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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 10996/245/001	South Africa	G1994
Central and Eastern Europe	479/1999	Switzerland	Nr 1397
France	674127-5/674129-8		
Germany	Nr. 483a/91		

Batch number	0563A	Packaging run	7379620
SAP Batch number	0563A10		
Pack type	Hungary	Storage conditions	2-8 degrees C

Date of testing/Manufacture	18/02/2016
Date of completion of potency	15/03/2016

Date of expiry

General	01/09/2016
Germany/Spain/Egypt	01/09/2016
Italy	18/09/2016
Argentina/Australia/Belarus/Chile	27/10/2016

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

Containers

Total number of containers	100ml (1000 dose)	2048
	500ml (5000 dose)	1238
Number released	100ml (1000 dose)	24

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

21 April 2016

MSD Animal Health, Trading as MSD Animal Health Registered Office: As above Registered in England and Wales No. 03200855

