

PHARMACOPOEIAL DISCUSSION GROUP

REVISION OF SIGN-OFF COVER SHEET

CODE: ... Q05c

NAME: ... Microbiological examination of non-sterile products: acceptance criteria for pharmaceutical preparations and substances for pharmaceutical use)

(Revision of the sign-off cover sheet: 8 November 2005

Item to be revised: ...

Addition of another EP local requirement

Route of administration	TAMC (CFU/g or CFU/mL)	TYMC (CFU/g or CFU/mL)	Specified micro-organism
Special Ph. Eur. provision for premixes for medicated feeding stuffs for veterinary use using excipients of plant origin for which antimicrobial treatment is not feasible	10^5	10^4	Not more than 10^4 CFU of bile-tolerant gram-negative bacteria (1 g or 1 mL) Absence of <i>Escherichia coli</i> (1 g or 1 mL) Absence of <i>Salmonella</i> (25 g or 25 mL)

European Pharmacopoeia

Signature C. Ste Name KEITEL Date 27/6/11

Japanese Pharmacopoeia

Signature T. Kawasumi Name Teru KAWANISHI Date 27/6/2013
for Haruo Akagawa

United States Pharmacopeia

Signature *Catherine M. Sheehan* Name CATHERINE M. SHEEHAN Date *June 27, 2013*