

1 PHARMACOPOEIAL DISCUSSION GROUP

2 SIGN-OFF DOCUMENT

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

6 **Non-harmonised parts**

7 None.

8 **Local requirement**

9 *EP*: For oral dosage forms, other than herbal medicinal products, containing raw materials of  
10 natural (animal, vegetable, or mineral) origin for which antimicrobial pre-treatment is not feasible  
11 and for which the competent authority accepts TAMC of the raw material exceeding  $10^3$  CFU per  
12 gram or per millilitre, the acceptance criteria are: TAMC  $10^4$  CFU per gram or per millilitre,  
13 TYMC  $10^2$  CFU per gram or per millilitre. Tests for specified micro-organisms: not more than  
14  $10^2$  bile-tolerant gram-negative bacteria per gram or per millilitre; absence of *Salmonella* (10 g or  
15 10 ml); absence of *Escherichia coli* (1 g or 1 ml); and absence of *Staphylococcus aureus* (1 g or  
16 1 ml).

17 **Scope**


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


20 **Reagents and reference materials**

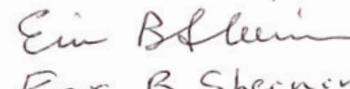
21 Each pharmacopoeia will adapt the text to take account of local reference materials and reagent  
22 specifications.

23 **Date:** 8 november 2005

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