PHARMAGAL BIO s.r.o., Nitra, SR
Producer of immunological veterinary medicinal products
Murgašova 5,
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ANALYTICAL CERTIFICATE

CASTOREX
CALICIVAC
Anivac VHD

Batch: 54 05 13 21
Expiry: 27.05.2015

TESTS	METHODS	STANDARD	RESULT
Biological parameters			
Sterility	501-III/01	Absence of growth of micro-organisms.	Absence of growth of micro-organisms.
Potency In rabbits / Challenge trial	501-III/03	In minimum 90% of animals resistance to challenge with virulent strain of RHDV.	In 100% of animals resistance to challenge with virulent strain of RHDV.
Identity In rabbits / Challenge trial	501-III/04	In minimum 90% of animals resistance to challenge with virulent strain of RHDV.	In 100% of animals resistance to challenge with virulent strain of RHDV.
Physicochemical parameters			
Appearance	501-III/09	Suspension of red-brown colour with easy shakeable sediment of inactivated RHDV adsorbed on aluminium hydroxide that forms 40-60% of the vaccine if left undisturbed.	Suspension of red-brown colour with easy shakeable sediment of inactivated RHDV adsorbed on aluminium hydroxide that forms 50% of the vaccine if left undisturbed.
Extractable volume	501-III/10	20 ml	20 ml
pH value	501-III/05	pH 5.0 – 7.5	pH 6.88
Content of formaldehyde	501-III/06	1.10 – 1.80 g/l	1.33 g/l
Content of thiomersal	501-III/07	0.08 – 0.12 g/l	0.10 g/l
Content of aluminium	501-III/08	2.4 – 2.8 g/l	2.59 g/l

- CONFORMING -

I herewith certify that **CASTOREX (CALICIVAC, Anivac VHD), Batch 54 05 13 21** was manufactured and tested and complies with the quality requirements given in Marketing Authorisation Dossier as they were approved by the competent authorities and that all measures have been taken to demonstrate compliance with Directive 2001/82/EC as amended by Directive 2009/9/EC.

In Nitra, October 04, 2013

PHARMAGAL BIO s.r.o.
Murgašova 5
949 01 NITRA

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MVDr. Denisa Svitačová
Quality Control Laboratory

ÚSTAV ŠTÁTNEJ KONTROLY VETERINÁRNYCH BIOPREPARÁTOV A LIEČIV
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Administrative Code:82/14-Sk *Certificate Number: R-4/14/OB/OBPR* *Date: Nitra, 15.1.2014*

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

CERTIFIKÁT EURÓPSKEHO SPOLOČENSTVA/EEA O ÚRADNOM PROTOKOLOVOM UVOĽNENÍ ŠARŽE IMUNOLOGICKÉHO VETERINÁRNEHO LIEKU

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.*(Kontrolovaný podľa článku 81 Smernice 2001/82/ES v znení Smernice 2004/28/ES v súlade s aktuálnym pokynom Postup pre úradné protokolové uvoľňovanie šarží imunologických veterinárnych liekov v Európskom spoločenstve)*

Trade name *(obchodný názov)*	**CASTOREX** **(CALICIVAC, Anivac VHD)**
International non-proprietary Name /Ph.Eur. name/common name *(medzinárodný nechránený názov/Ph.Eur. názov /bežný názov)*	ATC vet code: *QI 08 AA01* **Vaccinum morbi haemorrhagici cuniculi inactivatum** Inactivated RHDV (Rabbit haemorrhagic disease virus vaccine)
Name and address of marketing authorisation holder *(meno a adresa držiteľa rozhodnutia o registrácii)*	**PHARMAGAL-BIO spol. s r.o.** **Murgašova 5, 949 01 NITRA, Slovak republic**
Name and address of manufacturer, if different *(meno a adresa výrobcu ak je odlišný)*	**As above**
Marketing authorisation number (Member State/EC) *(číslo rozhodnutia o registrácii -členský štát/ES)*	**Czech Republic: 97/030/00-C** **Germany: PEI.V.03397.01.1** **Hungary: 2209/3/07 MgSzH ÁTI (40 adag)** **Poland: 1770/07** **Spain: 1780 ESP** **Portugal: AIM no 782/07RIVPT** **France: FR/V/8993419 1/2008** **United Kingdom: Vm 33225/4000** **Ireland: VPA 10556/001/001** **Slovak Republic : 97/119/99-S**
Manufacturer's batch number appearing on package and other identification numbers associated with this batch *(číslo výrobnej šarže a ďalšie súvisiace identifikačné čísla)*	**54 05 13 21** **Final batch from Bulk 54 05 13**
Batch number of diluent (where appropriate) *(číslo šarže riedidla)*	**Not appropriate.**
Type of container *(druh obalu)*	**Glass vials (hydrolytic resistance Type I), rubber chlorobutyl stoppers and aluminium cap with central tear-off**
Total number of containers in this batch *(veľkosť šarže)*	**3 553 pcs**
Number of doses/volume per container *(počet dávok/objem)*	**40 doses**
Date of start of period of validity/exp. *(dátum začiatku doby platnosti)*	**28.05.2013/ 27.05.2015**