	<b>BATCH RELEASE PROTOCOL</b> BRP 268-543 <b>POULVAC IB QX</b>	Edition 10 Issued 16Jun14
	<b>FILLED UNLABELED BATCH NUMBER:</b> E19478	<b>FINAL BATCH NUMBER:</b> 19478D5

**1 SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT**

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): 19478D5 (A – Z)

Target species: Chickens

Total number of containers in this batch: 38,941

Number of containers the release is applied for: 38,794

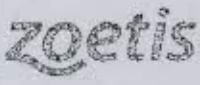
Number of doses per container: 5,000 doses

Number of samples for the competent authority: NA

Date of expiry: 29/OCT/2015

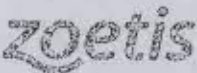
Name and address of Marketing Authorisation Holder (if different from manufacturer in section 2): N/A

Country	Country specific name	Licensing number	Shelf life
Austria	Poulvac IB QX	Z.Nr: 8-20336	18 months
Belgium	Poulvac IB QX	BE-V438051	18 months
Bulgaria	Poulvac IB QX	MR/V/0431/001	18 months
Cyprus	Poulvac IB QX	2300/13	18 months
Czech Republic	Poulvac IB QX	97/014/13-C	18 months
Denmark	Poulvac IB QX	MTnr. 51965	18 months
Estonia	Poulvac IB QX	MR/V/0431/001	18 months
France	Poulvac IB QX	FR/V/4182701 1/2009	18 months
Germany	Poulvac IB QX	Zul.Nr: PEI.V.11668.01.1	18 months
Greece	Poulvac IB QX	2300/13	18 months
Hungary	Poulvac IB QX	3359/2/13 NÉBIH ÁTI	18 months
Ireland	Poulvac IB QX	VPA 10438/115/1	18 months
Italy	Poulvac IB QX	AIC n.104597024 (5,000 doses) AIC n.104597012 (2,000 doses)	18 months
Latvia	Poulvac IB QX	V/MRP/13/0019	18 months
Lithuania	Poulvac IB QX	LT/2/13/2171/001	18 months
Netherlands	Poulvac IB QX	REG NL 113104 - UDA	18 months
Poland	Poulvac IB QX	2300/13	18 months

	<b>BATCH RELEASE PROTOCOL</b> BRP 268-543 <b>POULVAC IB QX</b>	Edition 10 Issued 16Jun14
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Country	Country specific name	Licensing number	Shelf life
Portugal	Poulvac IB QX	863/01/13RIVPT	18 months
Romania	Poulvac IB QX	MR/V/0431/001	18 months
Russia	Poulvac IB QX	840-1-26.13-1623N°ПВИ-1-26.13/04101	18 months
Slovakia	Poulvac IB QX	97/039/MR/13-S	18 months
Slovenia	Poulvac IB QX	EE1773	18 months
Spain	Poulvac IB QX	2848 ESP	18 months
United Kingdom	Poulvac IB QX	Vm 42058/4175	18 months



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

<b>Trade name:</b>	Poulvac IB QX
<b>International non-proprietary name (INN) / Ph. Eur. name / common name of product (whichever is appropriate):</b>	Live Infectious Bronchitis disease vaccine, strain L1148
<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>	E19478
<b>Final bulk:</b>	E19478
<b>Type of final container:</b>	Hydrolytic type I glass vial with butyl-rubber stopper and metal tear-off cap
<b>Date of start of period of validity (start of titration / potency test):</b>	29/APR/2014
<b>Storage temperature:</b>	+2°C to +8°C
<b>Names and addresses of manufacturers:</b>	<p>Pfizer Global Manufacturing Weesp CJ van Houtenlaan 36 1381 CP Weesp, The Netherlands</p> <p>ZOETIS Manufacturing &amp; Research Spain SL (formerly Pfizer Olot SLU) Ctra. Camprodon, s/n. – "La Riba" 17813 Vall De Bianya (Girona), Spain</p>
<b>Names and addresses of the batch release sites (if different from that of manufacturer):</b>	<p>Pfizer Global Manufacturing Weesp CJ van Houtenlaan 36 1381 CP Weesp, The Netherlands</p> <p>ZOETIS Manufacturing &amp; Research Spain SL (formerly Pfizer Olot SLU) Ctra. Camprodon, s/n. – "La Riba" 17813 Vall De Bianya (Girona), Spain</p>
<b>Antigen for this batch is produced at site:</b>	ZOETIS M & R Spain SL
<b>The in-process controls on this batch are performed by site:</b>	ZOETIS M & R Spain SL
<b>The final product testing on this batch is performed by site:</b>	ZOETIS M & R Spain SL
<b>The final packaging and labeling of this batch is conducted by site:</b>	ZOETIS M & R Spain SL
<b>The release of this batch is done by site:</b>	ZOETIS M & R Spain SL

	BATCH RELEASE PROTOCOL BRP 268-543 POULVAC IB QX		Edition 10 Issued 16Jun14
	FILLED UNLABELED BATCH NUMBER: E19478		FINAL BATCH NUMBER: 19478D5

### 3.3.2 Filling

#### 3.3.2.1 Antigen component

Bulk Batch number	Start	End	Volume per vial (ml)	Number of vials filled
E19478	08 Apr 14	08 Apr 14	1.55 ml	39,125

### 3.3.3 Lyophilisation

Bulk Batch number	Start	End	Number of vials freeze dried
E19478	08 Apr 14	10 Apr 14	38,794

### 3.4 In process controls

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


Test: Quantitative assay of Infectious Bronchitis virus in eggs (Reference: 16-02-010)  
Threshold:  $\geq 10^{7.0}$  EID<sub>50</sub>/ml

Culture batch	Start	End	Result	Conclusion
F45896	04 Feb 14	11 Feb 14	$10^{9.0}$ EID <sub>50</sub> /ml	Meets threshold
F46019	25 Feb 14	04 Mar 14	$10^{8.5}$ EID <sub>50</sub> /ml	Meets threshold

Test: Viable microbial count (Reference: 16-03-002)  
Threshold:  $\leq 100$  germs/ml

Culture batch	Start	End	Result	Conclusion
F45896	24 Jan 14	29 Jan 14	< 100 CFU/ml	Meets threshold
F46019	21 Feb 14	26 Feb 14	0 CFU/ml	Meets threshold



	BATCH RELEASE PROTOCOL BRP 268-543 POULVAC IB QX		Edition 10 Issued 16Jun14
	FILLED UNLABELED BATCH NUMBER: E19478		FINAL BATCH NUMBER: 19478D5

#### 4 FINAL PRODUCT TESTING

Test: Visual inspection (Reference: 16-10-013) Threshold: AQL 0-0.65, depending on type of deviation.			
Start	End	Result	Conclusion
11 Apr 14	11 Apr 14	Satisfactory	Meets threshold

Test: Vacuum (Reference: 16-10-021) Threshold: Vacuum: AQL ≤ 0.65			
Start	End	Result	Conclusion
11 Apr 14	11 Apr 14	Satisfactory	Meets threshold

Test: Quantitative assay of Infectious Bronchitis virus in eggs (Reference: 16-02-010) Threshold: $10^{4.0} \leq \text{EID}_{50}/\text{ds} \leq 10^{5.0}$				
Doses	Start	End	Result	Conclusion
5,000	29 Apr 14	06 May 14	$10^{4.0} \text{EID}_{50}/\text{ds}$	Meets threshold

Test: Virus identity (References: 16-10-089, 16-10-090) Threshold: When the primer sets 'QX-139-fw' and 'QX-394-rv' are used, a clear band should be visible in the agarose gel corresponding to a fragment length of 256 base pairs.			
Start	End	Result	Conclusion
18 Jun 14	26 Jun 14	Satisfactory	Meets threshold

Test: Number of germs (References: 16-03-025, Ph.Eur.) Threshold: ≤ 1 nonpathogenic micro-organism/dose, no pathogenic micro-organism			
Start	End	Result	Conclusion
29 Apr 14	05 May 14	< 1 nonpathogenic micro-organism/dose, no pathogenic micro-organism	Meets threshold

Test: Avian mycoplasma (References: 16-11-123, Ph.Eur.) Threshold: No growth.			
Start	End	Result	Conclusion
21 May 14	18 Jun 14	Satisfactory	Meets threshold

<b>zoetis</b>	<b>BATCH RELEASE PROTOCOL</b>	Edition 10
	BRP 268-543 <b>POULVAC IB QX</b>	Issued 16Jun14
FILLED UNLABELED BATCH NUMBER: E19478		FINAL BATCH NUMBER: 19478D5

**Test: Absence of extraneous agents in fertilised eggs (References: 16-04-003, Ph.Eur.)**  
**Thresholds: No deaths and/or abnormalities attributable to the vaccine and no evidence of extraneous agents.**

	Start	End	Result	Conclusion
ALL	21 May 14	12 Jun 14	Satisfactory	Meets threshold
CAM	21 May 14	12 Jun 14	Satisfactory	Meets threshold

**Test: Absence of Egg Drop Syndrome virus using Chicken Embryo Liver cells**  
**(References: 16-04-051, Ph.Eur.)**  
**Threshold: No evidence of the presence of EDS virus or any other extraneous agent.**

Start	End	Result	Conclusion
10 Apr 14	21 May 14	Satisfactory	Meets threshold

**Test: Absence of Turkey Rhinotracheitis virus using Vero cells**  
**(References: 16-04-052, Ph.Eur.)**  
**Threshold: No evidence of the presence of Turkey Rhinotracheitis virus or any other extraneous agent.**

Start	End	Result	Conclusion
10 Apr 14	12 Jun 14	Satisfactory	Meets threshold

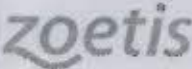
**Test: Absence of Turkey Rhinotracheitis virus using Chicken Embryo Fibroblasts**  
**(References: 16-04-053, Ph.Eur.)**  
**Threshold: No evidence of the presence of Turkey Rhinotracheitis virus or any other extraneous agent.**

Start	End	Result	Conclusion
15 May 14	11 Jun 14	Satisfactory	Meets threshold

**Test: Absence of extraneous agents using Chicken Embryo Fibroblasts**  
**(References: 16-04-054, Ph.Eur.)**  
**Threshold: No evidence of the presence of any extraneous agents.**

Start	End	Result	Conclusion
15 May 14	11 Jun 14	Satisfactory	Meets threshold



	<b>BATCH RELEASE PROTOCOL</b> BRP 268-543 <b>POULVAC IB QX</b>	Edition 10 Issued 16Jun14
	FILLED UNLABELED BATCH NUMBER: E19478	FINAL BATCH NUMBER: 19478D5

<b>Test: Absence of Chicken Anaemia virus (CAV) using MSB1 cells</b> (References: 16-04-055, Ph.Eur.)			
<b>Threshold: No evidence of the presence of Chicken Anaemia virus or any other extraneous agent.</b>			
<b>Start</b>	<b>End</b>	<b>Result</b>	<b>Conclusion</b>
27 May 14	16 Jun 14	Satisfactory	Meets threshold

<b>Test: Absence of Marek's Disease virus using Chicken Embryo Fibroblasts</b> (References: 16-04-056, Ph.Eur.)			
<b>Threshold: No evidence of the presence of Marek's Disease virus or any other extraneous agent.</b>			
<b>Start</b>	<b>End</b>	<b>Result</b>	<b>Conclusion</b>
25 Apr 14	22 May 14	Satisfactory	Meets threshold

<b>Test: Residual humidity (Reference: TA030)</b> <b>Threshold: 0.5 - 4%</b>			
<b>Start</b>	<b>End</b>	<b>Result</b>	<b>Conclusion</b>
06 May 14	06 May 14	2.0 %	Meets threshold

## 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 QX batch no **19478D5 (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

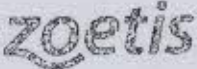
Function: Qualified Person

Date: 10Jul14

Signature:




Ctra. Campredó, 10  
Val de Danya - Girona

	<b>BATCH RELEASE PROTOCOL</b> BRP 268-543 <b>POULVAC IB QX</b>	Edition 10 Issued 16Jun14
	FILLED UNLABELED BATCH NUMBER: E19478      FINAL BATCH NUMBER: 19478D5	

### 3 PRODUCTION INFORMATION

#### 3.1 Starting materials

##### 3.1.1 Virus seed lots

Component	Batch number	Date of last testing
Master seed virus	Avian Infectious Bronchitis Virus, strain L1148, Master Seed, batch 9039	13 Jan 09
Working seed virus	8161	MAY/09

#### 3.1.2 Substrates

##### 3.1.2.1 Eggs for production

Culture batch number	Supplier	Flock number	Date of sampling
F45860	Valo	10305 10406	16 Dec 13
F45974	Valo	40402	20 Jan 14

#### 3.2 Intermediate stages of production

Culture batch number	WSV used for inoculation	Inoculation (Eggs)	Harvest (Allantoic fluid)	Total volume (ml)
F45896	8161	21 Jan 14	23 Jan 14	46,400 mL
F46019	8161	18 Feb 14	21 Feb 14	48,800 ml

#### 3.3 Creation of the final product

##### 3.3.1 Blending and vaccine composition

###### 3.3.1.1 Blending

Bulk Batch number	Start	End	Quantity (g or L)
E19478	07 Apr 14	07 Apr 14	61.0 L

###### 3.3.1.2 Vaccine composition

Component	Batch number	Target quantity (g or L)	Final quantity (g or L)
Culture batch (including 25% stabilizer solution)	F45896	16.0 L	16.0 L
Culture batch (including 25% stabilizer solution)	F46019	45.0 L	45.0 L