OFFICIAL CONTROL AUTHORITY BATCH RELEASE OF IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS

2012

TUBERCULIN PURIFIED PROTEIN DERIVATIVE (PPD), BOVINE

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OFFICIAL CONTROL AUTHORITY BATCH RELEASE OF TUBERCULIN PURIFIED PROTEIN DERIVATIVE (PPD), BOVINE

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.

The Ph Eur monograph 0536 is relevant for this product.

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 5 multiple dose containers or 20 single dose containers of each final lot of both the freeze-dried component and diluent, where applicable.

The Control Laboratory should perform the following tests:

- Appearance
- Sensitising effect
- Potency