Pihak Berkuasa Kawalan Dadah
Drug Control Authority
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA

Ruj Kami: (33) dlm BPFK/ 02/5/1.3
Tarikh: 12 Ogos 2004

SEMUA PEMEGANG PENDAFTARAN DAN PERSATUAN BERKAITAN

Tuan ,

PENAMBAHAN UJIAN KADMIUM (Cd) DALAM PENGUJIAN LOGAM TOKSIK UNTUK PRODUK TRADITIONAL

Adalah saya dengan hormatnya merujuk kepada keputusan Mesyuarat Pihak Berkuasa Kawalan Dadah (PBKD) kali ke **161** yang telah diadakan pada **5hb. Ogos 2004** mengenai perkara di atas.

2. PBKD dalam mesyuaratnya tersebut telah bersetuju memasukkan ujian **kadmium** dalam pengujian produk tradisional dimana :
   2.1 had bagi ujian kadmium tersebut adalah **0.3mg/kg;** dan
   2.2 penambahan ujian kadmium tersebut akan berkuatkusa mulai **1hb. Januari 2005** .

3. Mesyuarat juga menerima had kawalan kualiti produk tradisional (Quality Control Test Specifications for Traditional medicine Products) seperti dalam **Lampiran 1 sebagai spesifikasi yang terkini**. Sila ambil maklum bahawa :
   3.1 spesifikasi/had untuk semua ujian melainkan ujian kadmium adalah berkuatkuasa serta merta; dan
   3.2 had-had yang ditetapkan untuk ujian-ujian pengecaian (*disintegration*), keseragaman berat (*uniformity of weight*) serta kontaminasi mikrobial (*microbial contamination*) akan sentiasa diselaraskan mengikut spesifikasi terkini British Pharmacopoeia.

Sekian, terima kasih.

'BERKHIDMAT UNTUK NEGARA'
'UTAMAKAN KUALITI, EFIKASI DAN KESELAMATAN'
Saya yang menurut perintah,

.....
(EISAH BT. A. RAHMAN)
Setiausaha
Pihak ~~Berkuasa Kawalan Dadah~~
Kementerian Kesihatan Malaysia

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LAMPIRAN 1

Quality Control Test Specifications for Traditional Medicine Products

1. Limit Test for Heavy Metals

Maximum limit for heavy metals

1.1	Lead	:	≤ 10.0 mg/kg or mg/litre (≤ 10.0ppm)
1.2	Arsenic	:	≤ 5.0 mg/kg or mg/litre (≤ 5.0ppm)
1.3	Mercury	:	≤ 0.5 mg/kg or mg/litre (≤ 0.5ppm)
1.4	Cadmium	:	≤ 0.3 mg/kg or mg/litre (≤ 0.3 ppm)

2. Disintegration Test (for tablets, capsules and pills)

Disintegration time

2.1	Uncoated tablets	:	≤ 30 minutes
2.2	Film-coated tablets	:	≤ 30 minutes
2.3	Sugar-coated tablets	:	≤ 60 minutes
2.4	Enteric-coated tablets	:	≥ 120 minutes in an acid solution ≤ 60 minutes in buffer solution
2.5	Capsules	:	≤ 30 minutes
2.6	Pills	:	≤ 120 minutes

3. Test for Uniformity of Weight (tablets and capsules only)

≤ 2 capsules / tablets exceed the limit by ± 10% from the average weight.
No tablet / capsule exceed the limit by ± 20% from the average weight.

4. Test for Microbial Contamination

4.1 Preparations for topical use and for use in the respiratory tract except where required to be sterile

4.1.1	Total viable aerobic count (aerobic bacteria and fungi)	:	≤ 5×10^2 cfu/gram or cfu/ml
4.1.2	Enterobacteria and certain other Gm-negative bacteria	:	≤ 5×10^1 cfu/gram or cfu/ml
4.1.3	*Pseudomonas aeruginosa*	:	Absent in 1 gram or 1 millilitre
4.1.4	Staphylococcus aureus	:	Absent in 1 gram or 1 millilitre

4.2 Transdermal Patches

4.2.1	Total viable aerobic count (aerobic bacteria and fungi)	:	≤ 5×10^2 cfu/patch
4.2.2	Enterobacteria and certain other Gm-negative bacteria	:	Absent in 1 patch

4.2.3 *Pseudomonas aeruginosa* : Absent in 1 patch

4.2.4 Staphylococcus aureus : Absent in 1 patch

4.3 Preparations for oral administration containing raw materials of natural origin (animal, vegetable or mineral) for which antimicrobial pre-treatment is not feasible, and for which the competent authority accepts a microbial contamination of the raw material exceeding 5×10^3 viable microorganisms per gram or per millilitre (excluding herbal remedies described in 4.4)

4.3.1 Total viable aerobic count : Bacteria : $\leq 5 \times 10^4$ cfu/gram or cfu/ml
Fungi : $\leq 5 \times 10^2$ cfu/gram or cfu/ml

4.3.2 Enterobacteria and certain other Gm-negative bacteria : $\leq 5 \times 10^2$ cfu/gram or cfu/ml

4.3.3 *Salmonella* : Absent in 10 gram or 10 ml

4.3.4 *Escherichia coli* : Absent in 1 gram or 1 ml

4.3.5 *Staphylococcus aureus* : Absent in 1 gram or 1 ml

4.4 Herbal medicinal products consisting solely of one and more herbal drugs (whole, reduced or powdered)

4.4.1 Herbal medicinal products to which boiling water is added before use

4.4.1.1 Total viable aerobic count : Bacteria : $\leq 5 \times 10^7$ cfu/gram or cfu/ml
Fungi : $\leq 5 \times 10^5$ cfu/gram or cfu/ml

4.4.1.2 *Escherichia coli* : $\leq 5 \times 10^2$ cfu/gram or cfu/ml

4.4.2 Herbal medicinal products to which boiling water is not added before use

4.4.2.1 Total viable aerobic count : Bacteria : $\leq 5 \times 10^5$ cfu/gram or cfu/ml
Fungi : $\leq 5 \times 10^4$ cfu/gram or cfu/ml

4.4.2.2 Enterobacteria and certain other Gm-negative bacteria : $\leq 5 \times 10^3$ cfu/gram or cfu/ml

4.4.2.3 *Escherichia coli* : Absent in 1 gram or 1 ml

4.4.2.4 *Salmonella* : Absent in 10 gram or 10 ml

References:-

Test 1.1, 1.2 & 1.3 : Akta Racun 1952
Test 1.4: WHO Guideline
Tests 2, 3 & 4 : BP 2003*

* The specifications for tests 2,3 and 4 will depend on the changes in the pharmacopoeia (The latest edition of the British Pharmacopoeia is followed)