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

<table>
<thead>
<tr>
<th>Route of administration</th>
<th>TAMC (CFU/g or CFU/mL)</th>
<th>TYMC (CFU/g or CFU/mL)</th>
<th>Specified micro-organism</th>
</tr>
</thead>
<tbody>
<tr>
<td>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</td>
<td>$10^5$</td>
<td>$10^4$</td>
<td>Not more than $10^4$ CFU of bile-tolerant gram-negative bacteria (1 g or 1 mL) Absence of <em>Escherichia coli</em> (1 g or 1 mL) Absence of <em>Salmonella</em> (25 g or 25 mL)</td>
</tr>
</tbody>
</table>

**European Pharmacopoeia**

Signature: [Signature]  
Name: [WINTER]  
Date: 23/6/2014

**Japanese Pharmacopoeia**

Signature: [Signature]  
Name: [KAWASAKI]  
Date: 27/6/2013  
For: Kameo Takano