UPDATED WORK PROGRAMME OF THE EUROPEAN PHARMACOPOEIA

(June 2008)

The following items have recently been added to the work programme of the European Pharmacopoeia. Please note that the accumulative work programme is available in the Knowledge database (http://www.edqm.eu/site/Databases-10.html).

Interested parties are invited to contact the EDQM (lynn.kelso@edqm.eu) with a view to participating in the work on items of interest.

TEXTS TO BE REVISED

2.5.28. Water in gases	Analytical improvement
2.6.17. Test for anticomplementary activity of immunoglobulin	pH adjustment of immunoglobulin to be examined
3.2.9. Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze-dried powders	
Acesulfame potassium (1282)	Related substances
Amoxicillin sodium (0577)	Related substances
Amoxicillin trihydrate (0260)	Related substances
Ampicillin, anhydrous (0167)	Related substances
Ampicillin sodium (0578)	Related substances
Ampicillin trihydrate (0168)	Related substances
Ascorbic acid (0253)	Assay
Asparagine monohydrate (2086)	Loss on drying
Benzylpenicillin, benzathine (0373)	Related substances
Benzylpenicillin potassium (0113)	Related substances
Benzylpenicillin, procaine (0115)	Related substances
Benzylpenicillin sodium (0114)	Related substances
Chlortetracycline hydrochloride (0173)	Related substances
Demeclocycline hydrochloride (0176)	Related substances
Doxycycline hyclate (0272)	Related substances
Doxycycline monohydrate (0820)	Related substances
Furunculosis vaccine (inactivated, oil-adjuvanted, injectable) for salmonids (1521)	Batch potency test
Heparin calcium (0332)	Related substances (second revision step)
Heparin sodium (0333)	Related substances (second revision step)
Imipenem (1226)	Specific optical rotation
Insulin, human (0838)	Assay
Insulin preparations, injectable (0854)	Assay
Lymecycline (1654)	Related substances
Magnesium chloride 4.5-hydrate (1341)	Expression of limits for substances with high water content
Minocycline hydrochloride dihydrate (1030)	Related substances
Naloxone hydrochloride dihydrate (0729)	Impurity D
Oxytetracycline dihydrate (0199)	Related substances
Oxytetracycline hydrochloride (0198)	Related substances
Tetracycline (0211)	Related substances
Tetracycline hydrochloride (0210)	Related substances
Thyme oil / Thymi aetheroleum (1374)	Chromatographic profile
Ubidecarenone (1578)	Related substances, assay
Wool alcohols (0593)	Butylhydroxytoluene, cholesterol
Wool fat (0134)	Definition (antioxidant)

NEW TEXTS

2.6.32. Test for bacterial endotoxins using recombinant factor C

Arnica montana for homoeopathic preparations (2580)

Arnica montana radix for homoeopathic preparations (2488)

Donepezil hydrochloride (2582)

Macrogol 30 dipolyhydroxystearate (2584)

Starch, hydroxypropyl (2165)

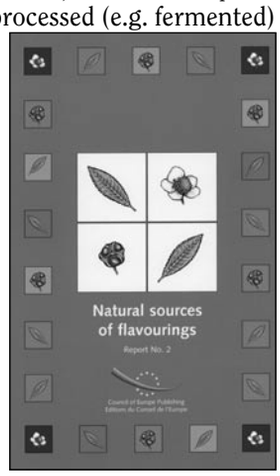
Starch, oxidised (2587)

Turkey infectious rhinotracheitis vaccine (live) (2461) *(instead of Avian pneumovirus vaccine (live))*

NATURAL SOURCES OF FLAVOURINGS Report No. 2 (2007)

The Committee of Experts on Flavouring Substances has engaged in a major toxicological evaluation of the safety-in-use of over 600 natural flavouring source materials. This is the second interim report, which provides safety-in-use evaluations of 60 source materials.

Natural sources of flavourings are materials of vegetable or animal origin that may or may not normally be consumed as food. The committee of experts has predominantly evaluated materials in the raw or dried state, with the exception of certain special products, such as vanilla, cocoa and black pepper, which are traditionally processed (e.g. fermented) before their use as source materials. Each source species is identified primarily by its systematic name based on the botanical nomenclature of Zander or, where the source species is not listed in that reference book, on that of Mansfeld. Source species not listed in either book are treated on a case-by-case basis. Names in English, French, German and Italian, as well as any other synonyms, are noted under each entry.



Each datasheet indicates the parts used and provides a list of the 'important constituents', including the known 'active principles' and 'other chemical components', found in each part of the plant and/or preparation used in flavourings. Where possible, the levels at which the various constituents are present in the parts/preparations are given and the main food categories in which parts/preparations are used are listed. The types of preparation made from each part are stated, e.g. oleoresin, extract, etc. Main toxicological data are indicated such as metabolism; sub-acute and sub-chronic toxicity; chronic toxicity; carcinogenicity; reproductive and teratogenicity studies; mutagenicity; and other relevant studies such as photosensitivity and beneficial effects.

National and international evaluations are specified, together with the main references and databases used.

Alphabetical list of the evaluated natural sources of flavourings:

Allium ascalonicum Strand; Allium cepa L.; Allium porrum L.; Allium sativum L.; Allium schoenoprasum L.; Aloe barbadensis Mill.; Aloysia triphylla (L'Hérit.) Britt.; Angelica sylvestris L.; Asparagus officinalis L.; Capsicum annuum L.; Capsicum frutescens L.; Coffea arabica L.; Coffea canephora Pierre ex Froehner; Crocus sativus L.; Cuminum cyminum L.; Cymbopogon martinii (Roxb.) W. Wats. var. sofia; Dipteryx odorata (Aubl.) Willd; Eriodictyon californicum (Hook. et Arn) Tor.; Gentiana acaulis L.; Hamamelis virginiana L.; Hedeoma pulegioides (L.) Pers.; Hyssopus officinalis L.; Iris florentina L.; Iris germanica L.; Iris pallida Lam.; Leptospermum citratum Chall.; Liquidambar styraciflua L.; Litsea cubeba (Lour.) Pers.; Malva sylvestris L.; Marrubium vulgare L.; Melaleuca leucadendron (L.) L.Mant.; Melaleuca linariifolia Smith; Melissa officinalis L.; Menyanthes trifoliata L.; Myroxylon balsamum (L.) Harms; Myroxylon balsamum (L.) Harms var. pereirae; Myrrhis odorata (L.) Scop.; Narcissus poeticus L.; Nepeta cataria L.; Paullinia cupana H.K.B.; Petroselinum crispum (Mill.) Nym. ex A.W. Hill; Pimpinella anisum L.; Pogostemon cablin (Blanco) Benth.; Polianthes tuberosa L.; Potentilla erecta (L.) Raeusch.; Pterocarpus santalinus L.; Salvia lavandulifolia Vahl; Salvia sclarea L.; Sambucus canadensis L.; Sesamum indicum L.; Silybum Marianum (L.) Gaertn.; Smilax aristolochiifolia Mill.; Smilax officinalis Kunth in H.B.K.; Smilax regelii Killip et C.V. Morton; Styrax benzoin Dryand.; Uncaria gambir (Hunter) Roxb.; Viburnum prunifolium L.; Vitis vinifera L.; Yucca filamentosa L.; Yucca schidigera Roezl ex Ortigies.

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