**Decisions Ph. Eur. Com.**
**November 2003**

*Report of the 117th session*
*of the European Pharmacopoeia Commission*
*25-27 November 2003*

**Participants**:
Member Sates: 29 delegations were present
Observer States: 6 delegations participated in the session

**Decisions:**
**EUROPEAN PHARMACOPOEIA WORK PROGRAMME**

**NEW MONOGRAPHS AND GENERAL CHAPTERS**

Trehalose
Van Willebrand factor

**REVISION OF MONOGRAPHS AND GENERAL CHAPTERS**

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|---|---|
| Activated coagulation factors (2.6.22) (Gr. 6B) | reagent description to allow commercial reagents |
| Almond oil, refined (1064) (rev) (Gr. 13H) | added to the work programme of Group 13H |
| Almond oil, virgin (0261) (rev) (Gr. 13H) | added to the work programme of Group 13H |
| Aluminium hydroxide hydrated, for adsorption (1664) | limit for iron |
| Assay of human coagulation factor XI (2.7.22) (Gr. 6B) | predilution in deficient plasma, reagent description to allow commercial reagents |
| Avian infectious bursal disease vaccine (inactivated) (960) | acceptance criteria (titre) in the immunogenicity and potency tests |
| Avian viral vaccines: tests for extraneous agents (2.6.24) | addition of a test for goose polyomavirus on seed lots |
| Azithromycin (1649) (rev) (Gr. 7) | method for related substances assay |
| Brucellosis vaccine (live) (brucella melitensis rev. 1) (793) | 50 per cent persistence time test |

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| Ceftriaxone atricum (0991) (rev) (Gr. 7) | limit for bacterial endotoxins |
| Cholecalciferol (0072) (rev) (gr. VIT) | control of impurities |
| Cholecaliferol concentrate (powder form) (0574) (rev) (Gr. VIT) | control of impurities |
| Chromatographic separation techniques | gradient delution |
| Diethylcarbamazine citrate (0271) | related substances, assay |
| Doxepin hydrochloride (1096) (rev) | (Advice from author and correction if necessary) |
| DTP (acellular, component) and poliomyelitis (1934) | poliomyelitis component: waiving of in vivo assay subject to validation |
| DTP (acellular, component) poliomyelitis (2065) | poliomyelitis component: waiving of in vivo assay subject to validation |
| DTP (acellular, component), hepatitis B (2067) | poliomyelitis component: waiving of in vivo assay subject to validation |
| DTP and poliomyelitis (inactivated) (2061) | poliomyelitis component: waiving of in vivo assay subject to validation |
| DTP poliomyelitis (inactivated) (2066) | poliomyelitis component: waiving of in vivo assay subject to validation |
| Ethanol content and alcoholimetric tables (2.9.10) (rev) (Gr. 13A) | cross reference to 2.9.11 and necessary modifications in 2.9.11 if suitable. Otherwise elaboration of a head-space GC procedure |
| Eye Preparations (1163) (rev) (Gr. 12) | maximum content of a container |
| Fluoxetin HCl (1104) | related substances |
| Marek's disease vaccine (live) (589) | adaptation of the monograph to egg vaccination |
| Marshmallow leaf (1856) (rev) (Gr. 13B) | refused by the group |
| Measles vaccine (live) (213) | neurovirulence test: harmonisation with FDA requirements to avoid duplication of animal testing |
| Mumps vaccine (live) (538) | neurovirulence test: harmonisation with FDA requirements to avoid duplication of animal testing |
| Omega-3 acidorum esteri ethylici 90 (rev) (Gr. 13H) | added to the work programme of Group 13H |
| Rhei radix (0291) (rev) (Gr. 13A) | assay, content |
| RRR-a-Tocopherol (1256) (rev) (Gr. VIT) | inclusion of a test for polycyclic aromatic hydrocarbons |
| Rubella vaccine (live) (162) | neurovirulence test: harmonisation with FDA requirements to avoid duplication of animal testing |
| Solidaginis virgaureae herba (rev) (Gr. 13B) | referred to Group 13B |

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| Test for deliverable mass or volume of liquid and semi-solid preparations (2.9.28) (rev) (Gr. 12) | exemption for certain preparations |
| Thyme herb (0865) (rev) (Gr. 13B) | it was concluded that all monographs on herbal drugs containing essential oils would be harmonised in the identification section for the 5th Edition |
| Test for deliverable mass or volume of liquid and semi-solid preparations (2.9.28) (rev) (Gr.12) | WP Homeo to investigate |
| Tobramycinum (0645) (rev) (Gr. 7) | guidance on how to use this electrochemical detection |
| Varicella vaccine (live) (648) | neurovirulence test: harmonisation with FDA requirements to avoid duplication of animal testing |