Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

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- 2. ‘Usual terminology’
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D. CONTROL TESTS DURING THE MANUFACTURING PROCESS
- 1. The dossier shall include particulars relating to the control tests,...
- 2. For inactivated or detoxified vaccines, inactivation or detoxification shall be...

E. CONTROL TESTS ON THE FINISHED PRODUCT
- 1. General characteristics of the finished product
- 2. Identification of active substance(s)
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1. General principles

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A. General requirements
- 1. The choice of antigens or vaccine strains shall be justified...
- 2. Efficacy trials carried out in the laboratory shall be controlled...
- 3. The efficacy of an immunological veterinary medicinal product shall be...
- 4. The efficacy of each of the components of multivalent and...
- 5. Whenever a product forms part of a vaccination scheme recommended...
- 6. The dose to be used shall be the quantity of...
- 7. If there is a compatibility statement with other immunological products...

8. For diagnostic immunological veterinary medicinal products administered to animals, the...
9. For vaccines intended to allow a distinction between vaccinated and...

B. Laboratory trials
1. In principle, demonstration of efficacy shall be undertaken under well-controlled...
2. If possible, the immune mechanism (cell-mediated/humoral, local/general classes of immunoglobulin)...

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A. VACCINE ANTIGEN MASTER FILE
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CORRELATION TABLE

(**1**) OJ C 75, 15.3.2000, p. 11.

(**2**) Opinion of the European Parliament of 3 July 2001 (not yet published in the Official Journal) and Council Decision of 27 September 2001.

(**3**) OJ L 317, 6.11.1981, p. 1. Directive as last amended by Commission Directive 2000/37/EC (OJ L 139, 10.6.2000, p. 25).

(**4**) OJ L 317, 6.11.1981, p. 16. Directive as last amended by Commission Directive 1999/104/EC (OJ L 3, 6.1.2000, p. 18).

(**5**) OJ L 373, 31.12.1990, p. 26.

(**6**) OJ L 297, 13.10.1992, p. 12.

(**7**) OJ L 214, 24.8.1993, p. 1. Regulation as amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p. 7).

(**8**) OJ L 184, 17.7.1999, p. 23.

(**9**) OJ L 224, 18.8.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1274/2001 (OJ L 175, 28.6.2001, p. 14).