



PHARMAGAL BIO s.r.o., Nitra, SR
Producer of immunological veterinary medicinal products

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ANALYTICAL CERTIFICATE

CASTOREX
CALICIVAC
Anivac VHD

Batch: 58 12 13 21

Expiry: 09.01.2016

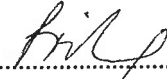
TESTS	METHODS	STANDARD	RESULT
Biological parameters			
<i>Sterility</i>	501-III/01	Absence of growth of micro-organisms.	Absence of growth of micro-organisms.
<i>Potency</i> In rabbits / Challenge trial	501-III/03	In minimum 90% of animals resistance to challenge with virulent strain of RHDV.	In 100% of animals resistance to challenge with virulent strain of RHDV.
<i>Identity</i> 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			
<i>Appearance</i>	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.
<i>Extractable volume</i>	501-III/10	20 ml	20 ml
<i>pH value</i>	501-III/05	pH 5.0 – 7.5	pH 6.98
<i>Content of formaldehyde</i>	501-III/06	1.10 – 1.80 g/l	1.65 g/l
<i>Content of thiomersal</i>	501-III/07	0.08 – 0.12 g/l	0.11 g/l
<i>Content of aluminium</i>	501-III/08	2.4 – 2.8 g/l	2.51 g/l

- CONFORMING -

I herewith certify that **CASTOREX (CALICIVAC, Anivac VHD)**, Batch **58 12 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, April 11, 2014

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MVDr. Denisa Svitačová
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