

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

Date



LESTER

27 Oct 08

Japanese Pharmacopoeia

Signature

Name

Date



Hiroyuki Hamamoto

for Masatoshi Narita 27. Oct. 2009

United States Pharmacopoeia

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Susan S. de Mas

27 October 2009