Hungary Kft. Oldal/Lap 16 / 2 Anyaglap: PN0134/15
Az eredetiről készült hiteles másolat. Nyomtatás dátuma: 2015.09.02

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CertEx v 3.03a

SFP Batch Number: 100563	Product Name: RISPOVAL 3 LIQUIDE
Number of Doses: 5	

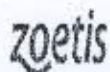
QC Tests on Finished Product

Test	Result	Result Unit	Acceptance Criteria	Date In	Date Out
Description	Conform	N/A	Slightly coloured turbid liquid	18-NOV-2014	
Individual volume (min.)	110	%	105-115% of the nominal volume	18-NOV-2014	
Individual volume (max.)	111	%	105-115% of the nominal volume	18-NOV-2014	
Individual volume (average)	110	%	105-115% of the nominal volume	18-NOV-2014	
Aluminium concentration	3.8	mg Al ₂ O ₃ /ml	<=6.2 mg Al ₂ O ₃ /ml	03-NOV-2014	
pH	7.0	N/A	6.9<=x<=7.5	18-NOV-2014	
Sterility	No growth	N/A	No growth	05-NOV-2014	28-NOV-2014
Inactivation test on pooled BVDs preadjuvantation	No live BVD detected	N/A	No live BVD detected	05-NOV-2014	24-NOV-2014
Identification BVD	See potency test	N/A	See potency test	10-NOV-2014	22-DEC-2014
BVD potency test	6.6	log ₂	3.0<=GMT(log ₂)<=11.5	10-NOV-2014	22-DEC-2014

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Wdr: emestc060

Instance Name: LICRBE7P



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SFP Batch Number: 100354	Product Name: RISPOVAL RS-PI3 LYO
Number of Doses: 5	

COMPOSITION

Active Ingredient Batch Number	Active Ingredient Name
1314218	AG BR5V 375 concentrated (MS lot number 507-10, tested Jan-96)
1401145	AG PI3 TS RLB103 (MS lot number A, tested Jan-98)
1401907	AG BR5V 375 concentrated (MS lot number 507-10, tested Jan-96)

Finished Product Production Data

Data	Result
Blending date	08/10/2014
Blended volume (L)	167.9
Number of filled containers	38711
Volume filled (ml)	4
Freeze-drying start date	08/10/2014
Freeze-drying end date	11/10/2014
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	05-NOV-2014	
Residual humidity	0.9	%	0.3% <= x <= 3%	05-NOV-2014	

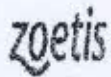
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Note: ema02903

Instance Name: UCR927P

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Szállító: Zoetis Hungary Kft. Oldal/Lap 16 / 4 Anyaglap: PN0134/15
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Page: 5 of 16

SFP Batch Number: 100354	Product Name: RISPOVAL RS-PI3 LYO
Number of Doses: 5	

QC Tests on Finished Product

Test	Result	Result Unit	Acceptance Criteria	Date In	Date Out
Sterility	No growth	N/A	No growth	17-OCT-2014	31-OCT-2014
Absence of Mycoplasma	No Mycoplasma detected	N/A	No Mycoplasma detected	23-OCT-2014	17-NOV-2014
Identification BRSV (immunofluorescence)	Positive	N/A	Positive for BRSV	24-OCT-2014	27-OCT-2014
Identification PI3 (immunofluorescence)	Positive	N/A	Positive for PI3	24-OCT-2014	27-OCT-2014
BRSV titre	6.1	log ₁₀ CCID50/dls	5.7<=x<=7.2	24-OCT-2014	03-NOV-2014
PI3 titre	6.9	log ₁₀ CCID50/dls	6.4<=x<=8.6	24-OCT-2014	31-OCT-2014
Absence of extraneous agents (on NL-BK4 cells)	No live extraneous virus detected	N/A	No live extraneous virus detected	20-OCT-2014	12-NOV-2014
Absence of extraneous agents (on NL-BT cells)	No live extraneous virus detected	N/A	No live extraneous virus detected	20-OCT-2014	12-NOV-2014

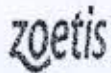
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Mod: em000200

Instance Name: LCRSEIF

Diszpó: PN-ZA15002330 Vevő: Alpha-Vet 8000 File név: PN00008346 Egyedi sorszám: PN0000075303 1 másolat
Szállító: Zoetis Hungary Kft. Oldal/Lap 16 / 5 Anyaglap: PN0134/15
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Page: 6 of 16

Active Ingredient Batch Number: 1314218

Active Ingredient Name: AG BRSV 375 concentrated (MS lot number 597-10, tested Jan-95)

Active Ingredient Production Data

Data	Result
Manufactured by	Zoetis, Lincoln
Working seed lot number	3262
WS last testing date	30 JUN 2008
WS passage level (from MS)	4
Batch size (L)	90
Inoculation date	15 JAN 2014
Harvest date (harvest A)	27 JAN 2014
Harvest date (harvest B)	29 JAN 2014
Harvest date (harvest C)	30 JAN 2014
Concentration date (harvest A+ harvest B+ harvest C)	30 JAN 2014
Conditioning for storage date (harvest A+ harvest B+ harvest C)	31 JAN 2014

QC Tests on Active Ingredient

Test	Result	Result Unit	Acceptance Criteria	Date In	Date Out
Absence of Mycoplasma before concentration (harvest A)	No Mycoplasma detected	N/A	No Mycoplasma detected	28-JAN-2014	25-FEB-2014
Absence of Mycoplasma before concentration (harvest B)	No Mycoplasma detected	N/A	No Mycoplasma detected	04-FEB-2014	04-MAR-2014
Absence of Mycoplasma before concentration (harvest C)	No Mycoplasma detected	N/A	No Mycoplasma detected	04-FEB-2014	04-MAR-2014
Absence of extraneous agents before concentration on NL-636 cells (harvest A)	No live extraneous virus detected	N/A	No live extraneous virus detected	05-FEB-2014	19-FEB-2014

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Code: 130000000

Instance Name: UKREP7P

Diszpó: PN-2A15002330 Vevő: Alpha-Vet 8000

Szállító: Zoetis Hungary Kft.

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Kizárólag a kék tintával szignált másolat tekinthető hitelesnek!

File név: PN00008346

Egyedi sorszám: PN0000075303

1 másolat

Oldal/Lap 16 /

6 Anyaglap: PN0134/15

Nyomtatás dátuma: 2015.09.02

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Active Ingredient Batch Number: 1314218

Active Ingredient Name: AG BRSV 375 concentrated (MS lot number 597-10, tested Jan-95)

QC Tests on Active Ingredient

Test	Result	Result Unit	Acceptance Criteria	Date In	Date Out
Absence of extraneous agents before concentration on NL-BK6 cells (harvest B)	No live extraneous virus detected	N/A	No live extraneous virus detected	05-FEB-2014	19-FEB-2014
Absence of extraneous agents before concentration on NL-BK6 cells (harvest C)	No live extraneous virus detected	N/A	No live extraneous virus detected	05-FEB-2014	19-FEB-2014
Absence of extraneous agents before concentration on Vero cells (harvest A)	No live extraneous virus detected	N/A	No live extraneous virus detected	06-FEB-2014	19-FEB-2014
Absence of extraneous agents before concentration on Vero cells (harvest B)	No live extraneous virus detected	N/A	No live extraneous virus detected	06-FEB-2014	19-FEB-2014
Absence of extraneous agents before concentration on Vero cells (harvest C)	No live extraneous virus detected	N/A	No live extraneous virus detected	06-FEB-2014	19-FEB-2014
Absence of extraneous agents before concentration on NL-BT2 cells (harvest A)	No live extraneous virus detected	N/A	No live extraneous virus detected	05-FEB-2014	19-FEB-2014
Absence of extraneous agents before concentration on NL-BT2 cells (harvest B)	No live extraneous virus detected	N/A	No live extraneous virus detected	05-FEB-2014	19-FEB-2014
Absence of extraneous agents before concentration on NL-BT2 cells (harvest C)	No live extraneous virus detected	N/A	No live extraneous virus detected	05-FEB-2014	19-FEB-2014
Sterility	No growth	N/A	No growth	07-FEB-2014	21-FEB-2014
BRSV titre	6.4	log ₁₀ CCID ₅₀ /ml	≥ 6.0 log ₁₀ CCID ₅₀ /ml	11-FEB-2014	17-FEB-2014

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Note: enaeca00

Instance Name: UCRAG/P

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Szállító: Zoetis Hungary Kft. Oldal/Lap 16 / 7 Anyaglap: PN0134/15
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Active Ingredient Batch Number: 1401807

Active Ingredient Name: AG BRSV 375 concentrated (MS lot number 597-10, tested Jan-95)

Active Ingredient Production Data

Data	Result
Manufactured by	Zoetis, Lincoln
Working seed lot number	3262
WS last testing date	JUL 2008
WS passage level (from MS)	4
Batch size (L)	78
Inoculation date	10 FEB 2014
Harvest date (harvest A)	17 FEB 2014
Harvest date (harvest B)	19 FEB 2014
Harvest date (harvest C)	20 FEB 2014
Concentration date (harvest A+ harvest B+ harvest C)	20 FEB 2014
Conditioning for storage date (harvest A+ harvest B+ harvest C)	21 FEB 2014

QC Tests on Active Ingredient

Test	Result	Result Unit	Acceptance Criteria	Date In	Date Out
Absence of Mycoplasma before concentration (harvest A)	No Mycoplasma detected	N/A	No Mycoplasma detected	25-FEB-2014	25-MAR-2014
Absence of Mycoplasma before concentration (harvest B)	No Mycoplasma detected	N/A	No Mycoplasma detected	25-FEB-2014	25-MAR-2014
Absence of Mycoplasma before concentration (harvest C)	No Mycoplasma detected	N/A	No Mycoplasma detected	25-FEB-2014	25-MAR-2014
Absence of extraneous agents before concentration on NL-BK6 cells (harvest A)	No live extraneous virus detected	N/A	No live extraneous virus detected	19-FEB-2014	05-MAR-2014

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Node: entae030

Instance Name: LICR6E7P

Active Ingredient Batch Number: 1401907

Active Ingredient Name: AG BRSV 375 concentrated (MS lot number 597-10, tested Jan-96)

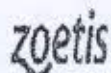
QC Tests on Active Ingredient

Test	Result	Result Unit	Acceptance Criteria	Date In	Date Out
Absence of extraneous agents before concentration on NL-BK6 cells (harvest B)	No live extraneous virus detected	N/A	No live extraneous virus detected	05-MAR-2014	19-MAR-2014
Absence of extraneous agents before concentration on NL-BK6 cells (harvest C)	No live extraneous virus detected	N/A	No live extraneous virus detected	05-MAR-2014	19-MAR-2014
Absence of extraneous agents before concentration on Vero cells (harvest A)	No live extraneous virus detected	N/A	No live extraneous virus detected	19-FEB-2014	05-MAR-2014
Absence of extraneous agents before concentration on Vero cells (harvest B)	No live extraneous virus detected	N/A	No live extraneous virus detected	05-MAR-2014	19-MAR-2014
Absence of extraneous agents before concentration on Vero cells (harvest C)	No live extraneous virus detected	N/A	No live extraneous virus detected	05-MAR-2014	19-MAR-2014
Absence of extraneous agents before concentration on NL-BT2 cells (harvest A)	No live extraneous virus detected	N/A	No live extraneous virus detected	19-FEB-2014	05-MAR-2014
Absence of extraneous agents before concentration on NL-BT2 cells (harvest B)	No live extraneous virus detected	N/A	No live extraneous virus detected	05-MAR-2014	19-MAR-2014
Absence of extraneous agents before concentration on NL-BT2 cells (harvest C)	No live extraneous virus detected	N/A	No live extraneous virus detected	05-MAR-2014	19-MAR-2014
Sterility	No growth	N/A	No growth	24-FEB-2014	10-MAR-2014
BRSV titre	8.4	log ₁₀ CCID ₅₀ /ml	≥ 8.0 log ₁₀ CCID ₅₀ /ml	04-MAR-2014	10-MAR-2014

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Node: ema2cs035

Instance Name: UC0817P



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Page: 10 of 16

Active Ingredient Batch Number: 1400808

Active Ingredient Name: AG BVD-K 5960 (MS lot number 51383, tested May-05)

Active Ingredient Production Data

Data	Result
Manufactured by	Pfizer, Lincoln
Working seed lot number	3505
WS last testing date	11/2008
WS passage level (from MS)	4
Batch size (L)	212.2
Inoculation date	23/01/2014
Harvest date	23/01/2014
Inactivation start date	29/01/2014
Inactivation end date/Neutralization start date	31/01/2014
Neutralization end date	31/01/2014
Conditioning for storage date	31/01/2014

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	04-FEB-2014	04-MAR-2014
Sterility test before inactivation	No growth	N/A	No growth	13-FEB-2014	27-FEB-2014
BVD6960 titre	8.7	log ₁₀ CCID ₅₀ /ml	7.7 <= x <= 10	20-FEB-2014	26-FEB-2014
Control of inactivation	No live BVD detected	N/A	No live BVD detected	13-FEB-2014	03-MAR-2014
Sterility	No growth	N/A	No growth	05-FEB-2014	19-FEB-2014
Residual sodium thiosulfate	Detected	N/A	Must be detected	03-FEB-2014	

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Model: 0000000000

Instance Name: UCRBEJP

Diszpó: PN-ZA15002330 Vevő: Alpha-Vet 8000 File név: PN00008346 Egyedi sorszám: PN0000075303 1 másolat
Szállító: Zoetis Hungary Kft. Oldal/Lap 16 / 10 Anyaglap: PN0134/15
Az eredetiről készült hiteles másolat. Nyomtatás dátuma: 2015.09.02
Kizárólag a kék tintával szignált másolat tekinthető hitelesnek!

D. H. M.
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Active Ingredient Batch Number: 1400957

Active Ingredient Name: AG BVD-K 5960 (MS lot number 51363, tested May-85)

Active Ingredient Production Data

Data	Result
Manufactured by	Zoetis, Lincoln
Working seed lot number	3505
WS last testing date	NOV 2008
WS passage level (from MS)	4
Batch size (L)	222.4
Inoculation date	30 JAN 2014
Harvest date	04 FEB 2014
Inactivation start date	04 FEB 2014
Inactivation end date/Neutralization start date	06 FEB 2014
Neutralization end date	06 FEB 2014
Conditioning for storage date	06 FEB 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-FEB-2014	11-MAR-2014
Sterility test before inactivation	No growth	N/A	No growth	13-FEB-2014	27-FEB-2014
BVD560 titre	8.4	log ₁₀ CCID ₅₀ /ml	7.7 <= x <= 10	20-FEB-2014	26-FEB-2014
Control of inactivation	No live BVD detected	N/A	No live BVD detected	13-FEB-2014	03-MAR-2014
Sterility	No growth	N/A	No growth	13-FEB-2014	27-FEB-2014
Residual sodium thiosulfate	Detected	N/A	Must be detected	24-FEB-2014	

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Note: emsdc03

Instance Name: UCP057P

