

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

**2012**

**BRUCELLOSIS VACCINES (BRUCELLA MELITENSIS REV.1  
STRAIN AND BRUCELLA ABORTUS S19 STRAIN) (LIVE)**

<b>Document title</b>	<b>Official control authority batch release of brucellosis vaccines (brucella melitensis rev.1 strain and brucella abortus S19 strain) (Live)</b>
<b>Legislative basis</b>	<b>Council Directive 2001/82/EC amended by Directive 2004/28/EC</b>
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<b>Custodian Organisation</b>	<b>The present document was elaborated by the EDQM through the OMCL network and is finalised under PA/PH/OMCL (03) 23 DEF CORR</b>

**OFFICIAL CONTROL AUTHORITY BATCH RELEASE OF  
BRUCELLOSIS VACCINES (BRUCELLA MELITENSES REV.1 STRAIN AND  
BRUCELLA ABORTUS S19 STRAIN) (LIVE)**

*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](http://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 the Ph Eur monographs relevant to these products apply.

The Ph Eur monograph 0793 is relevant for Brucella Melitensis Rev. 1 Strain.

## **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 of both freeze-dried component and the diluent.

The Control Laboratory should perform the following tests:

- Appearance
- Identity
- Extraneous micro-organisms
- Determination of dissociation phase
- Live bacteria count
- Solubility