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Protocol/Certificate of Analysis

PARACOX 5

Chicken Coccidiosis Vaccine, Live, Attenuated

Marketing Authorisation Numbers

Austria Zul.-Nr. 8-20215
France AMM n° 676994 8/676993 1
Greece 013670101/2
Italy A.I.C. n° 102949029/102949017
UK Vm 01708/4552

Germany Zul.-Nr. PEI.V.01272.01.1
Ireland VPA 10996/215/001
Portugal A.I.M. n° 650/99 DGV
Spain Reg N° 1313 ESP
Switzerland IVI No 1562

Batch number **A248B**
SAP Batch number **A248B07**
Pack type **Hungary**

Packaging run **7366380**
Storage conditions **2-8 degrees C**

Date of testing 15/10/2015
Date of completion of potency 10/11/2015

Date of expiry 02/06/2016

Sterility Complies with Ph. Eur.
Absence of Mycoplasma Complies with test
Potency Satisfactory

Containers

Total number of containers 20ml (5000 dose) 4830
Number released 20ml (5000 dose) 105

After reviewing all manufacturing and testing data, I am satisfied that the above batch of Paracox vaccine has been manufactured and tested in accordance with Good Manufacturing Practice and complies with the methods and standards described in the application dossier and appropriate Marketing Authorisation.

Robert Bush, BSc, MSc, CBiol, MRSB

Qualified Person

22 December 2015

Trade name	Paracox 5	
Product type	Live, attenuated coccidiosis vaccine	
Target species	Chicken (<i>Gallus gallus</i>)	
Marketing Authorisation UK	Vm 01708/4552	
Marketing Authorisations	Austria Zul.-Nr.8-20215 Belgium 282 IS 57 F17 France AMM n° 676994 8/676993 1 Finland 15170 Greece 013670101/2 Germany Zul.-Nr. PEI.V.01272.01.1 Hungary 2040/1-2/06 ÁOGYTI Italy A.I.C. n° 102949029 & 102949017 Ireland VPA 10996/215/001 Luxembourg V367/00/06/0658 Netherlands NL 9687 Spain Reg N° 1313 ESP Portugal A.I.M. n° 650/99 DGV Sweden 15967 Switzerland IVI-N°=1562	
Batch number	A248B	
Type of container	Clear, colourless polyethylene terephthalate G copolymer (PETG) vials , 4ml (1000 dose) and 20ml (5000 dose) sizes	
Total number of containers manufactured in this batch	5000 dose - 4944	
Number of containers for which release is required	5000 dose - 4830	
Number of doses per container	20ml -5000 dose	
Number of samples for competent authority	Nil	
Start date of potency test	15/10/15	
Date of expiry	02/06/16	
Shelf life	33 Weeks	
Storage temperature	2 - 8°C	
Address of Manufacture	Schering-Plough Animal Health Breakspear Road South Harefield, Uxbridge Middlesex, UB9 6LS	Schering-Plough Animal Health Churn Road Compton Berkshire, RG20 6PR
Address of Marketing Authorisation Holder	Intervet UK Limited Walton Manor Walton Milton Keynes Buckinghamshire, MK7 7AJ	

**Manufacturer's Batch Protocol
Paracox 5 Vaccine Batch Number A248B**

PRODUCTION INFORMATION

Master Seeds

Species	Batch Numbers	Date Testing Completed
E. acervulina HP	MS71s+13	Dec 1988
E. maxima CP	MS12s+11	Dec 1988
E. maxima MFP	MS15s+11	Dec 1988
E. mitis HP	MS12s+11	Dec 1988
E. tenella HP	MS38s+10	Dec 1988

Working Seeds

Species	Batch Numbers	QA Approval Dates
E. acervulina HP	MS2a/018	06/11/15
E. maxima CP	MS3a/028	06/11/15
E. maxima MFP	MS4a/027	30/07/15
E. mitis HP	MS4a/028	30/07/15
E. tenella HP	MS8c/017	13/07/15

Antigen Production

Species	Lot	Start	Oocyst Output per Bird (x 10 ⁶)			Finish	Volume (ml)
			Actual	Upper Acceptance Limit	Result		
E. acervulina HP	L328EaX101	10/09/15	299.7	600	Pass	22/09/15	3035
E. acervulina HP	L328EaX102	10/09/15	299.7	600	Pass	22/09/15	3034
E. maxima CP	L327CPX201	21/08/15	34.0	70	Pass	03/09/15	2835
E. maxima CP	L327CPX202	21/08/15	34.0	70	Pass	03/09/15	2836
E. maxima MFP	L327MFPX01	21/08/15	17.1	40	Pass	07/09/15	3037
E. maxima MFP	L327MFPX02	21/08/15	17.1	40	Pass	07/09/15	3035
E. mitis HP	L326EmXX03	31/07/15	85.4	300	Pass	11/08/15	3336
E. mitis HP	L327EmXX01	21/08/15	93.0	300	Pass	01/09/15	2936
E. tenella HP	L327EtX101	21/08/15	49.4	200	Pass	04/09/15	3236
E. tenella HP	L327EtX201	21/08/15	49.4	200	Pass	04/09/15	3233
E. tenella HP	L327EtX301	21/08/15	49.4	200	Pass	04/09/15	3234

**Manufacturer's Batch Protocol
Paracox 5 Vaccine Batch Number A248B**

Sterility Testing Of Bulk Antigens Used in the Blend

Species	Antigen	Medium	Volume	Start	Finish	Status
E. acervulina HP	L328EaX101	TSB Thio	7.5ml 7.5ml	28/09/15	12/10/15	Pass Pass
E. acervulina HP	L328EaX102	TSB Thio	7.5ml 7.5ml	28/09/15	12/10/15	Pass Pass
E. maxima CP	L327CPX201	TSB Thio	7.5ml 7.5ml	08/09/15	22/09/15	Pass Pass
E. maxima CP	L327CPX202	TSB Thio	7.5ml 7.5ml	08/09/15	22/09/15	Pass Pass
E. maxima MFP	L327MFPX01	TSB Thio	7.5ml 7.5ml	15/09/15	29/09/15	Pass Pass
E. maxima MFP	L327MFPX02	TSB Thio	7.5ml 7.5ml	15/09/15	29/09/15	Pass Pass
E. mitis HP	L326EmXX03	TSB Thio	7.5ml 7.5ml	25/08/15	08/09/15	Pass Pass
E. mitis HP	L327EmXX01	TSB Thio	7.5ml 7.5ml	11/09/15	25/09/15	Pass Pass
E. tenella HP	L327EtX101	TSB Thio	7.5ml 7.5ml	08/09/15	22/09/15	Pass Pass
E. tenella HP	L327EtX201	TSB Thio	7.5ml 7.5ml	08/09/15	22/09/15	Pass Pass
E. tenella HP	L327EtX301	TSB Thio	7.5ml 7.5ml	11/09/15	25/09/15	Pass Pass

TSB = Tryptone Soya Broth; Thio = Fluid Thioglycollate

Positive Controls - Tryptone Soya Broth

Test Species	Inoculum (cfu)	Specification	Result	Status
<i>C. albicans</i>	10-100	+ve	+ve	Pass
<i>B. subtilis</i>	10-100	+ve	+ve	Pass
<i>A. niger</i>	10-100	+ve	+ve	Pass

Positive Controls - Fluid Thioglycollate

Test Species	Inoculum (cfu)	Specification	Result	Status
<i>Cl. sporogenes</i>	10-100	+ve	+ve	Pass
<i>S. aureus</i>	10-100	+ve	+ve	Pass
<i>Ps. aeruginosa</i>	10-100	+ve	+ve	Pass

+ve = Positive growth of test organism.

**Manufacturer's Batch Protocol
Paracox 5 Vaccine Batch Number A248B**

Antigen Lot 326 - Pool Sample Preparation

Tests for the absence of Mycoplasma and the absence of extraneous agents were carried out using a pool sample. The pool sample was prepared using the antigen lots and volumes given in the table below formulated with PBS to a final volume of 60ml. SOP 791 (4)

Species and Lot Number		Volume (ml)	Species and Lot Number		Volume (ml)
E. acervulina HP	L326EaXX01	0.67	E. necatrix HP	L326EnX201	5.85
E. acervulina HP	L326EaXX02	0.68	E. necatrix HP	L326EnX301	5.36
E. brunetti HP	L326EbXX01	1.33	E. necatrix HP	L326EnX401	5.39
E. maxima CP	L326CPXX01	0.90	E. necatrix HP	L326EnX501	5.49
E. maxima CP	L326CPXX02	0.87	E. necatrix HP	L326EnX601	5.30
E. maxima MFP	L326MFPX01	0.87	E. praecox HP	L326EpXX01	1.01
E. maxima MFP	L326MFPX02	0.93	E. praecox HP	L326EpXX02	0.99
E. mitis HP	L326EmXX01	0.82	E. praecox HP	L326EpXX03	1.02
E. mitis HP	L326EmXX02	0.88	E. tenella HP	L326EtX101	1.22
E. mitis HP	L326EmXX03	0.92	E. tenella HP	L326EtX201	1.31
E. necatrix HP	L326EnX101	6.11			

**Antigen Lot 326 - Test For Extraneous Agents - Embryonated Eggs
Ph Eur 2.6.25**

Date testing started: 02/09/15 Date testing completed: 28/09/15

Sample and inoculation route	Passage Number	Specification*	Result	Status
Sample Chorioallantoic Sac	First Passage	Negative	Negative	PASS
	Second Passage	Negative	Negative	PASS
	Haemagglutination	Negative	Negative	PASS
Control Chorioallantoic Sac	First Passage	Negative	Negative	PASS
	Second Passage	Negative	Negative	PASS
	Haemagglutination	Negative	Negative	PASS
Sample Chorioallantoic Membrane	First Passage	Negative	Negative	PASS
	Second Passage	Negative	Negative	PASS
	Haemagglutination	Negative	Negative	PASS
Control Chorioallantoic Membrane	First Passage	Negative	Negative	PASS
	Second Passage	Negative	Negative	PASS
	Haemagglutination	Negative	Negative	PASS
Sample Yolk Sac	First Passage	Negative	Negative	PASS
	Second Passage	Negative	Negative	PASS
	Haemagglutination	Negative	Negative	PASS
Control Yolk Sac	First Passage	Negative	Negative	PASS
	Second Passage	Negative	Negative	PASS
	Haemagglutination	Negative	Negative	PASS

* Negative = No evidence of viral activity as indicated by Passage or haemagglutination.

**Manufacturer's Batch Protocol
Paracox 5 Vaccine Batch Number A248B**

**Antigen Lot 326 - Test For Extraneous Agents - Chicken Embryo Fibroblast
Cell Cultures Ph Eur 2.6.25**

Date testing started: 03/09/15 Date testing completed: 28/09/15

Test Type	Passage Number	Specification*	Result	Status
Sample Cultures	First Passage	Negative	Negative	PASS
	Second Passage	Negative	Negative	PASS
	Third Passage	Negative	Negative	PASS
	Fourth Passage	Negative	Negative	PASS
	Fifth Passage	Negative	Negative	PASS
	Haemagglutination	Negative	Negative	PASS
	Haemadsorption	Negative	Negative	PASS
	Stained Film (CPE)	Negative	Negative	PASS
Control Cultures	First Passage	Negative	Negative	PASS
	Second Passage	Negative	Negative	PASS
	Third Passage	Negative	Negative	PASS
	Fourth Passage	Negative	Negative	PASS
	Fifth Passage	Negative	Negative	PASS
	Haemagglutination	Negative	Negative	PASS
	Haemadsorption	Negative	Negative	PASS
	Stained Film (CPE)	Negative	Negative	PASS

* Negative = No evidence of viral activity by Passage, haemagglutination, haemadsorption or cytopathic effect (CPE) by stained film.

Antigen Lot 326 - Test for Absence of Mycoplasma – Ph Eur 2.6.7

Start date: 04/09/15 Finish date: 02/10/15
Result: No evidence of Mycoplasma contamination detected.

Positive Controls

Test Organism	Inoculum level (cfu)	Threshold	Result	Status
M. gallisepticum	<100	+ve	+ve	PASS
M. synoviae	<100	+ve	+ve	PASS
M. orale	<100	+ve	+ve	PASS

+ve = Positive growth of test organism.

Antigen Lot 326 - Absence of Newcastle Disease Virus

The antigen pool was tested for antibody inducing fragments of extraneous agents by the use of a validated Newcastle disease PCR test.

Test	Test Date	Result	Status
NDV-PCR	24/08/15	Negative	PASS

**Manufacturer's Batch Protocol
Paracox 5 Vaccine Batch Number A248B**

Antigen Lot 327 - Pool Sample Preparation

Tests for the absence of Mycoplasma and the absence of extraneous agents were carried out using a pool sample. The pool sample was prepared using the antigen lots and volumes given in the table below formulated with PBS to a final volume of 60ml. SOP 791 (4)

Species and Lot Number	Volume (ml)	Species and Lot Number	Volume (ml)
E. acervulina HP L327EaXX01	0.80	E. necatrix HP L327EnX101	4.13
E. acervulina HP L327EaXX02	0.83	E. necatrix HP L327EnX201	3.65
E. maxima CP L327CPX101	0.72	E. necatrix HP L327EnX301	3.40
E. maxima CP L327CPX102	0.76	E. necatrix HP L327EnX401	3.75
E. maxima CP L327CPX201	0.81	E. necatrix HP L327EnX501	3.80
E. maxima CP L327CPX202	0.77	E. necatrix HP L327EnX601	3.53
E. maxima CP L327CPX301	0.80	E. necatrix HP L327EnX701	3.19
E. maxima CP L327CPX302	0.88	E. necatrix HP L327EnX801	3.21
E. maxima MFP L327MFPX01	0.78	E. necatrix HP L327EnX901	3.55
E. maxima MFP L327MFPX02	0.84	E. tenella HP L327EtX101	0.85
E. mitis HP L327EmXX01	0.86	E. tenella HP L327EtX201	0.86
E. mitis HP L327EmXX02	0.94	E. tenella HP L327EtX301	0.94

**Antigen Lot 327 - Test For Extraneous Agents - Embryonated Eggs
Ph Eur 2.6.25**

Date testing started: 23/09/15 Date testing completed: 19/10/15

Sample and inoculation route	Passage Number	Specification*	Result	Status
Sample Chorioallantoic Sac	First Passage	Negative	Negative	PASS
	Second Passage	Negative	Negative	PASS
	Haemagglutination	Negative	Negative	PASS
Control Chorioallantoic Sac	First Passage	Negative	Negative	PASS
	Second Passage	Negative	Negative	PASS
	Haemagglutination	Negative	Negative	PASS
Sample Chorioallantoic Membrane	First Passage	Negative	Negative	PASS
	Second Passage	Negative	Negative	PASS
	Haemagglutination	Negative	Negative	PASS
Control Chorioallantoic Membrane	First Passage	Negative	Negative	PASS
	Second Passage	Negative	Negative	PASS
	Haemagglutination	Negative	Negative	PASS
Sample Yolk Sac	First Passage	Negative	Negative	PASS
	Second Passage	Negative	Negative	PASS
	Haemagglutination	Negative	Negative	PASS
Control Yolk Sac	First Passage	Negative	Negative	PASS
	Second Passage	Negative	Negative	PASS
	Haemagglutination	Negative	Negative	PASS

* Negative = No evidence of viral activity as indicated by Passage or haemagglutination.

**Manufacturer's Batch Protocol
Paracox 5 Vaccine Batch Number A248B**

**Antigen Lot 327 - Test For Extraneous Agents - Chicken Embryo Fibroblast
Cell Cultures Ph Eur 2.6.25**

Date testing started: 24/09/15 Date testing completed: 19/10/15

Test Type	Passage Number	Specification*	Result	Status
Sample Cultures	First Passage	Negative	Negative	PASS
	Second Passage	Negative	Negative	PASS
	Third Passage	Negative	Negative	PASS
	Fourth Passage	Negative	Negative	PASS
	Fifth Passage	Negative	Negative	PASS
	Haemagglutination	Negative	Negative	PASS
	Haemadsorption	Negative	Negative	PASS
	Stained Film (CPE)	Negative	Negative	PASS
Control Cultures	First Passage	Negative	Negative	PASS
	Second Passage	Negative	Negative	PASS
	Third Passage	Negative	Negative	PASS
	Fourth Passage	Negative	Negative	PASS
	Fifth Passage	Negative	Negative	PASS
	Haemagglutination	Negative	Negative	PASS
	Haemadsorption	Negative	Negative	PASS
	Stained Film (CPE)	Negative	Negative	PASS

* Negative = No evidence of viral activity by Passage, haemagglutination, haemadsorption or cytopathic effect (CPE) by stained film.

Antigen Lot 327 - Test for Absence of Mycoplasma – Ph Eur 2.6.7

Start date: 22/09/15 Finish date: 20/10/15

Result: No evidence of Mycoplasma contamination detected.

Positive Controls

Test Organism	Inoculum level (cfu)	Threshold	Result	Status
M. gallisepticum	<100	+ve	+ve	PASS
M. synoviae	<100	+ve	+ve	PASS
M. orale	<100	+ve	+ve	PASS

+ve = Positive growth of test organism.

Antigen Lot 327 - Absence of Newcastle Disease Virus

The antigen pool was tested for antibody inducing fragments of extraneous agents by the use of a validated Newcastle disease PCR test.

Test	Test Date	Result	Status
NDV-PCR	09/09/15	Negative	PASS

Manufacturer's Batch Protocol
Paracox 5 Vaccine Batch Number A248B
Antigen Lot 328 - Pool Sample Preparation

Tests for the absence of Mycoplasma and the absence of extraneous agents were carried out using a pool sample. The pool sample was prepared using the antigen lots and volumes given in the table below formulated with PBS to a final volume of 60ml. SOP 791 (4)

Species and Lot Number	Volume (ml)	Species and Lot Number	Volume (ml)
E. acervulina HP L328EaX101	0.88	E. mitis HP L328EmX102	1.03
E. acervulina HP L328EaX102	0.91	E. mitis HP L328EmX201	0.90
E. acervulina HP L328EaX201	0.87	E. mitis HP L328EmX202	0.87
E. acervulina HP L328EaX202	0.88	E. necatrix HP L328EnX101	4.68
E. brunetti HP L328EbXX01	1.00	E. necatrix HP L328EnX201	4.85
E. maxima CP L328CPXX01	0.98	E. necatrix HP L328EnN101	4.51
E. maxima CP L328CPNX01	0.86	E. necatrix HP L328EnN201	5.32
E. maxima CP L328CPNX02	0.86	E. praecox HP L328EpXX01	0.91
E. maxima MFP L328MFPX01	0.80	E. praecox HP L328EpXX02	0.95
E. maxima MFP L328MFPX02	0.80	E. tenella HP L328EtX101	1.43
E. mitis HP L328EmX101	1.15	E. tenella HP L328EtX201	1.32

Antigen Lot 328 - Test For Extraneous Agents - Embryonated Eggs
Ph Eur 2.6.25

Date testing started: 14/10/15 Date testing completed: 09/11/15

Sample and inoculation route	Passage Number	Specification*	Result	Status
Sample Chorioallantoic Sac	First Passage	Negative	Negative	PASS
	Second Passage	Negative	Negative	PASS
	Haemagglutination	Negative	Negative	PASS
Control Chorioallantoic Sac	First Passage	Negative	Negative	PASS
	Second Passage	Negative	Negative	PASS
	Haemagglutination	Negative	Negative	PASS
Sample Chorioallantoic Membrane	First Passage	Negative	Negative	PASS
	Second Passage	Negative	Negative	PASS
	Haemagglutination	Negative	Negative	PASS
Control Chorioallantoic Membrane	First Passage	Negative	Negative	PASS
	Second Passage	Negative	Negative	PASS
	Haemagglutination	Negative	Negative	PASS
Sample Yolk Sac	First Passage	Negative	Negative	PASS
	Second Passage	Negative	Negative	PASS
	Haemagglutination	Negative	Negative	PASS
Control Yolk Sac	First Passage	Negative	Negative	PASS
	Second Passage	Negative	Negative	PASS
	Haemagglutination	Negative	Negative	PASS

* Negative = No evidence of viral activity as indicated by Passage or haemagglutination.

Manufacturer's Batch Protocol
Paracox 5 Vaccine Batch Number A248B
Antigen Lot 328 - Test For Extraneous Agents - Chicken Embryo Fibroblast
Cell Cultures Ph Eur 2.6.25

Date testing started: 15/10/15 Date testing completed: 09/11/15

Test Type	Passage Number	Specification*	Result	Status
Sample Cultures	First Passage	Negative	Negative	PASS
	Second Passage	Negative	Negative	PASS
	Third Passage	Negative	Negative	PASS
	Fourth Passage	Negative	Negative	PASS
	Fifth Passage	Negative	Negative	PASS
	Haemagglutination	Negative	Negative	PASS
	Haemadsorption	Negative	Negative	PASS
	Stained Film (CPE)	Negative	Negative	PASS
Control Cultures	First Passage	Negative	Negative	PASS
	Second Passage	Negative	Negative	PASS
	Third Passage	Negative	Negative	PASS
	Fourth Passage	Negative	Negative	PASS
	Fifth Passage	Negative	Negative	PASS
	Haemagglutination	Negative	Negative	PASS
	Haemadsorption	Negative	Negative	PASS
	Stained Film (CPE)	Negative	Negative	PASS

* Negative = No evidence of viral activity by Passage, haemagglutination, haemadsorption or cytopathic effect (CPE) by stained film.

Antigen Lot 328 - Test for Absence of Mycoplasma – Ph Eur 2.6.7

Start date: 13/10/15 Finish date: 10/11/15
 Result: No evidence of Mycoplasma contamination detected.

Positive Controls

Test Organism	Inoculum level (cfu)	Threshold	Result	Status
M. gallisepticum	<100	+ve	+ve	PASS
M. synoviae	<100	+ve	+ve	PASS
M. orale	<100	+ve	+ve	PASS

+ve = Positive growth of test organism.

Antigen Lot 328 - Absence of Newcastle Disease Virus

The antigen pool was tested for antibody inducing fragments of extraneous agents by the use of a validated Newcastle disease PCR test.

Test	Test Date	Result	Status
NDV-PCR	29/09/15	Negative	PASS

**Manufacturer's Batch Protocol
Paracox 5 Vaccine Batch Number A248B**

VACCINE BLEND AND FILL – BATCH A248

Blend Date 13/10/15
Fill date 15/10/15
Volume of fill 120L

Vaccine composition

Strain	Lot no.	BULK OOCYSTS		Wt Used (mL)	SPOR. RATE %	SPOR. OOCYSTS PER DOSE	
		Total/mL	Sp/ml			Actual	Target
Ea	L328EAX101	4504086	3999726	3029.0	89	404	500
	L328EAX102	4404911	3816932	1345.3	87	171	
CP	L327CPX201	1919295	1707952	1490.0	89	85	200
	L327CPX202	2039889	1772833	2457.0	87	145	
MFP	L327MFPX01	1064858	903197	2388.0	85	72	100
	L327MFPX02	1024066	873853	1479.8	85	43	
Em	L326EMXX03	8085681	7536627	1980.4	93	498	1000
	L327EMXX01	8780659	8064141	2427.7	92	653	
Et	L327ETX101	4424055	4115606	910.6	93	125	500
	L327ETX201	4373886	4137948	3224.8	95	445	
	L327ETX301	3876842	3665049	43.6	95	5	
TOTAL/dose		2904	2645	20776.2	91.1	2645	2300

Non-antigen components
Diluent
Phosphate buffered saline

99.2L

PBS Salt Components

Sodium chloride
Di-sodium hydrogen phosphate dehydrate
Potassium di-hydrogen phosphate
Potassium chloride

Batch Number

0000320429
0000256717
0000326531
0000186550

**Manufacturer's Batch Protocol
Paracox 5 Vaccine Batch Number A248B**

FINAL PRODUCT TESTING

Sterility Test - Ph Eur 2.6.1

Start date: 23/10/15 **Finish date:** 06/11/15

Vial Size	Medium	Volume Tested	Number of Vials Tested	Result	Status
B-20ml	TSB	100ml	10	NEC	Pass
	Thio	100ml		NEC	

NEC = No evidence of contamination in the test broth.

TSB = Tryptone Soya Broth, Thio = Fluid Thioglycollate.

Positive Controls – Fluid Thioglycollate

Test Species	Date Tested	Batch Number	Inoculum Level (cfu)	Result	Conclusion
<i>Ps. aeruginosa</i>	23/10/15 – 26/10/15	1004032580	60	+ve	Pass
<i>Cl. sporogenes</i>	23/10/15 – 26/10/15	1004032580	98	+ve	Pass

Positive Controls – Tryptone Soya Broth

Test Species	Date Tested	Batch Number	Inoculum Level (cfu)	Result	Conclusion
<i>B. subtilis</i>	23/10/15 – 26/10/15	1003701560	79	+ve	Pass
<i>C. albicans</i>	23/10/15 – 26/10/15	1003701560	85	+ve	Pass

+ve = Positive growth of test organism.

Absence Of Campylobacter Contamination – SOP 734(6)

Start date: 02/11/15 **Finish date:** 06/11/15

Size tested	Medium	Volume tested	Number of vials tested	Result	Status
B-20 ml	CSEBP CSEAP	0.5 ml	1	NEC	Pass

NEC = No evidence of contamination in test medium

CSEBP = Campylobacter spp. Selective Enrichment Broth (Preston)

CSEAP = Campylobacter spp. Selective Enrichment Agar (Preston)

**Manufacturer's Batch Protocol
Paracox 5 Vaccine Batch Number A248B**

Potency Test

Final Container Oocyst Count - SOP 843(3)

Final Container Count 20ml Vials

Date Counted: 06/11/15

Count Type	Specification (ml ⁻¹)	Result (ml ⁻¹)	Status
Sporulated oocyst count	≥4.6 x 10 ⁵	4.94 x 10 ⁵	Pass
Number of oocysts > 30μ	≥4.0 x 10 ⁴	4.33 x 10 ⁴	Pass

Post Vaccination Output - SOP 803.5(9) and 842(6)

Start Date: 15/10/15

Finish Date: 23/10/15

Day (post-vaccination)	Specification	Oocyst output/bird	Status
5 – 6	≥0.8 x 10 ⁶	2.4 x 10 ⁶	Pass
6 – 7	≥1.3 x 10 ⁶	2.4 x 10 ⁶	Pass
7 – 8	≥0.8 x 10 ⁶	1.1 x 10 ⁶	Pass

Percentage Protection - SOP 803.5(9) and 842(6)

Start Date: 15/10/15

Finish Date: 10/11/15

Species	Oocyst Counts (Controls)	Oocyst Counts (Vaccinates)	Specification*	Result	Status
E. acervulina HP	6961	10	≥92.0%	99.9%	Pass
E. maxima CP	2652	197	≥90.0%	92.6%	Pass
E. maxima MFP	4878	0	≥96.5%	100.0%	Pass
E. mitis HP	3710	261	≥81.2%	93.0%	Pass
E. tenella HP	1380	0	≥85.8%	100.0%	Pass

* Percentage Protection = 100 x [(Control Count - Vaccinate Count)/Control Count]

**Manufacturer's Batch Protocol
Paracox 5 Vaccine Batch Number A248B**

Analytical Tests - SOP 849(4)

Date of test 05/11/15

Vial Size	20ml				
Specification	20.0 - 21.0 ml				
Vial number	6	7	8	9	10
Volume (ml)	20.3	20.0	20.0	20.2	20.4
Status	Pass	Pass	Pass	Pass	Pass

pH and Visual Appearance

Test	Vial Size	Date	Specification	Result	Status
pH	20ml	09/11/15	7.0 – 7.6	7.4	Pass
Appearance	20ml	05/11/15	Milky suspension	Milky suspension	Pass



11 December 2015

Robert Bush BSc. MSc. CBiol. MRSB.
Qualified Person

**EUROPEAN COMMUNITY/EEA OFFICIAL BATCH PROTOCOL REVIEW
CERTIFICATE OF APPROVAL
FOR IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS**

Name and address of the control authority performing the document review: Veterinary Medicines Directorate.
Woodham Lane, New Haw, Surrey. KT15 3LS


Examined under Article 81 of Directive 2001/82/EC as amended by Directive 2004/28/EC in accordance with the current Procedure for harmonised application of Article 81 for Official Batch Protocol Review of immunological veterinary medicinal products in the European Community.

Trade name:	Parcox-5, Oral Suspension
International non-proprietary Name / Ph. Eur. name / common name	Live, attenuated coccidiosis vaccine
Name and address of marketing authorisation holder	Intervet UK Ltd, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ, UK
Name and address of manufacturer, if different:	Schering-Plough Animal Health, Breakspear Road South, Harefield, Uxbridge, Middlesex, UB9 6LS, United Kingdom
Marketing authorisation number (Member State / EC) issued by	01708/4552
Manufacturer's batch number(s) appearing on package and other identification numbers associated with this batch (final bulk no, final lot no, packaging lot no)	A248B
Batch number of diluent (where appropriate)	
Type of container:	Clear, colourless polyethylene terephthalate G copolymer (PETG) vials, 4 ml (1000 dose) and 20 ml (5000 dose) size
Total number of containers in this batch ² :	4830
Number of doses/volume per container:	5000 / 20ml
Date of start of period of validity: Shelf life: Expiry date:	15/10/15 8 Months 02/06/16

The signed manufacturer's release protocol for this batch has been examined in conformity with the current procedure for harmonised application of Article 81 for OBPR in the European Community.

This batch IS in compliance with all of the approved specification laid down in the above noted marketing authorisation.

Certificate Number: 15/B1845

Signed:	
Name and function of signatory:	Sam Ward Manager of UK Batch Release Arrangements
Date of issue:	16/12/15

¹ Provision of different batch numbers of authorised diluent to different Member States should not impair mutual recognition of OPBR for the batch of active component covered by the certificate, however if a diluent batch different from that on the certificate is provided, protocol documentation on the new diluent batch may be requested in addition to the certificate.

² If different fillings exist, please indicate.