PHARMACOPOEIAL DISCUSSION GROUP

CORRECTION

CODE: Q11

STERILITY: REV 1 CORR 3 Stage 5B
(Correction of the sign-off document signed on 30 October 2007)

Items to be corrected:

- Replace *Aspergillus niger* by *Aspergillus brasiliensis* throughout the text

European Pharmacopoeia

Signature: [signature]
Name: [name]
Date: 10/06/09

Japanese Pharmacopoeia

Signature: [signature]
Name: [name]
Date: 10 June, 2009

United States Pharmacopoeia

Signature: [signature]
Name: [name]
Date: 10 June, 2009

Local requirements

- In the section on «Test for sterility of the product to be examined», USP will add a paragraph on «Number of articles to be tested».
- USP will add a requirements for testing of for pharmacy bulk packages (this includes description of media for penicillins and cephalosporins; use of alternative micro-organisms to the those indicated in Table 1; description of additional diluting and rinsing fluids for membrane filtration)
- USP will add requirements for medical devices in Table 2
- USP will add requirements for medical devices in Table 3
- Under «Membrane Filtration», USP will add subsections / paragraphs on Prefilled Syringes, Solids for Injection other than Antibiotics, Antibiotic Solids for Injection, Antibiotic Solids, Bulks and Blends, Sterile Aerosol Products, Devices with pathways labeled sterile
- Under «Direct Inoculation of the Culture Medium», USP will add subsections / paragraphs on Solids, Purified Cotton, Gauze, Surgical Dressings, and Related Articles, Sterile Devices
- JP will delete the descriptions related to *Catgut and other surgical sutures for veterinary use* in Table 2.6.1.-2 and Table 2.6.1.-3 as well as lines 27-33 of page 6 because they are out of the scope of JP.