Biro Pengawalan Farmaseutikal Kebangsaan
National Pharmaceutical Control Bureau
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA

Ruj Kami : Bil (4) dlm. BPFK/PKK/12/05

Tarikh : 30 Mac 2010

SEMUA PEMEGANG PENDAFTARAN
SEMUA PENGILANG
SEMUA YANG BERKENAAN

Tuan/ Puan,

MAKLUMAT LANJUTAN TENTANG SPESIFIKASI BARU UNTUK UJIAN KONTAMINASI MIKROBIAL

Adalah saya merujuk kepada perkara di atas.

2. Sejajar dengan *harmonization* terhadap kaedah dan spesifikasi Ujian Kontaminasi Mikrobial oleh European Pharmacopoeia, United States Pharmacopoeia dan Japanese Pharmacopoeia, BPFK telah mengguna-pakai kaedah dan spesifikasi *Harmonised Method* untuk pengujian kontaminasi mikrobial bagi produk farmaseutikal dan tradisional sejak Julai 2009.

3. Sila rujuk Jadual 1 dan 'Interpretation of the Results' untuk spesifikasi dan 'maximum acceptable count' yang digunapakai sekarang. (Rujukan: British Pharmacopoeia 2009)

4. Spesifikasi dalam Jadual 1 adalah selaras dengan spesifikasi yang terkandung dalam Drug Registration Guidance Document (Disember, 2009), para 12.6 Quality Control Test Specifications for Traditional Medicine Products- Test for Microbial Contamination (mukasurat 191).

5. Spesifikasi 'Non-aqueous Preparations for Oral Use' dan 'Aqueous Preparations for Oral Use' dalam Jadual 1 adalah untuk produk farmaseutikal sahaja.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menurut perintah,

(TAN ANN LING)
Ketua Penolong Pengarah Kanan
Pusat Kawalan Kualiti
Biro Pengawalan Farmaseutikal Kebangsaan
Kementerian Kesihatan Malaysia.

Jadual 1: Spesifikasi kualiti mikrobiologikal untuk persediaan bukan steril.

Route of administration	TAMC (CFU/g or CFU/ml)	TYMC (CFU/g or CFU/ml)	Specified micro-organisms
Non-aqueous preparations for oral use	10^3	10^2	Absence of *Escherichia coli* (1 g or 1 ml)
Aqueous preparations for oral use	10^2	10^1	Absence of *Escherichia coli* (1 g or 1 ml)
Rectal use	10^3	10^2	-
Oromucosal use Gingival use Cutaneous use Nasal use Auricular use	10^2	10^1	Absence of *Staphylococcus aureus* (1 g or 1 ml) Absence of *Pseudomonas aeruginosa* (1 g or 1 ml)
Vaginal use	10^2	10^1	Absence of *Pseudomonas aeruginosa* (1 g or 1 ml) Absence of *Staphylococcus aureus* (1 g or 1 ml) Absence of *Candida albicans* (1 g or 1 ml)
Transdermal patches (limits for one patch including adhesive layer and backing)	10^2	10^1	Absence of *Staphylococcus aureus* (1 patch) Absence of *Pseudomonas aeruginosa* (1 patch)
Inhalation use (special requirements apply to liquid preparations for nebulisation)	10^2	10^1	Absence of *Staphylococcus aureus* (1 g or 1 ml) Absence of *Pseudomonas aeruginosa* (1 g or 1 ml) Absence of bile-tolerant gram-negative bacteria (1 g or 1 ml)
Special Ph. Eur. provision for oral dosage forms containing raw materials of natural (animal, vegetal or mineral) origin for which antimicrobial pretreatment is not feasible and for which the competent authority accepts TAMC of the raw material exceeding 10^3 CFU per gram or per millilitre	10^4	10^2	Not more than 10^2 CFU of bile-tolerant gram-negative bacteria (1 g or 1 ml) Absence of *Salmonella* (10 g or 10 ml) Absence of *Escherichia coli* (1 g or 1 ml) Absence of *Staphylococcus aureus* (1 g or 1 ml)
Special Ph. Eur. provision for herbal medicinal products consisting solely of one or more herbal drugs (whole, reduced or powdered):			
– herbal medicinal products to which boiling water is added before use	10^7	10^5	Not more than 10^2 CFU of *Escherichia coli* (1 g or 1 ml)
– herbal medicinal products to which boiling water is not added before use	10^5	10^4	Not more than 10^3 CFU of bile-tolerant gram-negative bacteria (1 g or 1 ml) Absence of *Escherichia coli* (1 g or 1 ml) Absence of *Salmonella* (10 g or 10 ml)

Interpretation of the Results:

When an acceptance criterion for microbiological quality is prescribed it is interpreted as follows:

- 10^1 CFU: maximum acceptable count = 20;
- 10^2 CFU: maximum acceptable count = 200;
- 10^3 CFU: maximum acceptable count = 2000;

and so forth.

(Rujukan: British Pharmacopoeia 2009)