

EUROPEAN PHARMACOPOEIA BIOLOGICAL STANDARDISATION PROGRAMME ACHIEVEMENTS IN 2007

The following projects were pursued:

Vaccines for human use

- Validation of alternatives to Auszyme ELISA kits for in vitro potency assay of rDNA hepatitis B vaccine
- Validation of serological method for potency assay of acellular pertussis vaccine
- Standardisation of human influenza vaccine serology
- Validation of NMR methods for quality control of polysaccharide vaccines
- Establishment of (non-adsorbed) hepatitis A vaccine BRP
- Establishment of varicella vaccine BRP
- Establishment of diphtheria vaccine BRP replacement batch

Plasma-derived products

- Establishment of BRP for assay of SD-plasma and fibrin sealant kits
- Validation of in vitro assay method for tetanus immunoglobulin
- Establishment of von Willebrand factor BRP for ristocetin cofactor assay
- Establishment of BRPs for determination of anti-A, anti-B haemagglutinin titers in human normal immunoglobulin for intravenous administration
- Establishment of human coagulation Factor IX BRP replacement batch
- Establishment of BRP replacement batches for determination of pre-kallikrein titers in human albumin

Biotechnology products

- Establishment of an HPLC assay for interferon alfa2
- Establishment of low-molecular-mass-heparin for calibration BRP replacement batch
- Establishment of erythropoietin BRP replacement batch
- Establishment of BRPs and ELISA assays for two major recombinant allergens (Bet v 1, Phl p 5a)
- Establishment of filgrastim BRP
- Establishment of low-molecular-mass-heparin for assay BRP replacement batch

BRP replacement batches adopted in 2007

The studies led to the adoption of the following reference preparations by the Ph. Eur. Commission in 2007:

- Low-molecular-mass-heparin for calibration BRP batch 2
- Erythropoietin BRP batch 3