

Protocol/Certificate of Analysis

PARACOX 5

Chicken Coccidiosis Vaccine, Live, Attenuated

Marketing Authorisation Numbers

Austria	Zul.-Nr. 8-20215	Germany	Zul.-Nr. PEI.V.01272.01.1
France	AMM n° 676994 8/676993 1	Ireland	VPA 10996/215/001
Greece	013670101/2	Portugal	A.I.M. n° 650/99 DGV
Italy	A.I.C. n° 102949029/102949017	Spain	Reg N° 1313 ESP
UK	Vm 01708/4552	Switzerland	IVI No 1562

Batch number	A249B	Packaging run	7370995
SAP Batch number	A249B05	Storage conditions	2-8 degrees C
Pack type	Hungary		

Date of testing	12/11/2015
Date of completion of potency	09/12/2015

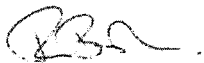
Date of expiry 30/06/2016

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

Containers

Total number of containers	20ml (5000 dose)	5227
Number released	20ml (5000 dose)	115

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

12 February 2016

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	A249B	
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 - 5422	
Number of containers for which release is required	5000 dose - 5227	
Number of doses per container	20ml -5000 dose	
Number of samples for competent authority	Nil	
Start date of potency test	12/11/15	
Date of expiry	30/06/16	
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 A249B**

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 MS4b/028	06/11/15 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	L328EaX201	10/09/15	299.7	600	Pass	22/09/15	3033
E. acervulina HP	L328EaX202	10/09/15	299.7	600	Pass	22/09/15	3034
E. acervulina HP	L329EaX101	01/10/15	254.5	600	Pass	13/10/15	2540
E. acervulina HP	L329EaX102	01/10/15	254.5	600	Pass	13/10/15	2535
E. maxima CP	L328CPXX01	11/09/15	40.3	70	Pass	26/09/15	4129
E. maxima CP	L328CPNX01	11/09/15	34.4	70	Pass	26/09/15	3834
E. maxima CP	L328CPNX02	11/09/15	34.4	70	Pass	26/09/15	3838
E. maxima MFP	L328MFPX01	11/09/15	17.6	40	Pass	23/09/15	3535
E. maxima MFP	L328MFPX02	11/09/15	17.6	40	Pass	23/09/15	3535
E. maxima MFP	L329MFP101	01/10/15	14.4	40	Pass	14/10/15	3133
E. mitis HP	L328EmX101	11/09/15	98.3	300	Pass	27/09/15	2735
E. mitis HP	L328EmX102	11/09/15	98.3	300	Pass	27/09/15	2735
E. mitis HP	L328EmX201	11/09/15	98.3	300	Pass	27/09/15	2735
E. mitis HP	L328EmX202	11/09/15	98.3	300	Pass	27/09/15	2734
E. tenella HP	L328EtX101	10/09/15	29.6	200	Pass	27/09/15	3235
E. tenella HP	L328EtX201	10/09/15	29.6	200	Pass	27/09/15	3237
E. tenella HP	L329EtX101	02/10/15	39.2	200	Pass	16/10/15	4335
E. tenella HP	L329EtX201	02/10/15	39.2	200	Pass	16/10/15	4334

**Manufacturer's Batch Protocol
Paracox 5 Vaccine Batch Number A249B**

Sterility Testing Of Bulk Antigens Used in the Blend

Species	Antigen	Medium	Volume	Start	Finish	Status
E. acervulina HP	L328EaX201	TSB Thio	7.5ml 7.5ml	28/09/15	12/10/15	Pass Pass
E. acervulina HP	L328EaX202	TSB Thio	7.5ml 7.5ml	28/09/15	12/10/15	Pass Pass
E. acervulina HP	L329EaX101	TSB Thio	7.5ml 7.5ml	22/10/15	05/11/15	Pass Pass
E. acervulina HP	L329EaX102	TSB Thio	7.5ml 7.5ml	22/10/15	05/11/15	Pass Pass
E. maxima CP	L328CPXX01	TSB Thio	7.5ml 7.5ml	02/10/15	16/10/15	Pass Pass
E. maxima CP	L328CPNX01	TSB Thio	7.5ml 7.5ml	02/10/15	16/10/15	Pass Pass
E. maxima CP	L328CPNX02	TSB Thio	7.5ml 7.5ml	02/10/15	16/10/15	Pass Pass
E. maxima MFP	L328MFPX01	TSB Thio	7.5ml 7.5ml	28/09/15	12/10/15	Pass Pass
E. maxima MFP	L328MFPX02	TSB Thio	7.5ml 7.5ml	28/09/15	12/10/15	Pass Pass
E. maxima MFP	L329MFP101	TSB Thio	7.5ml 7.5ml	22/10/15	05/11/15	Pass Pass
E. mitis HP	L328EmX101	TSB Thio	7.5ml 7.5ml	09/10/15	23/10/15	Pass Pass
E. mitis HP	L328EmX102	TSB Thio	7.5ml 7.5ml	09/10/15	23/10/15	Pass Pass
E. mitis HP	L328EmX201	TSB Thio	7.5ml 7.5ml	09/10/15	23/10/15	Pass Pass
E. mitis HP	L328EmX202	TSB Thio	7.5ml 7.5ml	09/10/15	23/10/15	Pass Pass
E. tenella HP	L328EtX101	TSB Thio	7.5ml 7.5ml	05/10/15	19/10/15	Pass Pass
E. tenella HP	L328EtX201	TSB Thio	7.5ml 7.5ml	05/10/15	19/10/15	Pass Pass
E. tenella HP	L329EtX101	TSB Thio	7.5ml 7.5ml	22/10/15	05/11/15	Pass Pass
E. tenella HP	L329EtX201	TSB Thio	7.5ml 7.5ml	22/10/15	05/11/15	Pass Pass

TSB = Tryptone Soya Broth; Thio = Fluid Thioglycollate

Manufacturer's Batch Protocol
Paracox 5 Vaccine Batch Number A249B

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 A249B**

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 A249B
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 A249B
Antigen Lot 329 - 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	L329EaX101	0.89	E. mitis HP	L329EmX201	0.82
E. acervulina HP	L329EaX102	0.95	E. necatrix HP	L329EnN101	4.90
E. acervulina HP	L329EaX201	0.89	E. necatrix HP	L329EnN201	4.74
E. acervulina HP	L329EaX202	0.90	E. necatrix HP	L329EnX101	3.36
E. brunetti HP	L329EbXX01	0.96	E. necatrix HP	L329EnX201	3.28
E. brunetti HP	L329EbXX02	0.92	E. necatrix HP	L329EnX301	3.05
E. maxima CP	L329CPX101	0.82	E. necatrix HP	L329EnX401	3.16
E. maxima CP	L329CPX201	0.75	E. tenella HP	L329EtX101	1.29
E. maxima MFP	L329MFP101	0.87	E. tenella HP	L329EtX201	1.23
E. maxima MFP	L329MFP201	0.88	E. tenella HP	L329EtX301	1.18
E. mitis HP	L329EmX101	0.86			

Antigen Lot 329 - Test For Extraneous Agents - Embryonated Eggs
Ph Eur 2.6.25

Date testing started: 04/10/15 Date testing completed: 30/11/15

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 A249B
Antigen Lot 329 - Test For Extraneous Agents - Chicken Embryo Fibroblast
Cell Cultures Ph Eur 2.6.25

Date testing started: 05/11/15 Date testing completed: 30/11/15

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 329 - Test for Absence of Mycoplasma – Ph Eur 2.6.7

Start date: 03/11/15 Finish date: 01/12/15
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 329 - 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	27/10/15	Negative	PASS

**Manufacturer's Batch Protocol
Paracox 5 Vaccine Batch Number A249B**

VACCINE BLEND AND FILL – BATCH A249

Blend Date 10/11/15
 Fill date 11/11/15 & 12/11/15
 Volume of fill 160L

Vaccine composition

Strain	Lot no.	BULK OOCYSTS		Wt Used (mL)	SPOR. RATE %	SPOR. OOCYSTS PER DOSE	
		Total/mL	Sp/ml			Actual	Target
Ea	L328EAX201	4485679	3967160	290.0	88	29	500
	L328EAX202	4563467	3921167	3029.0	86	297	
	L329EAX101	4295647	3870314	2530.0	90	245	
	L329EAX102	4077534	3647451	597.8	89	55	
CP	L328CPXX01	1548371	1406529	2490.0	91	88	200
	L328CPNX01	1761149	1617510	3828.0	92	155	
	L328CPNX02	1759373	1595615	191.7	91	8	
MFP	L328MFPX01	962788	871878	1100.0	91	24	100
	L328MFPX02	976769	865267	3527.0	89	76	
	L329MFP101	900558	793516	1246.5	88	25	
Em	L328EMX101	6496789	6019198	1307.8	93	197	1000
	L328EMX102	7394546	6771384	2730.0	92	462	
	L328EMX201	8356200	7750806	2734.0	93	530	
	L328EMX202	8606461	7934222	309.6	92	61	
Et	L328ETX101	2571668	2425136	850.0	94	52	500
	L328ETX201	2848076	2654398	3225.0	93	214	
	L329ETX101	2825677	2663542	4330.0	94	288	
	L329ETX201	2944515	2778733	1023.9	94	71	
TOTAL/dose		3145	2875	35340.3	91.4	2875	2300

Non-antigen components
Diluent
 Phosphate buffered saline

124.7L

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 A249B**

FINAL PRODUCT TESTING

Sterility Test - Ph Eur 2.6.1

Start date: 20/11/15 **Finish date:** 04/12/15

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>	27/11/15 – 30/11/15	1004032580	30	+ve	Pass
<i>Cl. sporogenes</i>	27/11/15 – 30/11/15	1004032580	40	+ve	Pass

Positive Controls – Tryptone Soya Broth

Test Species	Date Tested	Batch Number	Inoculum Level (cfu)	Result	Conclusion
<i>B. subtilis</i>	27/11/15 – 30/11/15	1004167930	68	+ve	Pass
<i>C. albicans</i>	20/11/15 – 24/11/15	1004167930	89	+ve	Pass

+ve = Positive growth of test organism.

Absence Of Campylobacter Contamination – SOP 734(6)

Start date: 17/11/15 **Finish date:** 20/11/15

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 A249B**

Potency Test

Final Container Oocyst Count - SOP 843(3)

Final Container Count 20ml Vials

Date Counted: 01/12/15

Count Type	Specification (ml ⁻¹)	Result (ml ⁻¹)	Status
Sporulated oocyst count	≥4.6 x 10 ⁵	5.99 x 10 ⁵	Pass
Number of oocysts > 30μ	≥4.0 x 10 ⁴	5.24 x 10 ⁴	Pass

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

Start Date: 12/11/15

Finish Date: 20/11/15

Day (post-vaccination)	Specification	Oocyst output/bird	Status
5 – 6	≥0.8 x 10 ⁶	2.8 x 10 ⁶	Pass
6 – 7	≥1.3 x 10 ⁶	2.1 x 10 ⁶	Pass
7 – 8	≥0.8 x 10 ⁶	0.8 x 10 ⁶	Pass

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

Start Date: 12/11/15

Finish Date: 09/12/15

Species	Oocyst Counts (Controls)	Oocyst Counts (Vaccinates)	Specification*	Result	Status
E. acervulina HP	7050	4	≥92.0%	99.9%	Pass
E. maxima CP	2704	86	≥90.0%	96.8%	Pass
E. maxima MFP	4997	1	≥96.5%	100.0%	Pass
E. mitis HP	5592	163	≥81.2%	97.1%	Pass
E. tenella HP	1045	2	≥85.8%	99.8%	Pass

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

**Manufacturer's Batch Protocol
Paracox 5 Vaccine Batch Number A249B**

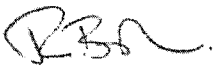
Analytical Tests - SOP 849(4)

Date of test 30/11/15

Vial Size	20ml				
Specification	20.0 - 21.0 ml				
Vial number	1	2	3	4	5
Volume (ml)	20.1	20.2	20.1	20.6	20.2
Status	Pass	Pass	Pass	Pass	Pass

pH and Visual Appearance

Test	Vial Size	Date	Specification	Result	Status
pH	20ml	12/11/15	7.0 – 7.6	7.4	Pass
Appearance	20ml	30/11/15	Milky suspension	Milky suspension	Pass


 _____ 28 January 2016
 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:	Paracox-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)	A249B
Batch number of diluent (where appropriate)	
Type of container:	Clear, colourless polyethylene terephthalate G copolymer (PETG) vials, 4ml (1000 dose) and 20ml (5000 dose) sizes
Total number of containers in this batch ² :	5227
Number of doses/volume per container:	5000 / 20ml
Date of start of period of validity:	12/11/15
Shelf life:	8 Months
Expiry date:	30/06/16

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/B2207

Signed:	
Name and function of signatory:	Sam Ward Manager of UK Batch Release Arrangements
Date of issue:	05/02/16

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.