

PHARMACOPOEIAL DISCUSSION GROUP

CORRECTION

E25

MAGNESIUM STEARATE

(Correction of the sign-off document from 3 June 2008)

Item to be corrected: Relative content of stearic and palmitic acid – exact number of replicates for the system suitability test to be stated. The following paragraph is amended to be consistent with the text for Stearic Acid, which has the same requirement.


“Chromatograph the *System suitability solution*, and record the peak responses as directed under *Procedure*: the relative retention times are about 0.9 for methyl palmitate and 1.0 for methyl stearate. The resolution, *R*, between the methyl palmitate and methyl stearate peaks is not less than 5.0. The relative standard deviation of the peak area responses for the palmitate and stearate peaks for 6 replicate injections of the *System suitability solution* is not greater than 3.0%. The relative standard deviation of the peak area response ratio of the palmitate to stearate peaks from these 6 replicate injections is not more than 1.0%. “

European Pharmacopoeia

Signature

Name

Date



W. TEL

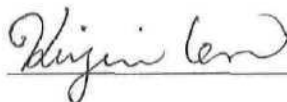
11/10/08

Japanese Pharmacopoeia

Signature

Name

Date



for Toshio Nakagaki

Nov. 11, 2008

United States Pharmacopoeia

Signature

Name

Date



DARREN R. ABERNETHY 11 Nov, 2008