EU Official Control Authority Batch Release

Immunological Veterinary Medicinal Products

**Guideline for Aujeszky’s Disease Vaccine (inactivated)**

**This version in force from 28 January 2022**

**Replacing version in force from 1 January 2013**

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| **Document title** | Official control authority batch release of Aujeszky’s disease 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 (21) 118 DEF |

**OFFICIAL CONTROL AUTHORITY BATCH RELEASE OF aujeszky’s Disease 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 paragraphs 3 to 9 of Article 128 of Regulation (EU) 2019/6 and following the current EU Administrative Procedure for Official Control Authority Batch Release of Immunological Veterinary Medicinal Products.

The Ph Eur monograph 0745 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 10 containers of each final lot.

The Control Laboratory should perform the following tests:

1. Appearance
2. Potency - 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.