

<b>Scientific Notes</b>	<b>3</b>	<b>General Information</b>	<b>67</b>
Collaborative study to assess the reproducibility of a reverse-phase LC method to determine the content and to estimate the impurities of benzathine benzylpenicillin	3	CD-ROM 2000 of the European Pharmacopoeia	67
System suitability criteria a case study: the determination of impurities in dicloxacillin sodium	8	<i>Press release: Conference in Berlin</i>	68
Inter-laboratory trials to assess a validation procedure for volumetric titrations	18	Conditions of sale of CRS	69
		List of CRS adopted in November 1999	70
		Prepublication brochure (June 1999)	72
		List of texts published in the June 1999 prepublication brochure	73
		List of texts adopted in November 1999	74
<b>Readers' Tribune</b>	<b>26</b>	<b>Draft monographs for comment</b>	<b>79</b>
Near IR spectrometry	26	Arnica tincture	84
		Assay of human coagulation factor II (2.7...)	80
<b>Enquiry</b>	<b>27</b>	Assay of human coagulation factor X (2.7...)	81
Alkyl mesilate (methanesulphonate) impurities in mesilate salts	27	Azaperone	144
		Bovine viral diarrhoea vaccine (inactivated)	97
		Canine adenovirus vaccine (live)	102
		Caraway oil	92
		Carbon dioxide	103
		Cetyl palmitate	125
		Dihydroergocristine mesilate	155
		Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed)	126
		Diphtheria, tetanus, pertussis (acellular, component) and haemophilus type b conjugate vaccine (adsorbed)	95
		Diphtheria, tetanus, pertussis (acellular, component) and hepatitis B (rDNA) vaccine (adsorbed)	129
		Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed)	107
		Framycetin sulphate	116
		Gemfibrozil	170
		Greater celandine	161
		Heptaminol hydrochloride	138
		Human coagulation factor VII, freeze-dried	80
		Human plasma (pooled and treated for virus inactivation)	168
		Human prothrombin complex, freeze-dried	79
		Hymecromone	157
		Ibuprofen	148
		Iodinated ( <sup>125</sup> I) human albumin injection	110
		Ioxaglic acid	141
		Java tea	87
		Levamisole	153
		Levamisole hydrochloride	150
		Lobeline hydrochloride	140
		Marsh mallow leaf	167
		Mesterolone	146
		Mint oil, dementholised	88
		Neomycin sulphate	119
		Netilmicin sulphate	122
		Nitrous oxide	105
		Oak bark	162
		Orphenadrine citrate	137
		Orphenadrine hydrochloride	135
		Phytosterol	165
		Pipemidic acid trihydrate	133
		Poloxamers	172
		Pravastatin sodium	114
		Rosemary oil	99
		Sage leaf ( <i>salvia officinalis</i> )	163
		Semi-solid preparations for cutaneous application	112
		Sodium perborate trihydrate	126
		Star anise	164
		Thyme	82
		Wild pansy (flowering aerial parts)	90
		Zinc stearate	159
<b>Certification of Suitability of the Monographs of the Ph. Eur.</b>	<b>28</b>		
List of certificates issued by the EDQM	28		
<b>Official Announcement - Rapid Implementation on 01/01/2000</b>	<b>45</b>		
Magnesium stearate	45		
Isopropyl alcohol	47		
Products with risk of transmitting agents of animal spongiform encephalopathies	48		
Minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products (5.2.8)	48		
<i>Replacement Production statements for monographs on TSE-risk products</i>	52		
Aprotinin	52		
Aprotinin concentrated solution	52		
Calcium stearate	52		
Cholesterol	52		
Chymotrypsin	52		
Decyl oleate	53		
Diethylene glycol monopalmitostearate	53		
Erythromycin stearate	53		
Ethyl oleate	53		
Ethylene glycol monopalmitostearate	53		
Glycerol distearate	53		
Glycerol mono-oleates	53		
Glycerol monostearate 40-55	53		
Hyaluronidase	53		
Insulin	53		
Macrogol stearate	53		
Macrogol stearyl ether	53		
Magnesium stearate	53		
Parnaparin sodium	53		
Propylene glycol monopalmitostearate	53		
Stearic acid	53		
Stearoyl macrogolglycerides	53		
Trypsin	53		
Vaccines for human use	53		
<b>International Conferences</b>	<b>55</b>		
Mycoplasma Testing the Potentialities & Roles of PCR Tests - <b>13-14 March 2000, Paris, France</b>	55		
The Future Face of the European Pharmacopoeia Current Concerns in Pharmaceutical Analysis <b>9-10 October 2000, Lisbon, Portugal</b>	59		
Tetanus Vaccines for Human Use <b>22-23 June 2000, Strasbourg, France</b>	63		

# 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

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