

**OFFICIAL CONTROL AUTHORITY
BATCH RELEASE
OF
IMMUNOLOGICAL VETERINARY
MEDICINAL PRODUCTS**

2012

**INFECTIOUS BOVINE RHINOTRACHEITIS VACCINE
(INACTIVATED)**

Document title	Official control authority batch release of infectious bovine rhinotracheitis vaccine (inactivated)
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Custodian Organisation	The present document was elaborated by the EDQM through the OMCL network and is finalised under PA/PH/OMCL (03) 9 DEF CORR

OFFICIAL CONTROL AUTHORITY BATCH RELEASE OF INFECTIOUS BOVINE RHINOTRACHEITIS VACCINE (INACTIVATED)

OMCLs performing batch release on this product should receive a completed signed protocol from the MAH (model template available separately on the EDQM website (www.edqm.eu)) and the required samples.

The licensing authority provides the OMCL with all necessary data from the quality part of the dossier such as relevant Pharmacopoeia monographs, list of tests to be performed on each batch and the SOPs as presented in the dossier.

1 INTRODUCTION

Official Control Authority Batch Release of immunological products for veterinary use is performed within the framework of Article 82 of Directive 2001/82/EC as amended by Directive 2004/28/EC and following the current guideline on EC administrative procedure for official control authority batch release of IVMPs.

All general and specific Ph Eur monographs relevant to this product apply.

2 SAMPLING AND TESTS TO BE PERFORMED BY THE OFFICIAL CONTROL LABORATORY

The following samples should be supplied to the Official Medicines Control Laboratory performing batch release:

At least 10 containers of each final lot.

The Control Laboratory should perform the following tests:

- Appearance
- Potency¹ – Potency testing is done on the first batch from a final bulk and then all other batches derived from that same bulk shall not be re-tested.

¹ In the cases where batches are tested in the target animals (eg cattle), under these exceptional circumstances, sera from the animals vaccinated by the manufacturers may be used by the OMCL.