

# Updated work programme of the European Pharmacopoeia

## (June 2018)

The following items have been added to or deleted from the work programme during the 161<sup>st</sup> session of the European Pharmacopoeia Commission. Consult the [Knowledge Database](#) to follow the work on individual texts.

**Interested parties are invited to contact the EDQM via the [HelpDesk](#) with a view to participating in the work on items of interest.**

## TEXTS TO BE REVISED

<b>Methods of analysis</b>	
2.6.7. Mycoplasmas	Update to include current practice in the field of mycoplasma testing
2.7.29. Nucleated cell count and viability	Inclusion of new automated technologies for cell enumeration
2.9.17. Test for extractable volume of parenteral preparations	General revision
<b>Materials and containers</b>	
3.1.3. Polyolefins	Increase in the number of significant figures for volumes to be used in the reducing substances test
3.1.4. Polyethylene without additives for containers for parenteral preparations and for ophthalmic preparations	Increase in the number of significant figures for volumes to be used in the reducing substances test
3.1.5. Polyethylene with additives for containers for parenteral preparations and for ophthalmic preparations	Increase in the number of significant figures for volumes to be used in the reducing substances test
<b>General texts</b>	
5.1.10. Guidelines for using the test for bacterial endotoxins	Addition of an endotoxin limit for intravitreal preparations
<b>General monographs</b>	
Vegetable fatty oils (1579)	Revision of the description of oils used in parenteral preparations in the definition section
<b>Vaccines</b>	
Influenza vaccine (split virion, inactivated) (0158)	Clarification on the applicability of chapter 2.6.16. <i>Tests for extraneous agents in viral vaccines for human use</i>
Influenza vaccine (surface antigen, inactivated) (0869)	Clarification on the applicability of chapter 2.6.16. <i>Tests for extraneous agents in viral vaccines for human use</i>
Influenza vaccine (surface antigen, inactivated, virosome) (2053)	Clarification on the applicability of chapter 2.6.16. <i>Tests for extraneous agents in viral vaccines for human use</i>

Influenza vaccine (whole virion, inactivated) (0159)	Clarification on the applicability of chapter 2.6.16. <i>Tests for extraneous agents in viral vaccines for human use</i>
<b>Herbal drugs</b>	
Centella (1498)	Revision regarding tests for <i>Bacopa monnieri</i> L., total ash and the assay
<b>Monographs</b>	
Beeswax, white (0069)	Revision of test for ceresin, paraffins and certain other waxes and for glycerol and other polyols; introduction of a test for adulteration
Beeswax, yellow (0070)	Revision of test for ceresin, paraffins and certain other waxes, and for glycerol and other polyols; introduction of a test for adulteration
Benzoyl peroxide, hydrous (0704)	Revision of the assay section
Calcium pantothenate (0470)	Revision of related substances test to replace TLC method with LC; update of identification section
Dapsone (0077)	Revision of the test for related substances
Epirubicin hydrochloride (1590)	Harmonisation of the definition section with that of <i>Daunorubicin hydrochloride</i> (0662)
Fish oil, rich in omega-3 acids (1912)	Revision of stearin test
Flubendazole (1721)	Revision of the test for related substances
Heparins, low-molecular-mass (0828)	Introduction of system suitability criteria for identification C
Hydroxyethyl salicylate (1225)	Revision of the test for related substances
Ichthammol (0917)	Revision to introduce a test for adulteration with ichthammol, in accordance with the Chinese Pharmacopoeia
Labetalol hydrochloride (0923)	Revision of the test for related substances: review of system suitability criterion
Letrozole (2334)	Revision of the test for related substances: update of specifications
Moxifloxacin hydrochloride (2254)	Revision to restrict monograph to the 'monohydrate' and to introduce a range for acceptance criteria for the water test; to investigate whether the substance is hygroscopic and, since the substance shows polymorphism, to investigate the introduction of a recrystallization step in the IR identification test
Oxytetracycline hydrochloride (0198)	Revision of related substances test
Propylthiouracil (0525)	Revision of test for related substances
Pyrantel embonate (1680)	Revision of test for related substances : addition of a correction factor for impurity C
Silver, colloidal, for external use (2281)	Revision of the title
Sodium lauroylsarcosinate for external use (2542)	Revision of the title
Sulfur for external use (0953)	Revision of the title
Sulindac (0864)	Revision of test for related substances

## ADDITIONS TO THE WORK PROGRAMME (new texts to be elaborated)

2.9.55. Tablet Compression Characterisation

Atazanavir capsules (3112)

Atazanavir oral powder (3111)  
Darunavir ethanolate (3124)  
Darunavir oral suspension (3125)  
Darunavir tablets (3126)  
Fluor-PSMA-1007 (3116)  
Levocetirizine dihydrochloride (3115)  
Midazolam hydrochloride (3110)  
Paliperidone (3123)

## DELETIONS FROM THE WORK PROGRAMME (new texts or requests for revision)

5.2.5. Substances of animal origin for the production of immunological veterinary medicinal products  
Air, medicinal (1238)  
Clostridium botulinum vaccine for veterinary use (0360)  
Clostridium chauvoei vaccine for veterinary use (0361)  
Fluoride (<sup>18</sup>F) solution for radiolabelling (2390)  
Phenelzine sulfate (2982)