

PHARMACOPOEIAL DISCUSSION GROUP

CODE: Q-03/04

NAME: Uniformity of Dosage Units
Revision 2

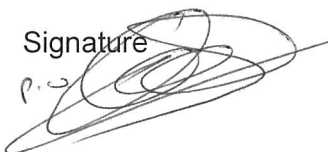
Harmonized provisions:

Minor changes to lines 11-12: The uniformity of dosage units specification is not intended to apply to solutions, suspensions, emulsions, or gels in unit-dose containers intended for local action following external, cutaneous administration.

Clarification of "Others" in Table 1: Dosage forms not addressed by the other categories in this table including but not limited to suppositories, transdermal systems (patches) and semisolid preparations applied cutaneously and intended for systemic distribution of the drug substance

European Pharmacopoeia

Signature



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Date

04/11/2015

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for M. Yamada

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Haruhiko Okuda

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