

Ruj. kami: ( 46 ) dlm. BPFK/02/5/1.2  
Tarikh : 14 Julai 2001

Semua Pemegang Pendaftaran

Tuan,

**KEPUTUSAN MESYUARAT PIHAK BERKUASA KAWALAN DADAH (PBKD) KE 125 BERHUBUNG PERUBAHAN HAD YANG DIGUNAKAN UNTUK UJIAN HAD MIKROBIAL BAGI KELUARAN FARMASEUTIKAL (TERMASUK UBAT TRADISIONAL)**

Adalah saya dengan hormatnya merujuk kepada perkara di atas.

2. PBKD didalam mesyuaratnya yang ke 125 telah pun meluluskan had baru bagi Ujian Had Mikrobial Bagi Keluaran Farmaseutikal (termasuk Ubat Tradisional). Perubahan ini perlu kerana had terkini yang terdapat didalam British Pharmacopoea 2000 adalah lebih sesuai digunakan kerana ianya meliputi lebih banyak jenis persediaan dan tatacara ujian yang sama telah digunakan dalam European Phamacopoea. Had baru ini juga telah diguna oleh lain-lain badan regulatori , oleh itu penggunaan had baru ini akan menyelaraskan dan memudahkan pemantauan kualiti dilaksanakan. Sekretariat PBKD juga akan mengemaskini had ini dari masa ke masa bila perlu.

3. Penggunaan had baru ini adalah berkuatkuasa serta merta dan satu salinan Ujian Had Mikrobial Bagi Keluaran Farmaseutikal (termasuk Ubat Tradisional) disertakan.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"  
"UTAMAKAN KUALITI, EFIKASI & KESELAMATAN"

Saya yang menurut perintah,

**(NORMAL BIN SHARIF)**  
Setiausaha,  
Pihak Berkuasa Kawalan Dadah,  
Kementerian Kesihatan Malaysia.

s.k. Pengarah Perkhidmatan Farmasi  
Kementerian Kesihatan Malaysia

Had ujian seperti dalam spesifikasi British Pharmacopoeia 2000**CATEGORY 1: Preparation for topical use and for use in the respiratory tract and transdermal patch**

Tests	BP 2000 specifications
<b>1. Preparation for topical use and for use in the respiratory tract</b>	
Total viable aerobic count (aerobic bacteria plus fungi)	Not > $5 \times 10^2$ per g or ml
Absence of enterobacteria and certain other Gram-negative bacteria	Not > $5 \times 10^1$ per g or ml
<i>Pseudomonas aeruginosa</i>	Absent in 1 g or 1 ml
<i>Staphylococcus aureus</i>	Absent in 1g or 1 ml
<b>2. Transdermal patch</b>	
Total viable aerobic count (aerobic bacteria plus fungi)	Not > $5 \times 10^2$ per patch
Absence of enterobacteria and certain other Gram-negative bacteria	Absent in 1 patch
<i>Pseudomonas aeruginosa</i>	Absent in 1 patch
<i>Staphylococcus aureus</i>	Absent in 1 patch

**CATEGORY 2: Preparation for oral and rectal administration [except preparations in category 3 and 4]**

Tests	BP 2000 specifications
Total viable aerobic count	Bacteria :Not > $5 \times 10^3$ per g or ml Fungi :Not > $5 \times 10^2$ per g or ml
<i>Escherichia coli</i>	Absent in 1 g or 1 ml

**CATEGORY 3: Preparation for oral administration containing raw material of natural origin (animal, vegetable or mineral) for which antimicrobial pretreatment is not feasible and for which the competent authority accepts a microbial contamination of the raw material exceeding  $5 \times 10^3$  viable micro-organisms per gram or per millilitre. Herbal remedies described in category 4 are included.**

Tests	BP 2000 specifications
Total viable aerobic count	Bacteria: Not > $5 \times 10^4$ per g or ml. Fungi: Not > $5 \times 10^2$ per g or ml.
Enterobacteria and certain other Gram-negative bacteria	Not > $5 \times 10^2$ per g or per ml
<i>Salmonella</i>	Absent in 10 g or 10 ml
<i>Escherichia coli</i>	Absent in 1 g or 1 ml
<i>Staphylococcus aureus</i>	Absent in 1 g or 1 ml

**CATEGORY 4: Herbal remedies consisting solely of one and more vegetable drugs (whole, reduced or powdered)**

Test	BP 2000 specifications
<b>1. Herbal remedies to which boiling water is added before use</b>	
Total viable aerobic count	Bacteria: Not > $5 \times 10^7$ per g or ml Fungi: Not > $5 \times 10^5$ per g or ml
<i>Escherichia coli</i>	Not > $5 \times 10^2$ per g or ml
<b>2. Herbal remedies to which boiling water is not added before use</b>	
Total viable aerobic count	Bacteria: Not > $5 \times 10^5$ per g or ml Fungi : Not > $5 \times 10^4$ per g or ml
Enterobacteria and certain other Gram-negative bacteria	Not > $5 \times 10^3$ per g or ml
<i>Escherichia coli</i>	Absent in 1 g or 1 ml
<i>Salmonella</i>	Absence in 10 g or 10 ml