

PHARMACOPOEIAL DISCUSSION GROUP

REVISION OF SIGN-OFF COVER SHEET

CODE: Q03/04

NAME: Uniformity of Content/Mass

Revision 1

(Revision of the sign-off cover sheet....signed on November 9, 2010)

Item to be revised:

The following will be included as local text for EP within the subsection on "Mass Variation":

Liquid dosage forms and semi-solid dosage forms presented in single-dose
containers intended for transdermal delivery of the active substance(s) in view of a
systemic effect (active substance(s) dissolved in the preparation)—Accurately weigh
the amount of liquid material that is removed from each of 10 individual containers in
conditions of normal use.

European Pharmacopoeia

Signature Ceste Name KESTER Date 6/11/13

Japanese Pharmacopoeia

Signature T. Kawanishi Name Toru KAWANISHI Date 6/11/2013
for Takeyuki Datou

United States Pharmacopoeia

Signature Catherine Sheehan Name CATHERINE SHEEHAN Date Nov. 6, 2013