

Update to work programme of the European Pharmacopoeia

(June 2021)

The following items have been added to or deleted from the work programme during the 170th 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

Methods of analysis			
1.	General notices	Prescriptions générales	Shelf life for all bio and biotech substances (not only for labile substances and certain antibiotics).
2.4.24.	Identification and control of residual solvents	Identification et contrôle des solvants résiduels	General revision and update to align with the latest version of ICH Q3C (R8).
2.7.20.	<i>In vivo</i> assay of poliomyelitis vaccine (inactivated)	Titration de l'activité <i>in vivo</i> du vaccin poliomyélique inactivé	Revision of test in chicks or guinea pigs, evaluation of <i>in vivo</i> and <i>in vitro</i> assays after significant changes to the manufacturing process and guidance on waiving the <i>in vivo</i> assay.
2.9.9.	Measurement of consistency by penetrometry	Mesure de la consistance par pénétrométrie	Amendment of cone dimensions to align international standards.
General monographs			
2031	Monoclonal antibodies for human use	Anticorps monoclonaux pour usage humain	Visible particles: to align with the requirements of the revised monograph <i>Parenteral preparations (0520)</i> .
Dosage forms			
0520	Parenteral preparations	Préparations parentérales	Revision to clarify requirements for non-aqueous and modified-release.
Vaccines			
0744	Aujeszky's disease vaccine (inactivated) for pigs	Vaccin inactivé de la maladie d'Aujeszky pour le porc	3Rs: revision to delete the test for residual live virus on the final product (section 3-3).

0959	Avian infectious bronchitis vaccine (inactivated)	Vaccin inactivé de la bronchite infectieuse aviaire	3Rs: revision to reduce the number of control birds for the routine batch potency test and to delete the test for residual live virus on the final product (section 3-3).
0960	Avian infectious bursal disease vaccine (inactivated)	Vaccin inactivé de la bursite infectieuse aviaire	3Rs: revision to reduce the number of control birds for the routine batch potency test and to delete the test for residual live virus on the final product (section 3-3).
0588	Avian infectious encephalomyelitis vaccine (live)	Vaccin vivant de l'encéphalomyélite infectieuse aviaire	3Rs: revision to add humane end-points for the immunogenicity test.
1392	Avian paramyxovirus 3 vaccine (inactivated) for turkeys	Vaccin inactivé du paramyxovirus aviaire 3 pour la dinde	3Rs: revision to delete the test for residual live virus on the final product (section 3-3).
1202	Egg drop syndrome '76 vaccine (inactivated)	Vaccin inactivé de la maladie des œufs hardés	3Rs: revision to reduce the number of control birds for the routine batch potency test and to delete the test for residual live virus on the final product (section 3-3).
0249	Equine influenza vaccine (inactivated)	Vaccin inactivé de la grippe équine	3Rs: revision to delete the test for residual live virus on the final product (section 3-3).
1945	Fowl cholera vaccine (inactivated)	Vaccin inactivé du choléra aviaire	3Rs: revision to reduce the number of control birds for the routine batch potency test and to add humane end-points for the immunogenicity test.
1942	<i>Mycoplasma gallisepticum</i> vaccine (inactivated)	Vaccin inactivé de <i>Mycoplasma gallisepticum</i>	3Rs: revision to reduce the number of control birds for the routine batch potency test.
0870	Newcastle disease vaccine (inactivated)	Vaccin inactivé de la pseudopeste aviaire (maladie de Newcastle)	3Rs: revision to reduce the number of control birds for the routine batch potency test and to delete the test for residual live virus on the final product (section 3-3).
0214	Poliomyelitis vaccine (inactivated)	Vaccin poliomyélitique inactivé	Use of primary cells in production and in the test for effective inactivation, evaluation of <i>in vivo</i> and <i>in vitro</i> assays after significant changes to the manufacturing process.
0963	Porcine influenza vaccine (inactivated)	Vaccin inactivé de la grippe porcine	3Rs: revision to delete the test for residual live virus on the final product (section 3-3).

1947	<i>Salmonella</i> Enteritidis vaccine (inactivated) for chickens	Vaccin inactivé de la salmonellose à <i>Salmonella</i> Enteritidis pour le poulet	3Rs: revision to reduce the number of control birds for the routine batch potency test.
2361	<i>Salmonella</i> Typhimurium vaccine (inactivated) for chickens	Vaccin inactivé de la salmonellose à <i>Salmonella</i> Typhimurium pour le poulet	3Rs: revision to reduce the number of control birds for the routine batch potency test.
Herbal drugs			
1222	Hop strobile	Houblon (cône de)	Revision of foreign matter criteria.
Monographs			
0578	Ampicillin sodium	Ampicilline sodique	Deletion of the methylene chloride test.
0985	Croscarmellose sodium	Croscarmellose sodique	Revision of the test for water-soluble substances.
0188	Fructose	Fructose	Revision of the TLC identification (REACH).
0332	Heparin calcium	Héparine calcique	Revision of the limit for proteins.
0333	Heparin sodium	Héparine sodique	Revision of the limit for proteins.
0029	Imipramine hydrochloride	Imipramine (chlorhydrate d')	Test for related substances: introduction of a rational approach for the control of impurity B, and verification of the current LC method as a quantitative test in order to support the expression of the acceptance criteria in the quantitative style.
1119	Isoxsuprine hydrochloride	Isoxsuprine (chlorhydrate d')	Title: restriction of the monograph for veterinary use only in accordance with the current use of this API in Europe. Tests for related substances and phenones: introduction of an alternative test covering at least impurities A and B, as well as allowing the introduction of a specification for unspecified impurities and a reporting threshold, in order to comply with general monograph <i>Substances for pharmaceutical use (2034)</i> .
0921	Ketoconazole	Kétoconazole	Revision of the second identification series.
2283	Paroxetine hydrochloride	Paroxétine (chlorhydrate de)	Addition of a test for impurity G.

2018	Paroxetine hydrochloride hemihydrate	Paroxétine (chlorhydrate de) hémihydraté	Addition of a test for impurity G. Test for enantiomeric purity: optimisation of the current LC test, particularly its system suitability test.
0426	Polysorbate 20	Polysorbate 20	Functionality-related Characteristics (FRC) section: evaluation of the use of polysorbate in parenteral preparations.
1914	Polysorbate 40	Polysorbate 40	Functionality-related Characteristics (FRC) section: evaluation of the use of polysorbate in parenteral preparations.
0427	Polysorbate 60	Polysorbate 60	Functionality-related Characteristics (FRC) section: evaluation of the use of polysorbate in parenteral preparations.
0428	Polysorbate 80	Polysorbate 80	Functionality-related Characteristics (FRC) section: evaluation of the use of polysorbate in parenteral preparations.
2270	Sildenafil citrate	Sildénafil (citrate de)	Inclusion of a second identification series.

TEXTS TO BE REVISED: REPLACEMENT OF THE RABBIT PYROGENS TEST

2.6.30.	Monocyte-activation test	Essai d'activation des monocytes	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
3.3.4.	Sterile plastic containers for human blood and blood components	Réipients stériles en matière plastique pour le sang humain et les produits du sang	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
3.3.7.	Sets for the transfusion of blood and blood components	Nécessaires pour la transfusion du sang et des produits du sang	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
5.1.10.	Guidelines for using the test for bacterial endotoxins	Recommandations pour la réalisation de l'essai des endotoxines bactériennes	Rearrangement or removal of general information relative to pyrogen testing, in consideration of the new general chapter 5.1.13. <i>Pyrogenicity</i> .

5.2.11.	Carrier proteins for the production of conjugated polysaccharide vaccines for human use	Protéines vectrices pour la production de vaccins polysidiques conjugués pour usage humain	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
2537	3-O-Desacyl-4'-monophosphoryl lipid A	Lipide A 3-O-désacyl-4'-monophosphorylé	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
1290	Amikacin sulfate	Amikacine (sulfate d')	Deletion of the test for pyrogens (2.6.8) from the Test section and introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> , if relevant and appropriate.
0209	Anticoagulant and preservative solutions for human blood	Solutions anticoagulantes et de conservation du sang humain	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
1928	Anti-T lymphocyte immunoglobulin for human use, animal	Immunoglobuline animale anti-lymphocytes T pour usage humain	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
1296	Calcium levulinate dihydrate	Calcium (lévulinate de) dihydraté	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
0709	Chloramphenicol sodium succinate	Chloramphénicol (succinate sodique de)	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
0319	Colistimethate sodium	Colistiméthate sodique	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
0663	Dicloxacillin sodium	Dicloxacilline sodique	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
2062	Diphtheria, tetanus and hepatitis B (rDNA) vaccine (adsorbed)	Vaccin diphtérique, tétanique et de l'hépatite B (ADNr), absorbé	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
1932	Diphtheria, tetanus, pertussis (acellular, component) and haemophilus type b conjugate vaccine (adsorbed)	Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé) et conjugué de l'haemophilus type b, adsorbé	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .

1933	Diphtheria, tetanus, pertussis (acellular, component) and hepatitis B (rDNA) vaccine (adsorbed)	Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé), et de l'hépatite B (ADNr), adsorbé	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
2067	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed)	Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé), de l'hépatite B (ADNr), poliomyélique (inactivé) et conjugué de l'haemophilus type b, adsorbé	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
2065	Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed)	Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé), poliomyélique (inactivé) et conjugué de l'haemophilus type b, adsorbé	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
2066	Diphtheria, tetanus, pertussis (whole cell), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed)	Vaccin diphtérique, tétanique, coquelucheux (à cellules entières), poliomyélique (inactivé) et conjugué de l'haemophilus type b, adsorbé	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
0668	Flucloxacillin sodium monohydrate	Flucloxacilline sodique monohydratée	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
0177	Glucose	Glucose	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
0178	Glucose monohydrate	Glucose monohydraté	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
0128	Haemodialysis, solutions for	Solutions pour hémodialyse	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
0861	Haemofiltration and haemodiafiltration, solutions for	Solutions pour hémofiltration et pour hémodiafiltration	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
2622	Haemophilus type b and meningococcal group C conjugate vaccine	Vaccin haemophilus type b et méningococcique groupe C conjugué	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .

1219	Haemophilus type b conjugate vaccine	Vaccin conjugué de l'haemophilus type b	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
1056	Hepatitis B vaccine (rDNA)	Vaccin de l'hépatite B (ADNr)	Deletion of the tests for pyrogens (2.6.8) and bacterial endotoxins (2.6.14) and introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
0255	Human albumin solution	Albumine humaine (solution d')	Deletion of the tests for pyrogens (2.6.8) and bacterial endotoxins (2.6.14) and introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
0878	Human antithrombin III concentrate	Antithrombine III humaine (concentré d')	Deletion of the tests for pyrogens (2.6.8) and bacterial endotoxins (2.6.14) and introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
2818	Human C1-esterase inhibitor	Inhibiteur de la C1-estérase humain	Deletion of the tests for pyrogens (2.6.8) and bacterial endotoxins (2.6.14) and introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
1223	Human coagulation factor IX	Facetur IX de coagulation humain	Deletion of the tests for pyrogens (2.6.8) and bacterial endotoxins (2.6.14) and introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
1224	Human coagulation factor VII	Facteur VII de coagulation humain	Deletion of the tests for pyrogens (2.6.8) and bacterial endotoxins (2.6.14) and introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
0275	Human coagulation factor VIII	Facteur VIII de coagulation humain	Deletion of the tests for pyrogens (2.6.8) and bacterial endotoxins (2.6.14) and introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
1644	Human coagulation factor XI	Facteur XI de coagulation humain	Deletion of the tests for pyrogens (2.6.8) and bacterial endotoxins (2.6.14) and introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .

0024	Human fibrinogen	Fibrinogène humain	Deletion of the tests for pyrogens (2.6.8) and bacterial endotoxins (2.6.14) and introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
0338	Human normal immunoglobulin for intramuscular administration	Immunoglobuline humaine normale pour administration par voie intramusculaire	Deletion of the tests for pyrogens (2.6.8) and bacterial endotoxins (2.6.14) and introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
0918	Human normal immunoglobulin for intravenous administration	Immunoglobuline humaine normale pour administration par voie intraveineuse	Deletion of the tests for pyrogens (2.6.8) and bacterial endotoxins (2.6.14) and introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
2788	Human normal immunoglobulin for subcutaneous administration	Immunoglobuline humaine normale pour administration par voie sous-cutanée	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
1646	Human plasma (pooled and treated for virus inactivation)	Plasma humain (mélange de) traité pour viro-inactivation	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
0554	Human prothrombin complex	Complexe prothrombique humain	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
2298	Human von Willebrand factor	Facteur Willebrand humain	Deletion of the tests for pyrogens (2.6.8) and bacterial endotoxins (2.6.14) and introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
2387	Human α -1-proteinase inhibitor	Inhibiteur d' α -1-protéinase humain	Deletion of the tests for pyrogens (2.6.8) and bacterial endotoxins (2.6.14) and introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
0084	Immunosera for human use, animal	Immunosérums d'origine animale pour usage humain	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
2811	Intravesical preparations	Préparations intravésicales	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .

0033	Kanamycin acid sulfate	Kanamycine (sulfate acide de)	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
0032	Kanamycin monosulfate	Kanamycine (monosulfate de)	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
3066	Meningococcal group A, C, W135 and Y conjugate vaccine	Vaccin méningococcique groupes A, C, W135 et Y conjugué	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
2112	Meningococcal group C conjugate vaccine	Vaccin conjugué méningococcique groupe C	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
0250	Meningococcal polysaccharide vaccine	Vaccin méningococcique polysidique	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
0520	Parenteral preparations	Préparations parentérales	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
0862	Peritoneal dialysis, solutions for	Solutions pour dialyse péritonéale	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
2150	Pneumococcal polysaccharide conjugate vaccine (adsorbed)	Vaccin pneumococcique polysidique conjugué adsorbé	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
0966	Pneumococcal polysaccharide vaccine	Vaccin pneumococcique polysidique	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
0203	Polymyxin B sulfate	Polymyxine B (sulfate de)	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
1116	Preparations for irrigation	Préparations pour irrigation	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .

0216	Rabies vaccine for human use prepared in cell cultures	Vaccin rabique pour usage humain préparé sur cultures cellulaires	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
0125	Radiopharmaceutical preparations	Préparations radiopharmaceutiques	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
0412	Sodium citrate	Sodium (citrate de)	Deletion of the test for pyrogens (2.6.8) from the Test section and introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> , if relevant and appropriate.
1264	Solutions for organ preservation	Solutions pour conservation d'organes	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
2034	Substances for pharmaceutical use	Substances pour usage pharmaceutique	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .
1375	Tick-borne encephalitis vaccine (inactivated)	Vaccin inactivé de l'encéphalite verno-estivale	Deletion of the test for pyrogens (2.6.8) and possible introduction of a reference to the new general chapter 5.1.13. <i>Pyrogenicity</i> .

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

2.6.41.	High throughput sequencing for the detection of extraneous agents	N/A
5.1.13.	Pyrogenicity	Pyrogénicité
5.31.	Phage therapy active substances and medicinal products for human and veterinary use	Substances actives et médicaments à usage humain et vétérinaire utilisés en phagothérapie
5.33.	Design of experiments	Plans d'expériences
5.34.	Additional information on gene therapy medicinal products for human use	N/A
3193	Coriolus versicolor	N/A
3195	Oral films	N/A
3194	PSMA ITG for radiopharmaceutical preparations	N/A

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

4.4.1. Reagent Water for chromatography R

1295 Calcifediol monohydrate

0532 Tragacanth

0306 Zinc stearate
