PHARMACOPOEIAL DISCUSSION GROUP

CORRECTION
CODE: Q11

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

Items to be corrected:

- Delete last sentence of the italicised introductory paragraph.

- Add the following paragraph and sentence at the end of the document: MINIMUM NUMBER OF ITEMS TO BE TESTED. The minimum number of items to be tested in relation to the size of the batch is given in Table 2.6.1.-3.

European Pharmacopoeia

Signature: UESTEL Name: UESTEL Date: 03/06/08

Japanese Pharmacopoeia

Signature: for Toshiro Nakagaki Name: Date: 03 June, 2008

United States Pharmacopoeia

Signature: DARRELL R. BERRY Date: 03 June, 2008

14/01/08