
	<b>BATCH RELEASE PROTOCOL</b> BRP 268-524 / 1231.U4 / Olot-331	Edition 04 Issued 08Jul14
	<b>POULVAC IB PRIMER</b>	
<b>FILLED UNLABELED BATCH NUMBER:</b> 1306722 <b>FINAL BATCH NUMBER:</b> 1306722D5		


## 1 MEMBER STATE SPECIFIC INFORMATION

<b>Lot number for batch to be placed on the market in the Member State (if final packaging batch number is different from filled unlabeled product number in section 2):</b>	1306722D5 (A - Z)
<b>Target species:</b>	Chickens
<b>Total number of containers in this batch:</b>	24,522
<b>Number of containers the release is applied for:</b>	24,057
<b>Number of doses per container:</b>	5,000 doses
<b>Number of samples for the competent authority:</b>	20
<b>Date of expiry:</b>	22/Oct/15 22/Jan/16 (Only BE) 22/Jul/15 (Only HU and IT)
<b>Name and address of Marketing Authorisation Holder (if different from manufacturer in section 2):</b>	N/A

Country	Country specific name	Licensing number	Shelf life
Belgium	Poulvac IB Primer	BE-V148111	21 months
Bulgaria	Poulvac IB Primer	022-2037-07.06.2013	18 months
Cyprus	Poulvac IB Primer	16178	18 months
Czech Republic	Poulvac IB Primer	97/685/92-C	18 months
Germany	Poulvac IB Primer	167a/88	18 months
Hungary	Poulvac IB Primer	2389/3/08 (5,000 doses)	15 months
Italy	Poulvac IB Primer	101490035 (2,500 doses) 101490047 (5,000 doses)	15 months
Morocco	Poulvac IB Primer	1284.2/07/V1 (2,500 doses) 1284.3/07/V1 (5,000 doses)	18 months
The Netherlands	Poulvac IB Primer	Reg. NL 08446	18 months
Poland	Poulvac IB Primer	110/95	18 months
Portugal	Poulvac IB Primer	275/89	18 months
Romania	Poulvac IB Primer	130185	18 months
Russia	Пулвак IB Праймер Poulvac IB Primer	840-1-3.14-1934N°ПВИ-1- 2.3/01471	18 months
Slovakia	Poulvac IB Primer	97/129/04-S	18 months
Spain	Poulvac IB Primer	8859 IMP	18 months
Switzerland	Poulvac IB Primer	1398	18 months
Turkey	Poulvac IB Primer	31.10.2011/037279	18 months


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<b>Country</b>	<b>Country specific name</b>	<b>Licensing number</b>	<b>Shelf life</b>
Ukraine	Poulvac IB Primer	BA-00372-02-11	18 months
United Kingdom	Poulvac IB Primer	Vm 00057/4407	18 months

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## 2 SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

<b>Trade name:</b>	Poulvac IB Primer
<b>International non-proprietary name (INN) / Ph. Eur. name / common name of product (whichever is appropriate):</b>	Live infectious bronchitis vaccine, strains H120 and D274 clone
<b>Type of final product:</b>	Lyophilised, live vaccine against Infectious Bronchitis in chickens
<b>Batch number(s) of:</b>	
<b>Filled unlabeled product:</b>	1306722
<b>Final bulk:</b>	1306722
<b>Type of final container:</b>	Hydrolytic type I glass vial with butyl-rubber stopper and aluminium cap
<b>Date of start of period of validity (start of titration / potency test):</b>	22Apr14
<b>Storage temperature:</b>	+2°C to +8°C
<b>Names and addresses of manufacturers:</b>	<p>ZOETIS Inc. (Formerly Pfizer Animal Health) 2000 Rockford Road Charles City, Iowa 50616-9101, U.S.A.</p> <p>Pfizer Global Manufacturing Weesp CJ van Houtenlaan 36 1381 CP Weesp, The Netherlands</p>
<b>Names and addresses of the batch release sites (if different from that of manufacturer):</b>	<p>ZOETIS Manufacturing &amp; Research Spain, S.L. (Formerly Pfizer Olot, S.L.) Ctra. Camprodon, s/n. – “La Riba” 17813 Vall De Bianya (Girona), Spain</p> <p>Pfizer Global Manufacturing Weesp CJ van Houtenlaan 36 1381 CP Weesp, The Netherlands</p>
<b>Antigen for this batch is produced at site:</b>	Charles City, Iowa
<b>The blending of the bulk batch is performed by site:</b>	Charles City, Iowa
<b>The in-process controls on this batch are performed by site:</b>	Charles City, Iowa
<b>The final product testing on this batch is performed by site:</b>	Zoetis M&R Spain S.L.
<b>The final packaging and labeling of this batch is conducted by site:</b>	Zoetis M&R Spain S.L.
<b>The release of this batch is done by site:</b>	Zoetis M&R Spain S.L.

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### 3 PRODUCTION INFORMATION

#### 3.1 Starting materials


##### 3.1.1 Virus seed lots

Component	Batch number	Date of last testing
Master seed virus strain D274 clone	XL9991	06 September 1984
Master seed virus strain IB H120	TL9993 / 9901	07 September 1990
Working seed virus strain D274 clone	IBV D274 Lot # 41011 HD 21 Feb 07	02 October 2007
Working seed virus strain IB H120	IB H120 Lot 04111 HD. 01 Feb 06	12 Apr 2006

##### 3.1.2 Substrates: SPF eggs for production

Culture batch	Start date	End date	Quantity
82735E	29Sep13	10Oct13	9,389
82739E	10Oct13	21Oct13	9,100
82742E	26Oct13	06Nov13	8,696
82772E	30Oct13	10Nov13	8,341
1307391E	23Nov13	04Dec13	9,230

Culture batch	Flock ID number	Flock supplier	Date of SPF testing and result	
1307391E	936GR2-2 CAV-	VALO	15 Nov 13	Satisfactory
	936T26 CAV-	Charles River	28 Oct 13	Satisfactory
82772E	933GR1-2 CAV-	VALO	25 Oct 13	Satisfactory
82735E	928B22-20 CAV-	VALO	20 Sep 13	Satisfactory
	928GR2-2 CAV-	VALO	20 Sep 13	Satisfactory
	928S34 CAV-	Charles River	03 Sep 13	Satisfactory
82739E	930B31-18 CAV-	VALO	04 Oct 13	Satisfactory
	930T26 CAV-	Charles River	16 Sep 13	Satisfactory
	930W57 CAV-	Charles River	16 Sep 13	Satisfactory
	930W58 CAV-	Charles River	16 Sep 13	Satisfactory
82742E	932B22-20 CAV-	VALO	18 Oct 13	Satisfactory
	932GR2-2 CAV-	VALO	18 Oct 13	Satisfactory
	932W56 CAV-	Charles River	30 Sep 13	Satisfactory

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### 3.2 Intermediate stages of production

Culture batch number	Inoculation (Eggs)	Harvest (Allantoic fluid)	Stabiliser batch number	Total volume of stabilised harvest (ml)
82735	10Oct13	12Oct13	1305743	96,355
82739	21Oct13	23Oct13	1305984	99,005
82742	06Nov13	08Nov13	1305985	81,297
82772	10Nov13	12Nov13	1305985	86,064
1307391	04Dec13	06Dec13	1306526	102,748

### 3.3 Creation of the final product

#### 3.3.1 Blending

Bulk Batch number	Start	End	Total (g or ml)
1306722	28Jan14	28Jan14	103,000 ml

#### 3.3.2 Vaccine composition

Stabilised component	Batch number	Target (g or ml)	Final (g or ml)
Bronchitis D274	82735	3,000 ml	3,000 ml
Bronchitis D274	82739	32,900 ml	32,900 ml
Bronchitis H120	82742	28,475 ml	28,475 ml
Bronchitis H120	82772	28,800 ml	28,800 ml


#### 3.3.3 Filling

##### 3.3.3.1 Antigen component

Filled unlabeled batch number	Start	End	Volume per vial (ml)	Number of vials filled
1306722	28 Jan 14	28Jan14	4.00	24,522

#### 3.3.4 Lyophilisation

Filled unlabeled batch number	Start lyophilisation	End lyophilisation
1306722	28Jan14	30Jan14

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### 3.4 In process controls

#### 3.4.1 In process controls on live viral suspension

<b>Test: Quantitative assay of Infectious Bronchitis virus in eggs (Reference: 16-02-010)</b>					
Culture batch	Start	End	Result	Threshold	Conclusion
82735	22Oct13	29Oct13	10 <sup>7.8</sup> EID <sub>50</sub> /ml	≥10 <sup>7.0</sup> EID <sub>50</sub> /ml	Meets threshold
82739	26Nov13	03Dec13	10 <sup>7.0</sup> EID <sub>50</sub> /ml		Meets threshold
82742	26Nov13	03Dec13	10 <sup>7.9</sup> EID <sub>50</sub> /ml		Meets threshold
82772	06Dec13	13Dec13	10 <sup>8.7</sup> EID <sub>50</sub> /ml		Meets threshold
1307391	13Dec13	20Dec13	10 <sup>8.5</sup> EID <sub>50</sub> /ml		Meets threshold


<b>Test: Total viable microbial count (Reference: 16-03-002)</b>					
Culture batch	Start	End	Result	Threshold	Conclusion
82735	14Oct13	22Oct13	≤ 100 germs/ml	≤ 100 germs/ml	Meets threshold
82739	24Oct13	31Oct13	≤ 100 germs/ml		Meets threshold
82742	11Nov13	18Nov13	≤ 100 germs/ml		Meets threshold
82772	13Nov13	21Nov13	≤ 100 germs/ml		Meets threshold
1307391	09Dec13	17Dec13	≤ 100 germs/ml		Meets threshold

<b>Test: Visual inspection (Reference: 16-10-013)</b>				
Start	End	Result	Threshold	Conclusion
12 Mar 14	13 Mar 14	Satisfactory	AQL = 0.65 for visual appearance and impurities. AQL = 0.10 for volume, vials and damaged closures.	Meets threshold

<b>Test: Vacuum test (Reference: 16-10-021)</b>				
Start	End	Result	Threshold	Conclusion
12 Mar 14	13 Mar 14	Satisfactory	Vacuum: AQL ≤ 0.65	Meets threshold

## 4 FINAL PRODUCT TESTING

<b>Test: Visual inspection (Reference: 16-10-013)</b>				
Start	End	Result	Threshold	Conclusion
19 Feb 14	19 Feb 14	Satisfactory	Off-white to tan coloured cake, lyophilised. Free of impurities. No vials or stoppering defect.	Meets threshold

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Test: Vacuum test (Reference: 16-10-021)				
Start	End	Result	Threshold	Conclusion
30 Jun 14	30 Jun 14	Vacuum present	Vacuum: blue luminescence is visible inside the vial	Meets threshold


Test: Identification of active substance (Reference: TA541)				
Start	End	Result	Threshold	Conclusion
26 Mar 14	04 Jun 14	Satisfactory	Positive identification of Infectious Bronchitis virus strains H120 and D274 by PCR	Meets threshold

Test: Quantitative assay of Infectious Bronchitis virus in eggs (Reference: 16-02-010)				
Start	End	Result	Threshold	Conclusion
22 Apr 14	29 Apr 14	$10^{5.2}$ EID <sub>50</sub> /ds	$10^{4.3} - 10^{5.7}$ EID <sub>50</sub> /ds	Meets threshold
This result is given for a presentation of 5000 doses per vial.				
Reference batch number		Result of reference testing	Range values for reference	
9037-NAT		$10^{7.87}$ EID <sub>50</sub>	$10^{7.47} - 10^{8.23}$ EID <sub>50</sub>	

Test: Germ count (Reference: 16-03-025, Ph. Eur. 2.6.12)				
Start	End	Result	Threshold	Conclusion
27 Feb 14	04 Mar 14	≤ 1 germs/ds	≤ 1 Non-pathogenic micro-organism per dose.	Meets threshold

Test: Absence of <i>Mycoplasma</i> (References: 16-11-123, Ph.Eur. 2.6.7)				
Start	End	Result	Threshold	Conclusion
12 Mar 14	02 May 14	Satisfactory	No <i>Mycoplasma</i> on any of the plates.	Meets threshold

Test: Absence of Extraneous Agents in eggs (References: 16-04-003, Ph.Eur. 2.6.25)					
	Start	End	Result	Threshold	Conclusion
ALL	26 Feb 14	13 Mar 14	Satisfactory	No abnormalities and/or deaths attributable to the vaccine.	Meets threshold
CAM	26 Feb 14	13 Mar 14	Satisfactory		Meets threshold
Yolk Sac	20 Mar 14	14 Apr 14	Satisfactory		Meets threshold

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<b>Test: Absence of extraneous agents in tissue culture using Chicken Embryo Fibroblast [CEF] cells (References: 16-04-054, Ph.Eur. 2.6.25)</b>				
Start	End	Result	Threshold	Conclusion
06 Mar 14	03 Apr 14	Satisfactory	No extraneous agents detected.	Meets threshold

<b>Test: Absence of EDS virus in chicken embryo liver cells (References: 16-04-051, Ph.Eur. 2.6.25)</b>				
Start	End	Result	Threshold	Conclusion
27 Feb 14	21 Mar 14	Satisfactory	No EDS virus detected.	Meets threshold

<b>Test: Absence of TRT using Vero cells (References: 16-04-052, Ph.Eur. 2.6.25)</b>				
Start	End	Result	Threshold	Conclusion
28 Feb 14	26 Mar 14	Satisfactory	No TRT virus detected.	Meets threshold


<b>Test: Absence of TRT using CEF cells (References: 16-04-053, Ph.Eur. 2.6.25)</b>				
Start	End	Result	Threshold	Conclusion
06 Mar 14	03 Apr 14	Satisfactory	No TRT virus detected.	Meets threshold

<b>Test: Absence of CAV using MSB-1 cells (References: 16-04-055, Ph.Eur. 2.6.25)</b>				
Start	End	Result	Threshold	Conclusion
06 May 14	04 Jun 14	Satisfactory	No CAV detected.	Meets threshold

<b>Test: Absence of Marek's Disease virus using CEF cells (References: 16-04-056, Ph.Eur. 2.6.25)</b>				
Start	End	Result	Threshold	Conclusion
20 Feb 14	19 Mar 14	Satisfactory	No Marek's Disease virus detected.	Meets threshold

<b>Test: Residual humidity (Reference: TA030/KFI, Ph.Eur. 2.5.12)</b>				
Start	End	Result	Threshold	Conclusion
04 Mar 14	04 Mar 14	2.0 %	0.5 – 3.5 %	Meets threshold



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## 5 CERTIFICATION BY THE MANUFACTURER

Certification by qualified person taking the overall responsibility for production and control of the product:

I herewith certify that **Poulvac IB Primer** batch no. **1306722D5 (A – Z)** was manufactured and tested according to the procedures approved by the competent authorities and complies with the quality requirement and that all measures have been taken to demonstrate compliance with Directive 2001/82/EC as amended by Directive 2004/28/EC.

Name: Núria Juanola Bassols

Function: Qualified Person

Date: 22Jul14

Signature:




Ctra. Camprodon, s/n  
Val de Bianya - Girona

