

SPECIFIC REQUIREMENTS FOR THE PRODUCTION AND CONTROL OF EQUINE LIVE AND INACTIVATED VIRAL AND BACTERIAL VACCINES

Guideline Title	General Requirements for the Production and Control of Equine Live and Inactivated Viral and Bacterial Vaccines for Veterinary Use
Legislative Basis	Directive 81/852/EEC as amended
Date of First Adoption	prior to September 1994
Date of Entry into Force	prior to September 1994
Status	Last revised September 1994
Previous Titles	Equine vaccines
Other References	
Additional Notes	This note for guidance is intended to provide general guidance on the type of data which should be included in applications for marketing authorisations for equine bacterial and viral vaccines. It is intended to supplement Directive 81/852/EEC as amended, and should be read in conjunction with that Directive. Cross-references to the notes for guidance on <i>General Requirements for the Production and Control of Live Mammalian Bacterial and Viral Vaccines for Veterinary Use</i> and <i>General Requirements for the Production and Control of Inactivated Mammalian Bacterial and Viral Vaccines for Veterinary Use</i> are made.

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SPECIFIC REQUIREMENTS FOR THE PRODUCTION AND CONTROL OF EQUINE LIVE AND INACTIVATED VIRAL AND BACTERIAL VACCINES

This document is intended to provide guidance on the type of data which should be included in applications for marketing authorisations for equine viral and bacterial vaccines. It is intended to supplement Directive 81/852/EEC, as amended by Directive 92/18/EEC, and must be read in conjunction with that Directive.

Where requirements have been included in the *General Requirements for the Production and Control of Live Mammalian Bacterial and Viral Vaccines for Veterinary Use* or the *General Requirements for the Production and Control of Inactivated Mammalian Bacterial and Viral Vaccines for Veterinary Use*, those requirements have not been repeated here but a cross-reference to these has been given. For brevity, these have been referred to as the “General Requirements for Live Mammalian Vaccines” (GRLMV) or the “General Requirements for Inactivated Mammalian Vaccines” (GRIMV), as appropriate.

I. LIVE VACCINES

1. STARTING MATERIALS

1.1 Substances of animal origin

Paragraphs 1.1 to 1.1.4.2 of GRLMV apply.

1.2 Cell Substrates

1.2.1 General requirements

The requirements of GRLMV paragraphs 1.2.1 apply.

1.2.2 Requirements for cell lines

1.2.2.1 Extraneous agents

The requirements of GRLMV paragraph 1.2.2.1 apply.

Tests should be carried out for equine viruses listed in Table 1.

Where the cell line has originated from cells other than the equine species, the relevant agents listed in Table 1 must be looked for by appropriate and validated methods, using the most sensitive system, as indicated in GRLMV paragraphs 1.2.2.1.4 to 1.2.2.1.4.3.

1.2.3 Requirements for primary cells

The requirements of GRLMV paragraphs 1.2.3 to 1.2.3.2 apply.

If a vaccine has to be produced on primary cells, the specific pathogen free herd as specified in GRLMV paragraph 1.2.3 must be free from the appropriate, relevant pathogens listed in Table 1. Tests should be carried out for contaminants specific for the species of origin of the

cells and for horses in accordance with Table 1 and in accordance with sections 1.2.3.1.1 to 1.2.3.1.4.4 of GRLMV.

1.3 Virus seed

The requirements of GRLMV paragraphs 1.3 to 1.3.5 apply.

1.4 Bacterial seed

The requirements of GRLMV paragraphs 1.4 to 1.4.3 apply.

2. FINISHED PRODUCT – ASSAY RESULTS REQUIRED IN THE APPLICATION FOR MARKETING AUTHORISATION

2.1 Safety

The requirements of GRLMV paragraphs 2.1 to 2.1.5 apply.

Where the vaccine is intended for use in pregnant mares, the studies, including the overdose studies (GRLMV paragraphs 2.1.2), must be carried out in accordance with the recommendations for use and be extended to include observations of the effect of vaccination on foaling.

The safety studies, including the overdosage studies, should include tests in thoroughbred horses to assess the incidence of local and systematic reactions in these.

The types of systematic reactions which may be observed and should be recorded if present include change in normal demeanour for the horse and loss of appetite.

If local reactions are observed, the size and the type of lesions and their duration must be recorded.

2.1.1 Field trials

As part of the studies of the safety in the field trials (GRLMV paragraph 2.1.5), the following should be performed on a sufficient number of target animals, located on more than two farms or stables.

Daily for three days before vaccination:

- a) all test animals shall be given a general examination;
- b) the selected injection site shall be carefully examined in all test animals;
- c) temperature shall be recorded in a representative number of test animals.

At vaccination: temperature shall be recorded in some animals as under c) above.

As a minimum, 4 hours after vaccination: all animals shall be observed for local and/or systematic reactions.

Daily dose for four days vaccination, temperature shall be recorded in the same animals as under c) above.

Note: test animals include both vaccinates and controls. The controls may be horses vaccinated with another vaccine, if justified.

If local lesions are observed, the size, the type of reaction as well as the duration of the reaction must be recorded.

2.2 Efficacy

The requirements of GRLMV paragraphs 2.2 apply. Control animals may be horses vaccinated with another vaccine, if justified.

3. FINISHED PRODUCT – BATCH TESTING

The requirements of GRLMV paragraphs 3 to 3.12 apply.

3.1 Extraneous agents

To comply with the requirements of GRLMV paragraph 3.4, after removal or neutralisation of the viral vaccinal strain, the mixture shall be tested for extraneous agents on one or more sensitive cellular systems. Observe the cells for 14 days. During this time, carry out at least one passage. The absence of cytopathic effect is checked and an haemadsorption test is also carried out if possible.

II. INACTIVATED VACCINES

1. STARTING MATERIALS

1.1 Substances of animal origin

Paragraphs 1.1 to 1.1.4.2 of GRIMV apply.

1.2 Cell substrates and virus and bacterial seed

See requirements for live equine vaccines.

1.3 Inactivation

The requirement of GRIMV paragraph 1.9 apply.

2. FINISHED PRODUCT – ASSAY RESULTS REQUIRED IN THE APPLICATION FOR MARKETING AUTHORISATION

See requirements for live equine vaccines.

2.1 Safety

In the safety tests, including in the field trials, particular note must be taken of any local reactions that occur and their size, type and duration must be recorded.

3. FINISHED PRODUCT – BATCH TESTING

The requirements of GRIMV paragraphs 3 to 3.9 apply.