

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

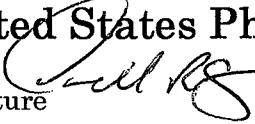
European Pharmacopoeia

Signature	Name	Date
	LESTER	10/06/09

Japanese Pharmacopoeia

Signature	Name	Date
	for Toshio Nakagaki	10 June, 2009

United States Pharmacopoeia

Signature	Name	Date
	ABERNETHY	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.

W H H Dms