European Medicines Agency
Veterinary Medicines and Inspections

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QUESTION AND ANSWER DOCUMENT ON THE POSSIBILITY TO EXTRAPOLATE PRE-INACTIVATION TITRES AS PART OF VALIDATION OF AN INACTIVATION PROCESS

INTRODUCTION

Validation of the inactivation process of immunological veterinary medicinal products is subjected to the provision of data showing complete inactivation of the vaccine micro-organism. To this aim, according to general Eur. Ph. monograph 0062, *Vaccines for veterinary use*, data on inactivation kinetics should be obtained using the selected method of inactivation, however a clear indication is only given concerning the time required for inactivation (which, normally, should not exceed 67% of the duration of the inactivation process). No additional indications can be found within other relevant European Guidelines. It was consequently decided to issue this question and answer document in order to harmonise the approach for the future with regard to the active ingredient only.

QUESTION:

Is it possible to extrapolate pre-inactivation titres as part of validation of an inactivation process?

ANSWER:

The CVMP considered that extrapolation of inactivation kinetics results (during a 1-step process) to higher pre-inactivation titres than those used in the corresponding validation studies is not permitted. The maximum titre of the vaccine micro-organism capable to be inactivated by the selected method of inactivation should be then established based on the actual data obtained from inactivation kinetics studies.

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