PHARMACOPOEIAL DISCUSSION GROUP

SIGN-OFF DOCUMENT

NAME: MICROBIOLOGICAL EXAMINATION OF NON-STERILE PRODUCTS: ACCEPTANCE CRITERIA FOR PHARMACEUTICAL PREPARATIONS AND SUBSTANCES FOR PHARMACEUTICAL USE

Non-harmonised parts

None.

Local requirement

EP: For oral dosage forms, other than herbal medicinal products, containing raw materials of natural (animal, vegetable, or mineral) origin for which antimicrobial pre-treatment is not feasible and for which the competent authority accepts TAMC of the raw material exceeding 10^3 CFU per gram or per millilitre, the acceptance criteria are: TAMC 10^4 CFU per gram or per millilitre, TYMC 10^2 CFU per gram or per millilitre. Tests for specified micro-organisms: not more than 10^2 bile-tolerant gram-negative bacteria per gram or per millilitre; absence of *Salmonella* (10 g or 10 ml); absence of *Escherichia coli* (1 g or 1 ml); and absence of *Staphylococcus aureus* (1 g or 1 ml).

Scope

This text will be published by the three pharmacopoeias as a non-mandatory information chapter. Herbal drugs and herbal drug preparations are not within the scope of harmonisation.

Reagents and reference materials

Each pharmacopoeia will adapt the text to take account of local reference materials and reagent specifications.

Date: 8 november 2005 Signatures:

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