




Ph. Eur. Monograph overview and revision proposals - Industry View

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AnimalhealthEurope: who are we?

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12 companies



18 associations
in 20 countries

- Belgium
- Czech Republic
- Denmark
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Netherlands
- Norway
- Poland
- Portugal
- Slovakia
- Spain
- Sweden
- Switzerland
- Ukraine
- United Kingdom

Working to ensure a ready availability of a wide range of animal health products throughout Europe

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Overview

- 1) We welcome the opportunity to comment on the draft monographs.
- 2) We appreciate the efforts of Group 15V to introduce the in-vitro alternative into the monograph.
- 3) Overall, we had very few comments to the proposed revisions.



Residual Toxicity Test

- We proposed a slight rephrasing to indicate that whilst tissue culture tests are the preferred way forward we do not exclude other suitable methods. In line with other monographs.



Antigen Content

As with the Residual toxicity test we propose to allow other suitable methods.



Batch Potency Test

Delete the statement:

“Use a homologous reference serum calibrated in International Units of C. septicum antitoxin. Clostridia (multicomponent) rabbit antiserum BRP is suitable for use as a reference serum.”

Provided the alternative test demonstrates satisfactory correlation with the test under potency, the use of a homologous reference serum or not does not matter.

Also reference serum calibrated in IU is not applicable to all alternative tests. E.g unless the reference serum has the exact IU/mL as the value of the pass/fail cut off it cannot be used as a reference for a cut-off based assay.



Consistency

We propose to keep the same revised wording for all recently modified monographs.

3-1. Identification. The vaccine contains the [antigen or antigens](#) ~~toxoid of C. septicum~~ as stated under Definition

- As a consequence definition may also need an edit to make it clear toxoids are the active component.

Clostridium septicum vaccine for veterinary use is prepared [with appropriate toxoid](#) from a liquid culture of a suitable strain of Clostridium septicum



Next Steps

Implementation of the revised monographs.

Acceptance of the alternative test on a global basis.

Non acceptance of in-vitro alternatives in some countries may leave companies double testing, the in-vitro test for one jurisdiction and the animal for another.



Thank you!

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