Schering-Plough Animal Health

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Schering-Plough

Protocol/Certificate of Analysis

PARACOX

Coccidiosis Vaccine, Live, Attenuated

Marketing Authorisation/Numbers

UK	Vm 01708/4572	Greece	008500101/2
Argentina	98008	Italy	AIC 101360028 101360016
Australia	61990/100/0208	Morocco	0328.2/96
	61990/500/0208	Portugal	496/93/IPPAA
Austria	Zul.-Nr.: 8-20214	Spain	1660 ESP
Eire	VPA 102996/245/001	South Africa	G1994
Central and Eastern Europe	479/1999	Switzerland	Nr 1397
France	674127-5/674129-8		
Germany	Nr. 483a/91		

Batch number	**0533B**	Packaging run	**7312428**
SAP Batch number	**0533B05**		
Pack type	**Hungary**	Storage conditions	2-8 degrees C

Date of testing/Manufacture	12/06/2014
Date of completion of potency	07/07/2014

Date of expiry

General	25/12/2014
Germany/Spain/Egypt	25/12/2014
Italy	12/01/2015
Argentina/Australia/Belarus/Chile	19/02/2015

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

Containers

Total number of containers	100ml (1000 dose)	339
	500ml (5000 dose)	927
Number released	500ml (5000 dose)	57

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, MSB

Qualified Person
31 July 2014

Schering-Plough

Trade name	Paracox	
Product type	**Live, attenuated coccidiosis vaccine**	
Target species	**Chicken (*Gallus gallus*)**	
Marketing Authorisation UK	**Vm 01708/4572**	
Marketing Authorisations	**Austria** Zul.-Nr. 8-20214 **Belgium** 282 IS 47 F11 **Denmark** Mtnr 15619 **Central and Eastern European** 479/1999 **Finland** 13530 **France** 674127-5/674129-8 **Germany** Nr. 483a/91 **Greece** 008500101/2 **Holland** REG NL 3070 **Hungary** 2335/1-2/08 MgSzH ÁTI **Ireland** VPA 10277/75/1 **Italy** 101360028-101360016 **Norway** MT nr 8234 **Portugal** 496/93/IPPAA **Spain** 1660 ESP **Sweden** 12039 **Switzerland** IVI-N°=1397	
Batch number	**0533**	
Type of container	**Irradiated nylon/polyethylene multidose sachet**	
Total number of containers manufactured in this batch	**1000 dose - 359**	
	5000 dose - 946	
Number of containers for which release is required	**1000 dose - 339**	
	5000 dose - 927	
Number of doses per container	**A 100ml - 1000 dose**	
	B 500ml - 5000 dose	
Number of samples for competent authority	**Nil**	
Start date of potency test	**12/06/14**	
Date of expiry	**25/12/14 UK and all others, 06/11/14 Holland** **12/01/15 Italy**	
Shelf life	**28 weeks - UK and all others, 21 weeks - Holland** **7 calendar months- Italy**	
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 Vaccine Batch Number 0533

PRODUCTION INFORMATION

Master Seeds

Species	Master Seed	Date Testing Completed
E. acervulina HP	MS71s+13	December 88
E. brunetti HP	MS27s+7	December 88
E. maxima CP	MS12s+11	December 88
E. maxima MFP	MS15s+11	December 88
E. mitis HP	MS12s+11	December 88
E. necatrix HP	MS42s+8	December 88
E. praecox HP	MS21s+2	December 88
E. tenella HP	MS38s+10	December 88

Working Seeds

Species	Working Seed	QA Approval Date
E. acervulina HP	MS3a/017	28/02/14
E. brunetti HP	MS3a/015	24/10/13
E. maxima CP	MS3a/026	16/05/14
E. maxima MFP	MS4c/025	04/02/14
E. mitis HP	MS4a/026	28/02/14
E. necatrix HP	MS3a/031	16/05/14
E. praecox HP	MS2a/014	04/02/14
E. tenella HP	MS7a/010	21/11/13

Antigen Production

Species	Lot	Start date	Oocyst Output per Bird (x 10^{-6})			Finish date	Volume (ml)
			Actual	Upper Acceptance Limit	Result		
E. acervulina HP	L304EaXX02	27/03/14	351.8	600	Pass	08/04/14	2535
E. brunetti HP	L304EbXX01	27/03/14	20.3	70	Pass	08/04/14	2936
E. maxima CP	L305CPXX01	17/04/14	21.2	70	Pass	30/04/14	3534
E. maxima MFP	L305MFP101	19/04/14	12.7	40	Pass	06/05/14	2635
E. mitis HP	L305EmX101	18/04/14	88.9	300	Pass	30/04/14	2635
E. mitis HP	L305EmX102	18/04/14	88.9	300	Pass	30/04/14	2635
E. necatrix HP	L304EnN301	01/04/14	1.6	40	Pass	17/04/14	3436
E. necatrix HP	L305EnX201	22/04/14	2.9	40	Pass	08/05/14	2136
E. necatrix HP	L305EnX401	22/04/14	2.9	40	Pass	09/05/14	2135
E. praecox HP	L304EpXX01	27/03/14	25.8	400	Pass	07/04/14	3035
E. tenella HP	L304EtX102	28/03/14	76.9	200	Pass	11/04/14	2635
E. tenella HP	L304EtX201	28/03/14	76.9	200	Pass	11/04/14	4336

Sterility Testing Of Bulk Antigens Used in the Blend

Species	Antigen	Medium	Volume	Start	Finish	Result	Status
E. acervulina HP	L304EaXX02	TSB Thio	7.5ml 7.5ml	16/04/14	30/04/14	NEC NEC	**Pass** **Pass**
E. brunetti HP	L304EbXX01	TSB Thio	7.5ml 7.5ml	16/04/14	30/04/14	NEC NEC	**Pass** **Pass**
E. maxima CP	L305CPXX01	TSB Thio	7.5ml 7.5ml	07/05/14	21/05/14	NEC NEC	**Pass** **Pass**
E. maxima MFP	L305MFP101	TSB Thio	7.5ml 7.5ml	14/05/14	28/05/14	NEC NEC	**Pass** **Pass**
E. mitis HP	L305EmX101	TSB Thio	7.5ml 7.5ml	07/05/14	21/05/14	NEC NEC	**Pass** **Pass**
E. mitis HP	L305EmX102	TSB Thio	7.5ml 7.5ml	07/05/14	21/05/14	NEC NEC	**Pass** **Pass**
E. necatrix HP	L304EnN301	TSB Thio	7.5ml 7.5ml	25/04/14	09/05/14	NEC NEC	**Pass** **Pass**
E. necatrix HP	L305EnX201	TSB Thio	7.5ml 7.5ml	15/05/14	29/05/14	NEC NEC	**Pass** **Pass**
E. necatrix HP	L305EnX401	TSB Thio	7.5ml 7.5ml	15/05/14	29/05/14	NEC NEC	**Pass** **Pass**
E. praecox HP	L304EpXX01	TSB Thio	7.5ml 7.5ml	16/04/14	30/04/14	NEC NEC	**Pass** **Pass**
E. tenella HP	L304EtX102	TSB Thio	7.5ml 7.5ml	24/04/14	08/05/14	NEC NEC	**Pass** **Pass**
E. tenella HP	L304EtX201	TSB Thio	7.5ml 7.5ml	24/04/14	08/05/14	NEC NEC	**Pass** **Pass**

NEC = No evidence of contamination in the test broth; **TSB** = Tryptone Soya Broth
Thio = Fluid Thioglycollate

Positive Controls - Tryptone Soya Broth

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

Positive Controls - Fluid Thioglycollate

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

+ve = Positive growth of test organism.

Manufacturer's Batch Protocol

Paracox Vaccine Batch Number 0533

Antigen Lot 304 - 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	L304EaXX01	1.44	E. necatrix HP	L304EnN101	19.01
E. acervulina HP	L304EaXX02	1.30	E. necatrix HP	L304EnN201	13.99
E. brunetti HP	L304EbXX01	0.99	E. necatrix HP	L304EnN301	15.51
E. maxima CP	L304CPXX01	0.77	E. praecox HP	L304EpXX01	0.76
E. maxima MFP	L304MFPX01	0.70	E. tenella HP	L304EtX101	1.05
E. mitis HP	L304EmXX01	0.80	E. tenella HP	L304EtX102	1.11
E. mitis HP	L304EmXX02	0.75	E. tenella HP	L304EtX201	1.02
E. necatrix HP	L304EnXX01	7.97			

Antigen Lot 304 - Test For Extraneous Agents - Embryonated Eggs Ph Eur 2.6.25

Date testing started: 30/04/14 **Date testing completed:** 28/05/14

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 Vaccine Batch Number 0533

Antigen Lot 304 - Test For Extraneous Agents - Chicken Embryo Fibroblast Cell Cultures Ph Eur 2.6.25

Date testing started: 01/05/14 **Date testing completed:** 29/05/14

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 304 - Test for Absence of Mycoplasma – Ph Eur 2.6.7

Start date: 29/04/14 **Finish date:** 27/05/14
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 304 - 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	16/04/14	**Negative**	**PASS**

Manufacturer's Batch Protocol

Paracox Vaccine Batch Number 0533

Antigen Lot 305 - 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	L305EaXX01	0.86	E. mitis HP	L305EmX201	0.88
E. acervulina HP	L305EaXX02	0.86	E. mitis HP	L305EmX202	0.89
E. brunetti HP	L305EbXX01	0.87	E. necatrix HP	L305EnX101	5.50
E. maxima CP	L305CPXX01	0.95	E. necatrix HP	L305EnX201	4.75
E. maxima CP	L305CPXX02	0.90	E. necatrix HP	L305EnX301	5.79
E. maxima MFP	L305MFP101	0.88	E. necatrix HP	L305EnX401	5.19
E. maxima MFP	L305MFP102	0.92	E. necatrix HP	L305EnX501	5.83
E. maxima MFP	L305MFP201	0.85	E. necatrix HP	L305EnX601	5.50
E. maxima MFP	L305MFP202	0.83	E. praecox HP	L305EpXX01	0.74
E. mitis HP	L305EmX101	0.89	E. tenella HP	L305EtXX01	0.96
E. mitis HP	L305EmX102	0.85	E. tenella HP	L305EtXX02	0.96

Antigen Lot 305 - Test For Extraneous Agents - Embryonated Eggs Ph Eur 2.6.25

Date testing started: 21/05/14 **Date testing completed:** 17/06/14

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 Vaccine Batch Number 0533

Antigen Lot 305 - Test For Extraneous Agents - Chicken Embryo Fibroblast Cell Cultures Ph Eur 2.6.25

Date testing started: 22/05/14 **Date testing completed:** 17/06/14

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 305 - Test for Absence of Mycoplasma – Ph Eur 2.6.7

Start date: 20/05/14 **Finish date:** 17/06/14
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 305 - 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	07/05/14	**Negative**	**PASS**

VACCINE BLEND AND FILL - BATCH 0533

Blend Date: 04/06/14

Fill date: 05/06/14

Volume of fill: 525L

Vaccine composition

Strain	Lot no.	BULK OOCYSTS		Wt Used	SPOR. RATE	SPOR. OOCYSTS PER DOSE	
		Total/mL	Sp/ml	(mL)	%	Actual	Target
Ea	L304EAXX02	2973075	2671079	1130.3	90	575	500
Eb	L304EBXX01	737111	704140	857.4	96	115	100
CP	L305CPXX01	1617218	1475515	818.6	91	230	200
MFP	L305MFP101	887150	784809	769.6	88	115	100
Em	L305EMX101	8404641	7713667	325.3	92	478	1000
	L305EMX102	8781647	8104348	435.6	92	672	
En	L304ENN301	253875	222500	270.1	88	11	500
	L305ENX201	823819	726303	2130.5	88	295	
	L305ENX401	751111	664278	2125.1	88	269	
Ep	L304EPXX01	1013974	931797	648.1	92	115	100
Et	L304ETX102	3241101	3110452	284.3	96	168	500
	L304ETX201	3518530	3395019	629.3	96	407	
TOTAL/dose		3766	3451	10424.2	91.6	3451	3000

Diluent Xanthan gum 3150g Batch 0000303974
Purified water 514.576 litres

FINAL PRODUCT TESTING

Sterility Test - Ph Eur 2.6.1

Start date: 23/06/14 **Finish date:** 07/07/14

Sachet Size	Medium	Volume Tested	Number of Sachets Tested	Result	Status
A-100ml	TSB	10ml	4	NEC	**Pass**
	Thio	10ml		NEC	**Pass**
B-500ml	TSB	50ml	6	NEC	**Pass**
	Thio	50ml		NEC	**Pass**

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	Status
Ps. aeruginosa	23/06/14 – 25/06/14	1002773230	53	+ve	**Pass**
Ps. aeruginosa	23/06/14 – 25/06/14	968154	53	+ve	**Pass**
Cl. sporogenes	23/06/14 – 25/06/14	1002773230	60	+ve	**Pass**
Cl. sporogenes	23/06/14 – 25/06/14	968154	60	+ve	**Pass**

Positive Controls – Tryptone Soya Broth

Test Species	Date Tested	Batch Number	Inoculum Level (cfu)	Result	Status
B. subtilis	23/06/14 – 25/06/14	1002859810	72	+ve	**Pass**
B. subtilis	23/06/14 – 25/06/14	969420	72	+ve	**Pass**
C. albicans	23/06/14 – 26/06/14	1002859810	66	+ve	**Pass**
C. albicans	23/06/14 – 26/06/14	969420	66	+ve	**Pass**

+ve = Positive growth of test organism.

Absence Of Campylobacter Contamination - SOP 734(6)

Start date: 30/06/14 **Finish date:** 04/07/14

Size tested	Medium	Volume tested	Number of sachets tested	Result	Status
B-500 ml	CSEBP	0.5 ml	1	NEC	**Pass**
	CSEAP				

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 Vaccine Batch Number 0533

Potency Test

Final Container Oocyst Count – SOP 803.7(7)

Date Counted: 27/06/14

Count Type	Total Oocysts per dose	Sporulated Oocysts per dose	Specification Sporulated oocysts per dose	Status
Total Oocysts	3950	3618	≥3000	**Pass**
Oocysts > 30μ	265	241	≥150	**Pass**

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

Start Date: 12/06/14 **Finish Date:** 23/06/14

Day (post-vaccination)	Specification	Oocyst output/bird	Status
3 – 4	$\geq 0.4 \times 10^6$	4.1×10^6	**Pass**
4 – 5	$\geq 0.8 \times 10^6$	3.0×10^6	**Pass**
5 – 6	$\geq 0.8 \times 10^6$	3.2×10^6	**Pass**
6 – 7	$\geq 1.3 \times 10^6$	6.7×10^6	**Pass**
7 – 8	$\geq 0.8 \times 10^6$	4.0×10^6	**Pass**
8 – 9	$\geq 0.3 \times 10^6$	2.6×10^6	**Pass**
0 – 9	$\geq 5.0 \times 10^6$	23.5×10^6	**Pass**

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

Start Date: 12/06/14 **Finish Date:** 07/07/14

Species	Oocyst Counts (Controls)	Oocyst Counts (Vaccinates)	Specification	Result	Status
E. acervulina HP	9270	39	≥92.0%	99.6 %	**Pass**
E. brunetti HP	708	1	≥ 95.5%	99.9 %	**Pass**
E. maxima CP	1040	14	≥90.0%	98.7 %	**Pass**
E. maxima MFP	593	0	≥96.5%	100.0 %	**Pass**
E. mitis HP	4039	390	≥81.2%	90.3 %	**Pass**
E. necatrix HP	1494	40	≥ 89.6%	97.3 %	**Pass**
E. praecox HP	6030	7	≥ 95.0%	99.9 %	**Pass**
E. tenella HP	3091	13	≥85.8%	99.6 %	**Pass**

Manufacturer's Batch Protocol

Paracox Vaccine Batch Number 0533

Analytical Tests – SOP 806(11)

Test	Sachet Size	Date	Specification	Result	Status
Specific Gravity ($g\ ml^{-1}$)	A-100ml	27/06/14	0.95 - 1.05	1.00	**Pass**
	B-500ml	27/06/14	0.95 -1.05	1.00	**Pass**
Viscosity Vaccine (centipoises)	A-100ml	27/06/14	>199	530	**Pass**
	B-500ml	27/06/14	>199	550	**Pass**
Volume of Fill (ml)	A-100ml	27/06/14	105 - 125	114	**Pass**
	B-500ml	27/06/14	505 - 525	510	**Pass**
Sachet Weight (g)	A-100ml#1	02/07/14	115 - 135	125	**Pass**
	A-100ml#2	02/07/14	115 - 135	125	**Pass**
	A-100ml#3	02/07/14	115 - 135	125	**Pass**
	A-100ml#4	02/07/14	115 - 135	124	**Pass**
	A-100ml#5	02/07/14	115 - 135	124	**Pass**
Sachet Weight (g)	B-500ml#1	02/07/14	520 - 540	526	**Pass**
	B-500ml#2	02/07/14	520 - 540	525	**Pass**
	B-500ml#3	02/07/14	520 - 540	523	**Pass**
	B-500ml#4	02/07/14	520 - 540	524	**Pass**
	B-500ml#5	02/07/14	520 - 540	527	**Pass**

Date: 18 July 2014

Robert Bush BSc. MSc. CBiol. MSB.
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 81of 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**
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 Schering-Plough Animal Health Churn Road Compton Berkshire, RG20 6PR
Marketing authorisation number (Member State / EC) issued by	01708/4572
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)	0533 A&B
Batch number of diluent (where appropriate)	
Type of container:	Irradicated nylon/polyethylene multidose sachet
Total number of containers in this batch[2]:	946 - 359
Number of doses/volume per container:	5000 / 500ml1000 / 100ml
Date of start of period of validity: Shelf life: Expiry date:	12/06/14 7 Months 25/12/14

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: 14/B0785

Signed:	T. NASH

[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.

Name and function of signatory:	**Tom Nash** Manager of UK Batch Release Arrangements
Date of issue:	23/07/14

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