

# PHARMACOPOEIAL DISCUSSION GROUP

## CORRECTION

Q-06

### Bacterial Endotoxins Test: Rev. 1, Correction 1

(Correction of the sign-off document signed on 11 November 2008)

#### Item to be corrected:

The page and line numbers are referred to the harmonized text dated 11 November 2008.

(Page 1, Lines 10-12) In the event of dispute, EP will make a decision based on a gel clot limit test only.

(Page 1, Lines 25-26) Delete the sentence "This reagent refers only to a product manufactured in accordance with the regulations of the competent authority." EP will keep this sentence in the official EP text as a local requirement.

(Page 2, Line 20) Change the phrase "the lysate" to read "the lysate TS." EP will not use the term "TS."

(Page 3, Line 9) Change the phrase "the labeled sensitivity" to read "the labeled lysate sensitivity."

(Page 3, Lines 13-14, 15) Change the phrase "the lysate reagent" to read "the lysate TS." EP will not use the term "TS."

(Page 4, Line 1) Change the phrase "the smallest concentration" to read "the lowest concentration."

(Page 4, Lines 2-4) Change the sentence "Determine the geometric mean endpoint by calculating the mean of the logarithms of the endpoint concentrations of the four replicate series and then take the antilogarithm of the mean value" to read "Determine the geometric mean endpoint concentration by calculating the mean of the logarithms of the endpoint concentrations of the four dilution series, take the antilogarithm of this value."

(Page 7, Line 10) Change the phrase "Two replicates" to read "A dilution series."

(Page 7, Lines 24-25) Change the phrase "the lowest dilution factor" to read "the smallest dilution factor." EP text will remain unchanged.

(Page 8, Line 25) Change the phrase "lysate reagent" to read "the lysate."

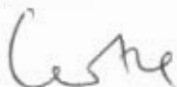
(Page 9, Lines 17, 18) Change the phrase "the lysate reagent" to read "the lysate." EP will not apply this editorial change.

(Page 9, Line 29) Change the phrase "suitable validated treatment" to read "suitable treatment." EP will not apply this change and keep the word "validated."

(Page 10, Line 19) Change the phrase "the lysate reagent" to read "the lysate."

#### European Pharmacopoeia

Signature



Name


WESTEL

Date

27/10/08

#### Japanese Pharmacopoeia

Signature



Name

Hiroyuki Hamamoto  
for Masatoshi Narita

Date

27 Oct. 2008

#### United States Pharmacopoeia

Signature



Name

Susan S. deRus

Date

27 October 2008

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