

# UPDATED WORK PROGRAMME OF THE EUROPEAN PHARMACOPOEIA

(November 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](mailto:lynn.kelso@edqm.eu)) with a view to participating in the work on items of interest.***

## TEXTS TO BE REVISED

2.2.22. Atomic emission spectrometry	Improvement of direct calibration method
5.1.2. Biological indicators of sterilisation	General revision to take into account technological and scientific developments
5.1.6. Alternative methods for control of microbiological quality	General revision to take account of recent technological developments
Amidotrizoic acid dihydrate (0873)	Related substances
Ascorbic acid (0253)	Related substances
BCG vaccine, freeze-dried (0163)	Deletion of the test for temperature stability
Calcium dobesilate monohydrate (1183)	Related substances
Camphor, racemic (0655)	Related substances
Chymotrypsin (0476)	Trypsin
Cladribine (2174)	pH
Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed) (1931)	Addition of an alternative method to the absence of residual pertussis toxin and irreversibility of pertussis toxoid test
Diphtheria, tetanus, pertussis (acellular, component) and haemophilus type b conjugate vaccine (adsorbed) (1932)	Addition of an alternative method to the absence of residual pertussis toxin and irreversibility of pertussis toxoid test
Diphtheria, tetanus, pertussis (acellular, component) and hepatitis B (rDNA) vaccine (adsorbed) (1933)	Addition of an alternative method to the absence of residual pertussis toxin and irreversibility of pertussis toxoid test
Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed) (1934)	Addition of an alternative method to the absence of residual pertussis toxin and irreversibility of pertussis toxoid test
Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) (2067)	Addition of an alternative method to the absence of residual pertussis toxin and irreversibility of pertussis toxoid test
Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) (2065)	Addition of an alternative method to the absence of residual pertussis toxin and irreversibility of pertussis toxoid test
Ear preparations (0652)	Definition
Etamsylate (1204)	Related substances
Fluphenazine dihydrochloride (0904)	Related substances
Gemfibrozil (1694)	Related substances
Glucagon, human (1635)	Deamidated glucagon, related proteins and assay

Hepatitis B vaccine (rDNA) (1056)	Addition of tests concerning the biological adjuvant MPL
Human antithrombin III concentrate (0878)	Inclusion of a provision for use of an <i>in vitro</i> method as an alternative to the pyrogen test and acceptance criteria for the bacterial endotoxin test
Human coagulation factor VII (1224)	Inclusion of a provision for use of an <i>in vitro</i> method as an alternative to the pyrogen test and acceptance criteria for the bacterial endotoxin test
Human coagulation factor IX (1223)	Inclusion of a provision for use of an <i>in vitro</i> method as an alternative to the pyrogen test and acceptance criteria for the bacterial endotoxin test
Human coagulation factor XI (1644)	Inclusion of a provision for use of an <i>in vitro</i> method as an alternative to the pyrogen test and acceptance criteria for the bacterial endotoxin test
Human fibrinogen (0024)	Inclusion of a provision for use of an <i>in vitro</i> method as an alternative to the pyrogen test and acceptance criteria for the bacterial endotoxin test
Human normal immunoglobulin (0338)	Test for IgA and maximum IgA content to be stated on the label
Human papillomavirus vaccine (rDNA) (2441)	Addition of tests concerning the biological adjuvant MPL
Human plasma (pooled and treated for virus inactivation) (1646)	Inclusion of a provision for use of an <i>in vitro</i> method as an alternative to the pyrogen test and acceptance criteria for the bacterial endotoxin test
Human prothrombin complex (0554)	Inclusion of a provision for use of an <i>in vitro</i> method as an alternative to the pyrogen test and acceptance criteria for the bacterial endotoxin test
Human von Willebrand factor (2298)	Inclusion of a provision for use of an <i>in vitro</i> method as an alternative to the pyrogen test and acceptance criteria for the bacterial endotoxin test
Imipenem (1226)	Impurities
Measles, mumps and rubella vaccine (live) (1057)	Pregnancy statement in the labelling section
Measles, mumps, rubella and varicella vaccine (live) (2442)	Pregnancy statement in the labelling section
Metamizole sodium (1346)	Related substances
Methylphenidate hydrochloride (2235)	Related substances
Oleyl alcohol (2073)	Refractive index
Opium tincture, standardised (1841)	Assay method: update and harmonisation with the monograph on raw opium
Opium, raw (0777)	Assay method: update and harmonisation with the monograph on standardised opium tincture
Pertussis vaccine (acellular, component, adsorbed) (1356)	Addition of an alternative method to the absence of residual pertussis toxin and irreversibility of pertussis toxoid test

Pertussis vaccine (acellular, co-purified, adsorbed) (1595)	Addition of an alternative method to the absence of residual pertussis toxin and irreversibility of pertussis toxoid test
Rabies vaccine (inactivated) for veterinary use (0451)	Potency test
Rubella vaccine (live) (0162)	Pregnancy statement in the labelling section
Sodium ascorbate (1791)	Related substances
Sodium bromide (0190)	Chlorides
Sodium lactate solution (1151)	Definition, test for aluminium
Triglycerides, medium-chain (0868)	Definition
Tri- <i>n</i> -butyl phosphate (1682)	Related substances
Varicella vaccine (live) (0648)	Pregnancy statement in the labelling section
Zinc sulphate monohydrate (2159)	pH

## NEW TEXTS

Abacavir sulphate (2589)	Polyoxypropylene-15-stearyl ether (2602)
Amprenavir (2590)	Pullulan (2603)
Cypermethrin (2592)	Ropinirole hydrochloride (2604)
Docetaxel, anhydrous (2593)	Rosiglitazone maleate (2605)
Fondaparinux sodium (2595)	Theobroma oil (cocoa butter) (2607)
Fosamprenavir (2596)	Topotecan hydrochloride (2608)
Hepatitis A (inactivated) and typhoid vaccine (2597)	Triclabendazole (2609)
Levofloxacin (2598)	Yttrium ( <sup>90</sup> Y) edotreotide injection (2610)
Nicotine ditartrate dihydrate (2599)	Zanamivir (2611)
Olmesartan medoxomil (2600)	

## TECHNICAL GUIDE FOR THE ELABORATION OF MONOGRAPHS

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and as a cumulative printed version

The Technical Guide for the Elaboration of Monographs (2005) describes the scientific approach used for the elaboration of monographs and the establishment of specifications of the European Pharmacopoeia. The guide also describes how to elaborate scientifically the various sections that must be included in each monograph, for example definition, characters, the physical and chemical reactions constituting the identification section, purity tests, assay methods and storage conditions. It is continually being updated.

Specific guides are also available for:

- Monographs on vaccines and other immunological human medicinal products (2008)
- Monographs on fatty oils and derivatives (2007)
- Monographs on herbal drugs and herbal drug preparations (2007)
- Monographs on synthetic peptides and recombinant DNA proteins (2006)
- The graphic representation and nomenclature of chemical formulae in the European Pharmacopoeia (2006)

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