THE EUROPEAN PHARMACOPOEIA

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— PHARMEUROPA — SPECIAL ISSUE —

"List of Standard Terms" 2000 Edition

The present List of Standard Terms is a revised List of Standard Terms which was drawn up in response to a request from the European Commission. It covers both medicines for human and veterinary use. Those Standard Terms are to be used in answering the questions 2, 2.1 and 2.2 of part IA and sections 3 and 6.5 of part IB (Summary of the Product Characteristics) of the EU application format.

The current issue of Standard Terms is composed of :

— an Introduction :
  - a section of general principles and instructions for the use of Standard Terms,
  - the summary of the changes (amendments, additions, deletions) performed since the last publication (February 1998),
  - procedure for the addition, deletion or modification of terms in the list of Standard Terms,

— three lists of standard terms :
  - list of pharmaceutical forms,
  - list of routes and/or methods of administration,
  - list of containers, closures and administration devices.

The previous edition contained translations in sixteen European languages : Croatian, Danish, Dutch, English, Finnish, French, German, Greek, Italian, Norwegian, Portuguese, Slovak, Slovenian, Spanish, Swedish and Turkish). The present lists have further been enlarged by adding the Bulgarian, Czech, Hungarian, Icelandic and Polish Terms.

Price: 38 Euro (Europe) - **42 Euro** (Outside Europe) .

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tifically sound rationale be used when building libraries and or calibrations. This rationale may vary depending on the application and products For example, in a quantitative calibration, correlation may not be a good indicator of performance, particularly when the calibration range is small and the error associated with primary method is comparatively large.

— Based on the definition of the identity test, NIR can be used for identification of mixtures. Depending on the requirements of the application, as long as the method is shown to be sensitive to significant changes in composition (selectivity - this may be difficult when concentrations are low), along with the other validation requirements, it should be considered acceptable. For example, if distinction between two different dosage strengths of a single product in tablet form is required, one should be able to use NIR for this purpose if the method is shown to be validatable and thus sensitive to the differences in composition. Therefore we do not believe that discussions should focus on the identification of single active ingredients or excipients.

Enquiry

ALKYL MESILATE (METHANESULPHONATE) IMPURITIES IN MESILATE SALTS

The need for limits on methyl, ethyl and isopropyl mesilate esters in active substances presented as mesilates has recently been discussed by the European Pharmacopoeia Commission. These esters are highly toxic and assurance is needed that they are not present in unacceptable quantities in medicinal products. However, they are also very reactive and it is therefore possible that in practice the level of contamination is negligible. Readers of Pharmeuropa are asked to inform EDQM of their opinion on the need for a test and limit in the light of their experience with mesilate salts. Information on analytical methods and the level of such impurities found in practice would be extremely valuable. Seven monographs on mesilates are at present included in the European Pharmacopoeia and would be concerned if a test and limit were to be added:

Betahistine mesilate
Bromocriptine mesilate
Deferoxamine mesilate
Dihydroergocristine mesilate
Dihydroergotamine mesilate
Pefloxacin mesilate dihydrate
Phentolamine mesilate

Please send your replies to:
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