

PHARMACOPOEIAL DISCUSSION GROUP

CORRECTION
CODE: Q11

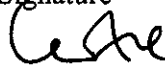
STERILITY: REV 1 CORR 1 Stage 5B
(Correction of the sign-off document signed on 30 October 2007)

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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.

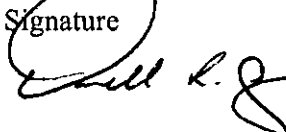
European Pharmacopoeia

Signature	Name	Date
	LESTEL	08/06/08

Japanese Pharmacopoeia

Signature	Name	Date
	for Toshiro Nakagaki	03 June, 2008

United States Pharmacopoeia

Signature	Name	Date
	DARRELL R. ABERNETHY	03 June, 2008