

1 PHARMACOPOEIAL DISCUSSION GROUP

2
3 CORRECTION

4 CODE: Q11

5 STERILITY: REV 1 CORR 3 Stage 5B

6 (Correction of the sign-off document signed on 30 October 2007)

7
8
9 Items to be corrected:

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

11
12
13 **European Pharmacopoeia**

14 Signature

Name

Date

15
16 

16
17 WEBER TEL

16
17 10/06/09

18 **Japanese Pharmacopoeia**

19
20 Signature

Name

Date

20
21 

21
22 for Toshino Nakagaki

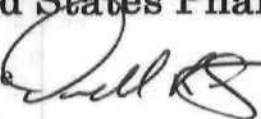
20
21 10 JUNE, 2009

23 **United States Pharmacopoeia**

24
25 Signature

Name

Date

25
26 

25
26 ABERNETHY

25
26 10 June, 2009

27 **Local requirements**

28 • In the section on « Test for sterility of the product to be examined », USP will add a
29 paragraph on « Number of articles to be tested ».

30 • USP will add a requirements for testing of for pharmacy bulk packages (this includes
31 description of media for penicillins and cephalosporins ; use of alternative micro-organisms
32 to the those indicated in Table 1 ; description of additional diluting and rinsing fluids for
33 membrane filtration)

34 • USP will add requirements for medical devices in Table 2

35 • USP will add requirements for medical devices in Table 3

36 • Under « Membrane Filtration », USP will add subsections / paragraphs on Prefilled
37 Syringes, Solids for Injection other than Antibiotics, Antibiotic Solids for Injection, Antibiotic
38 Solids, Bulks and Blends, Sterile Aerosol Products, Devices with pathways labeled sterile

39 • Under « Direct Inoculation of the Culture Medium », USP will add subsections /
40 paragraphs on Solids, Purified Cotton, Gauze, Surgical Dressings, and Related Articles,
41 Sterile Devices

42 • JP will delete the descriptions related to *Catgut and other surgical sutures for veterinary*
43 *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
44 of the scope of JP.