

Compendial Forum Updates Relevant to Microbiological Issues

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Compendium	Proposal Type	Title	New[N] / Revised[R]	Synopsis [requirements or description]	BG
BP	monograph	Ciclosporin Eye Drops	R	sterility	X
BP	monograph	Ciclosporin Eye Ointment	N	sterility, tests for specified microorganisms	X
BP	monograph	digoxin injection	R	sterility, endotoxins	X
BP	monograph	digoxin oral solution	R	tests for specified microorganisms	X
BP	monograph	digoxin tablets	R	tests for specified microorganisms	X
BP	monograph	Doxycycline Capsules	R	microbial enumeration, tests for specified microorganisms	X
BP	monograph	Doxycycline tablets	R	microbial enumeration, tests for specified microorganisms	X
BP	monograph	Doxycycline Capsules.pdf	R	microbial enumeration, tests for specified microorganisms	X
BP	monograph	Doxycycline Dispersible Tablets.pdf	R	microbial enumeration, tests for specified microorganisms	X
BP	monograph	Enrofloxacin Concentrate for Oral Solution.pdf	N	microbial enumeration, tests for specified microorganisms	X
BP	monograph	Enrofloxacin Injection.pdf	N	sterility, endotoxins	X
BP	monograph	Enrofloxacin Oral Solution.pdf	N	microbial enumeration, tests for specified microorganisms	X
BP	monograph	Enrofloxacin Oral Suspension.pdf	N	microbial enumeration, tests for specified microorganisms	X
BP	monograph	Enrofloxacin Solution for Use in Drinking Water.pdf	N	microbial enumeration, tests for specified microorganisms	X
BP	monograph	Erythromycin Gastro-resistant Capsules.pdf	R	microbial enumeration, tests for specified microorganisms	X
BP	monograph	Erythromycin Gastro-resistant Tablets.pdf	R	microbial enumeration, tests for specified microorganisms	X
BP	monograph	Erythromycin and Zinc Acetate Lotion.pdf	R	microbial enumeration, tests for specified microorganisms	X
BP	monograph	Esomeprazole for Injection.pdf	N	sterility, endotoxins	X
BP	monograph	Flecainide Oral Solution.pdf	N	microbial enumeration, tests for specified microorganisms	X
BP	monograph	Metformin Oral Solution.pdf	R	microbial enumeration, tests for specified microorganisms	X
BP	monograph	Metformin Tablets.pdf	R	microbial enumeration, tests for specified microorganisms	X

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BP	monograph	Omeprazole Gastro-resistant Capsules.pdf	R	microbial enumeration, tests for specified microorganisms	X
BP	monograph	Omeprazole Gastro-resistant Tablets.pdf	R	microbial enumeration, tests for specified microorganisms	X
BP	monograph	Omeprazole for Injection.pdf	N	sterility, endotoxins	X
BP	monograph	Propofol Injection.pdf	R	sterility, endotoxins	X
BP	monograph	Quinine Sulfate Oral Suspension.pdf	N	microbial enumeration, tests for specified microorganisms	X
BP	monograph	Rifaximin Tablets.pdf	R	microbial enumeration, tests for specified microorganisms	X
BP	monograph	Warfarin Tablets.pdf	R	microbial enumeration, tests for specified microorganisms	X
EP [35.1]	monograph	3-O-Desacyl-4'-monophosphoryl lipid A	R	pyrogen test replaced by monocyte activation test 2.6.30 microbial enumeration	
EP [35.1]	general chapter	3.3.4. Sterile plastic containers for human blood and blood components	R	pyrogen test replaced by reference to new chapter Pyrogenicity 5.1.13 The limit is approved by the competent authority.	
EP [35.1]	general chapter	3.3.7. Sets for the transfusion of blood and blood components	R	pyrogen test replaced by reference to new chapter Pyrogenicity 5.1.13 The limit is approved by the competent authority.	
EP [35.1]	general chapter	5.1.10. Guidelines for using the test for bacterial endotoxins	R	a goal of the EP is to eliminate the use of the rabbit pyrogen test. This proposal has changes designed to reflect this goal. Reference to recombinant factor C is made. Limit = K/M	
EP [35.1]	general chapter	5.1.13. Pyrogenicity	N	Related to goal of EP to eliminate the use of the rabbit pyrogen test, this proposal discusses the bacterial endotoxins test and the monocyte activation test.	
EP [35.1]	general chapter	5.2.11. Carrier proteins for the production of conjugated polysaccharide vaccines for human use	R	pyrogen test replaced by reference to new chapter Pyrogenicity 5.1.13 The limit is approved by the competent authority.	
EP [35.1]	monograph	Allergen products	R	<i>5.1.4. Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use mentioned. 2.6.1. Sterility mentioned.</i>	
EP [35.1]	monograph	Aluminum Phosphate Gel	R	microbial enumeration, tests for specified microorganisms TAMC: 10 ³ cfu/g TYMC: 10 ² cfu/g Absence of gram-negative bacteria Absence of <i>E. coli</i>	
EP [35.1]	monograph	Amikacin sulphate	R	rabbit pyrogen test delete, replace by reference to general monograph Substances for pharmaceutical use (2034)	

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EP [35.1]	monograph	Anti-T lymphocyte immunoglobulin for human use, animal	R	pyrogen test replaced by reference to new chapter Pyrogenicity 5.1.13 The limit is approved by the competent authority.	
EP [35.1]	monograph	Anticoagulant and preservative solutions for human blood	R	pyrogen test replaced by reference to new chapter Pyrogenicity 5.1.13 < 0.5 endotoxin equivalents/mL	
EP [35.1]	monograph	<i>Calcium levulinate dihydrate</i>	R	rabbit pyrogen test delete, replace by reference to general monograph Substances for pharmaceutical use (2034)	
EP [35.1]	monograph	<i>Chloramphenicol sodium succinate</i>	R	rabbit pyrogen test delete, replace by reference to general monograph Substances for pharmaceutical use (2034)	
EP [35.1]	monograph	Colistimethate sodium	R	rabbit pyrogen test delete, replace by reference to general monograph Substances for pharmaceutical use (2034)	
EP [35.1]	monograph	Dicloxacillin sodium monohydrate	R	rabbit pyrogen test delete, replace by reference to general monograph Substances for pharmaceutical use (2034)	
EP [35.1]	monograph	Diphtheria, tetanus, pertussis (acellular, component) and haemophilus type b conjugate vaccine (adsorbed)	R	Pyrogens and bacterial endotoxins test eliminated, reference now made to general monograph Vaccines for human use (0153), sterility, antimicrobial efficacy, bacterial endotoxins	
EP [35.1]	monograph	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed)	R	Pyrogens test eliminated, reference now made to general monograph Vaccines for human use (0153), sterility, antimicrobial efficacy Bacterial endotoxins: less than the limit approved for the product concerned.	
EP [35.1]	monograph	Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed)	R	Pyrogens and bacterial endotoxins test eliminated, reference now made to general monograph Vaccines for human use (0153), sterility, antimicrobial efficacy, bacterial endotoxins	
EP [35.1]	monograph	flucloxacillin sodium monohydrate	R	rabbit pyrogen test delete, replace by reference to general monograph Substances for pharmaceutical use (2034)	
EP [35.1]	monograph	glucose	R	pyrogen test replaced by reference to new chapter Pyrogenicity 5.1.13 NMT 0.01 endotoxin equivalents/mg	
EP [35.1]	monograph	glucose monohydrate	R	pyrogen test replaced by reference to new chapter Pyrogenicity 5.1.13 NMT 0.01 endotoxin equivalents/mg	

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EP [35.1]	monograph	haemodialysis, solutions for	R	pyrogen test replaced by reference to new chapter Pyrogenicity 5.1.13 2.6.1. Sterility TAMC: 10 ² cfu/mL NMT 0.25 endotoxin equivalents/mL	
EP [35.1]	monograph	haemofiltration and haemodiafiltration, solutions for	R	pyrogen test, bacterial endotoxins test replaced by reference to new chapter Pyrogenicity 5.1.13 2.6.1. Sterility NMT 0.05 endotoxin equivalents/mL	
EP [35.1]	monograph	Haemophilus type b and meningococcal group C conjugate vaccine	R	Pyrogens test eliminated, reference now made to general monograph Vaccines for human use (0153), sterility, antimicrobial efficacy, bacterial endotoxins: < 10 IU/microgram of PRP	
EP [35.1]	monograph	Haemophilus type b conjugate vaccine	R	pyrogens and bacterial endotoxin test eliminated, reference now made to general monograph Vaccines for human use (0153), sterility, antimicrobial efficacy, bacterial endotoxins	
EP [35.1]	monograph	Hepatitis B vaccine (rDNA)	R	pyrogens test eliminated, reference now made to general monograph Vaccines for human use (0153), sterility, antimicrobial efficacy	
EP [35.1]	monograph	Human albumin solution	R	pyrogen test, bacterial endotoxins test replaced by reference to new chapter Pyrogenicity 5.1.13 2.6.1 Sterility	
EP [35.1]	monograph	Human antithrombin III concentrate	R	pyrogen test replaced by reference to new chapter Pyrogenicity 5.1.13 2.6.1. Sterility < 0.1 endotoxin equivalents/IU of antithrombin III	
EP [35.1]	monograph	Human C1-esterase inhibitor	R	pyrogen test replaced by reference to new chapter Pyrogenicity 5.1.13 2.6.1. Sterility < 0.25 endotoxin equivalents/IU of C1-esterase inhibitor	
EP [35.1]	monograph	Human coagulation factor IX	R	pyrogen test replaced by reference to new chapter Pyrogenicity 5.1.13 2.6.1. Sterility < 0.03 endotoxin equivalents/IU of human coagulation factor IX	
EP [35.1]	monograph	Human coagulation factor VII	R	pyrogen test replaced by reference to new chapter Pyrogenicity 5.1.13 2.6.1. Sterility < 0.1 endotoxin equivalents/IU of human coagulation factor VII	
EP [35.1]	monograph	Human coagulation factor VIII	R	pyrogen test replaced by reference to new chapter Pyrogenicity 5.1.13 2.6.1. Sterility < 0.03 endotoxin equivalents/IU of human coagulation factor VIII	
EP [35.1]	monograph	Human coagulation factor XI	R	pyrogen test replaced by reference to new chapter Pyrogenicity 5.1.13 2.6.1. Sterility < 0.1 endotoxin equivalents/IU of human coagulation factor XI	
EP [35.1]	monograph	human fibrinogen	R	pyrogen test replaced by reference to new chapter Pyrogenicity 5.1.13 2.6.1. Sterility < 0.03 endotoxin equivalents/mg of fibrinogen	
EP [35.1]	monograph	Human normal immunoglobulin for intramuscular administration	R	pyrogen test replaced by reference to new chapter Pyrogenicity 5.1.13 2.6.1. Sterility < 5 endotoxin equivalents/mL	
EP [35.1]	monograph	Human normal immunoglobulin for intravenous administration	R	pyrogen test replaced by reference to new chapter Pyrogenicity 5.1.13 2.6.1. Sterility < 0.5 endotoxin equivalents/mL for solutions with < 50g/L protein, and < 1.0 endotoxin equivalents for solutions with > 50g/L protein but NMT 100 g/L	
EP [35.1]	monograph	Human normal immunoglobulin for subcutaneous administration	R	pyrogen test replaced by reference to new chapter Pyrogenicity 5.1.13 2.6.1. Sterility < 5 endotoxin equivalents/mL	

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EP [35.1]	monograph	Human plasma (pooled and treated for virus inactivation)	R	pyrogen test replaced by reference to new chapter Pyrogenicity 5.1.13 2.6.1. Sterility < 0.1 endotoxin equivalents/mL	
EP [35.1]	monograph	Human prothrombin complex	R	pyrogen test replaced by reference to new chapter Pyrogenicity 5.1.13 2.6.1. Sterility < 0.05 endotoxin equivalents/IU of human coagulation factor IX	
EP [35.1]	monograph	human von Willebrand factor	R	pyrogen test replaced by reference to new chapter Pyrogenicity 5.1.13 2.6.1. Sterility < 0.05 endotoxin equivalents/IU of human von Willebrand factor	
EP [35.1]	monograph	human α -1-proteinase inhibitor	R	pyrogen test replaced by reference to new chapter Pyrogenicity 5.1.13 2.6.1. Sterility < 0.08 endotoxin equivalents/IU of human α -1-proteinase inhibitor	
EP [35.1]	monograph	immunoserum for human use, animal	R	2.6.1. Sterility pyrogen test replaced by reference to new chapter Pyrogenicity 5.1.13. pyrogens: complies with the limit approved for the particular product	
EP [35.1]	monograph	Intravesical preparations	R	pyrogen test or bacterial endotoxins test replaced by reference to new chapter Pyrogenicity 5.1.13, sterility	
EP [35.1]	monograph	Kanamycin acid sulfate	R	rabbit pyrogen test deleted, replaced by reference to general monograph Substances for pharmaceutical use (2034)	
EP [35.1]	monograph	Kanamycin monosulfate monohydrate	R	rabbit pyrogen test deleted, replaced by reference to general monograph Substances for pharmaceutical use (2034)	
EP [35.1]	monograph	Meningococcal group A, C, W135 and Y conjugate vaccine	R	pyrogens test eliminated, reference now made to general monograph Vaccines for human use (0153) 2.6.1. Sterility bacterial endotoxins: within the limits approved by the competent authority	
EP [35.1]	monograph	Meningococcal group C conjugate vaccine	R	pyrogens test eliminated, reference now made to general monograph Vaccines for human use (0153) 2.6.1. Sterility bacterial endotoxins: < 100 IU/microgram of polysaccharide	
EP [35.1]	monograph	Meningococcal polysaccharide vaccine	R	pyrogen test or bacterial endotoxins test replaced by reference to new chapter Pyrogenicity 5.1.13. 2.6.1. Sterility Pyrogenicity: limit approved by the competent authority	
EP [35.1]	monograph	Parenteral preparations	R	pyrogen test or bacterial endotoxins test replaced by reference to new chapter Pyrogenicity 5.1.13. 2.6.1. Sterility	
EP [35.1]	monograph	Peritoneal dialysis, solutions for	R	pyrogen test or bacterial endotoxins test replaced by reference to new chapter Pyrogenicity 5.1.13 2.6.1. Sterility < 0.05 endotoxin equivalents/mL	
EP [35.1]	monograph	Pneumococcal polysaccharide conjugate vaccine (adsorbed)	R	pyrogens test eliminated, reference now made to general monograph Vaccines for human use (0153) 2.6.1. Sterility bacterial endotoxins: < 0.75 IU/microgram of polysaccharide	
EP [35.1]	monograph	Pneumococcal polysaccharide vaccine	R	pyrogens test eliminated, reference now made to general monograph Vaccines for human use (0153) 2.6.1. Sterility	
EP [35.1]	monograph	polymyxin B sulfate	R	rabbit pyrogen test delete, replace by reference to general monograph Substances for pharmaceutical use (2034)	

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EP [35.1]	monograph	Preparations for irrigation	R	pyrogen test or bacterial endotoxins test replaced by reference to new chapter Pyrogenicity 5.1.13 2.6.1. Sterility < 0.5 endotoxin equivalents/mL	
EP [35.1]	monograph	Rabies vaccine for human use prepared in cell cultures	R	pyrogens test and bacterial endotoxins test eliminated, reference now made to general monograph Vaccines for human use (0153) 2.6.1. Sterility	
EP [35.1]	monograph	radiopharmaceutical preparations	R	pyrogen test or bacterial endotoxins test replaced by reference to new chapter Pyrogenicity 5.1.13 2.6.1. Sterility	
EP [35.1]	monograph	sodium citrate dehydrate	R	rabbit pyrogen test delete, replace by reference to general monograph Substances for pharmaceutical use (2034)	
EP [35.1]	monograph	Solutions for organ preservation	R	pyrogen test or bacterial endotoxins test replaced by reference to new chapter Pyrogenicity 5.1.13 2.6.1. Sterility NMT 0.5 endotoxin equivalents/mL	
EP [35.1]	monograph	substances for pharmaceutical use	R	pyrogen test or bacterial endotoxins test replaced by reference to new chapter Pyrogenicity 5.1.13 2.6.1. Sterility, 5.1.4. Microbiological quality	
EP [35.1]	monograph	sugar spheres	R	microbial enumeration, tests for specified microorganisms TAMV: 10 ³ cfu/g TYMC: 10 ² cfu/g Absence of <i>E. coli</i> Absence of <i>Salmonella</i>	
EP [35.1]	monograph	Technetium (99mTc) human albumin injection	R	2.6.1. Sterility bacterial endotoxins: < 175/V IU/mL (V = maximum recommended dose in mL)	
EP [35.1]	monograph	Tick-borne encephalitis vaccine (inactivated)	R	pyrogens test eliminated, reference now made to general monograph Vaccines for human use (0153) 2.6.1. Sterility 2.6.7. Mycoplasmas	
EP [35.1]	monograph	Vaccines for human use	R	pyrogen test or bacterial endotoxins test replaced by reference to new chapter Pyrogenicity 5.1.13 2.6.1 Sterility	
IP	monograph	Atropine Ophthalmic Solution	N	2.2.11. Sterility	
IP	monograph	Azacitidine for Injection	N	2.2.11. Sterility 2.2.3. Bacterial endotoxins: NMT 1.0 endotoxin units/mg	
IP	monograph	Azilsartan Kamedoxomil	N	2.2.9. Microbial contamination: TAMC: NMT 1000 cfu/g, TYMC NMT 100 cfu/g, absence of <i>E. coli</i> in 1g.	
IP	monograph	Barium sulphate oral suspension	R	Change from: The total aerobic viable count is not more than 100 cfu per ml, the total combined molds and yeasts count is not more than 10 cfu per ml. 1 g is free from <i>Staphylococcus aureus</i> and <i>Pseudomonas aeruginosa</i> and 10 g is free from <i>Salmonella</i> species. to: The total aerobic viable count is not more than 100 cfu per ml, the total combined molds and yeasts count is not more than 10 cfu per ml. 1 g is free from <i>Escherichia coli</i> , <i>Staphylococcus aureus</i> and <i>Pseudomonas aeruginosa</i> and 10 g is free from <i>Salmonella</i> species.	
IP	monograph	Brivaracetam Injection	N	2.2.11. Sterility 2.2.3. Bacterial endotoxins: NMT 2 endotoxin units/mg	
IP	monograph	Brivaracetam Oral Solution	N	2.2.9. Microbial contamination: TAMC: NMT 100 cfu/mL, TYMC NMT 10 cfu/g, absence of <i>E. coli</i> in 1ml.	

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IP	monograph	Cetirizine Hydrochloride Oral Solution	N	2.2.9. Microbial contamination: TAMC: NMT 100 cfu/mL, TYMC NMT 10 cfu/mL, absence of <i>E. coli</i> in 1ml.	
IP	monograph	Dextrose	R	2.2.3. Bacterial endotoxins: NMT 0.5 endotoxin units/mL of 5% solution in water for injections	
IP	monograph	Lactulose Solution	N	2.2.9. Microbial contamination: TAMC: NMT 100 cfu/g, TYMC NMT 10 cfu/g, absence of <i>E. coli</i> in 1g	
IP	monograph	Mefenamic Acid Suspension	N	2.2.9. Microbial contamination	X
IP	monograph	Moxifloxacin Tablets	N	2.2.9. Microbial contamination	X
IP	monograph	Microcrystalline cellulose	N	2.2.9. Microbial contamination: TAMC: NMT 1000 cfu/g, TYMC NMT 10 cfu/g, absence of <i>S. aureus</i> , <i>E. coli</i> in 1g; <i>Salmonella</i> and <i>Shigella</i> in 10 g	
IP	monograph	Paracetamol and Tramadol Hydrochloride Tablets	N	2.2.9. Microbial contamination	X
IP	monograph	Perampanel	N	2.2.9. Microbial contamination: TAMC: NMT 1000 cfu/g, TYMC NMT 100 cfu/g, absence of <i>S. aureus</i> , <i>P. aeruginosa</i> , <i>E. coli</i> in 1g	
IP	monograph	Perampanel tablets	N	2.2.9. Microbial contamination: TAMC: NMT 1000 cfu/g, TYMC NMT 100 cfu/g, absence of <i>S. aureus</i> , <i>P. aeruginosa</i> , <i>E. coli</i> in 1g	
IP	monograph	Phenylephrine injection	R	change to NMT 25.0 endotoxin units/mg phenylephrine hydrochloride	
IP	monograph	Remogliflozin Etabonate Tablets	N	2.2.9. Microbial contamination: TAMC: NMT 1000 cfu/g, TYMC NMT 100 cfu/g, absence of <i>S. aureus</i> , <i>P. aeruginosa</i> , <i>E. coli</i> in 1g	
IP	monograph	Molnupiravir Capsules	N	2.2.9. Microbial contamination: TAMC: NMT 1000 cfu/g, TYMC NMT 100 cfu/g, absence of <i>S. aureus</i> , <i>P. aeruginosa</i> , <i>E. coli</i> in 1g	
IP	monograph	Starch	R	2.2.9. Microbial contamination: change to The total aerobic viable count is not more than 1000 cfu per g, the total fungal count is not more than 100 cfu per g, determined by plate count. 1 g is free from <i>Escherichia coli</i> and 10 g is free from <i>Salmonella</i> and <i>Shigella</i>	
IP	monograph	Gliclazide Prolonged-release Tablets	N	2.2.9. Microbial contamination	X
IP	monograph	Sofosbuvir and Velpatasvir Tablets	N	2.2.9. Microbial contamination	X
IP	monograph	Bilastine tablets	N	2.2.9. Microbial contamination	X
IP	monograph	cellulose acetate	N	2.2.9. Microbial contamination	
IP	monograph	Lenalidomide Capsules	N	2.2.9. Microbial contamination	X
IP	monograph	Miltefosine Capsules	N	2.2.9. Microbial contamination	X
IP	monograph	Pantoprazole for Injection	N	2.2.11. Sterility	
IP	monograph	saline nasal solution	N	2.2.9. Microbial contamination: TAMC: NMT 100 cfu/mL, TYMC NMT 10 cfu/mL, absence of <i>P. aeruginosa</i> , <i>S. aureus</i> , <i>B. cepacia</i> in 1ml.	
IP	monograph	Sodium bicarbonate tablets	N	2.2.9. Microbial contamination	X

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IP	general chapter	Substitution of in-vivo Method(s) by in-vitro Method(s) for the Quality Control of Vaccines	N	endotoxins	
IP	general chapter	Guidelines on the Bacterial Endotoxins Tests	N	endotoxins, alternate test method	
IP	monograph	Carprofen Tablets	N	2.2.9. Microbial contamination	X
IP	monograph	Pimobendan Capsules	N	2.2.9. Microbial contamination	X
IP	monograph	Tilmicosin Injection	N	2.2.11. Sterility 2.2.3. Bacterial endotoxins: NMT 0.5 endotoxin units/mL	
IP	general chapter	2.7.8. Tests for Absence of Non-Avian Mycoplasmas and Ureaplasmas	N	mycoplasmas	
IP	general chapter	2.7.9. Test for Absence of Avian Mycoplasma in Live Viral Poultry Vaccines	N	mycoplasmas	
IP	general chapter	Healthy Chicken Flocks for the Production of Inactivated Vaccines for Veterinary Use	N	mycoplasmas	
IP	general chapter	Management of Extraneous Agents in Immunological Veterinary Medicinal Products	R	2.2.11. Sterility 2.7.4/2.7.8./2.7.9. mycoplasmas	
IP	general chapter	Veterinary Vaccines: General Requirements	R	antimicrobial preservatives, pyrogens, sterility, mycoplasma	
IP	general chapter	2.2.9. Microbial contamination in Non sterile products	R	Change from: Then select the plates corresponding to a given dilution and showing the highest number of colonies but less than 250 for aerobic microorganisms and 25 colonies for fungi. to: Then select the plates corresponding to a given dilution and showing the highest number of colonies but less than 250 for aerobic microorganisms and 50 colonies for total fungal count.	
JP [Dec 2022]	monograph	Lithium Carbonate Tablets	R	microbial enumeration, tests for specified microorganisms	X
JP [Dec 2022]	monograph	Amlexanox	delete	microbial enumeration, tests for specified microorganisms	X
JP [Dec 2022]	monograph	Amlexanox Tablets	delete	microbial enumeration, tests for specified microorganisms	X
JP [Dec 2022]	monograph	Tolbutamine	delete	microbial enumeration, tests for specified microorganisms	X

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Compendium	Proposal Type	Title	New[N] / Revised[R]	Synopsis [requirements or description]	BG
JP [Dec 2022]	monograph	Tolbutamine Tablets	delete	microbial enumeration, tests for specified microorganisms	X
USP PF 48(6)	general chapter	Liposome drug products	N	sterility, endotoxins	
USP PF 48(6)	monograph	Acetylcysteine Injection	N	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 48(6)	monograph	boric acid	R	Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 48(6)	monograph	Celecoxib Capsules	N	Microbial Enumeration Tests <61>: TAMC NMT 10 ³ cfu/g TCMY NMT 10 ² cfu/g Tests for Specified Microorganisms <62>: absence of <i>E. coli</i>	
USP PF 48(6)	monograph	Chondroitin Sulfate Sodium, Shark	R	Microbial Enumeration Tests <2021>: TAMC NMT 10 ³ cfu/g TCMY NMT 10 ² cfu/g Tests for Specified Microorganisms <2022>: absence of <i>Salmonella sp.</i> , <i>E. coli</i>	
USP PF 48(6)	monograph	Cranberry Fruit Juice	R	Microbial Enumeration Tests <2021>: TAMC NMT 10 ⁴ cfu/g TCMY NMT 10 ³ cfu/g Tests for Specified Microorganisms <2022>: absence of <i>Salmonella sp.</i> , <i>E. coli</i>	
USP PF 48(6)	monograph	Cranberry Fruit Juice concentrate	R	Microbial Enumeration Tests <2021>: TAMC NMT 10 ⁴ cfu/g TCMY NMT 10 ³ cfu/g Tests for Specified Microorganisms <2022>: absence of <i>Salmonella sp.</i> , <i>E. coli</i>	
USP PF 48(6)	monograph	Desonide Cream	N	Microbial Enumeration Tests <61>: TAMC NMT 10 ² cfu/g TCMY NMT 10 ¹ cfu/g Tests for Specified Microorganisms <62>: absence of <i>S. aureus</i> , <i>P. aeruginosa</i>	
USP PF 48(6)	monograph	Desonide lotion	N	Microbial Enumeration Tests <61>: TAMC NMT 10 ² cfu/mL TCMY NMT 10 ¹ cfu/mL Tests for Specified Microorganisms <62>: absence of <i>S. aureus</i> , <i>P. aeruginosa</i>	
USP PF 48(6)	monograph	Desonide ointment	N	Microbial Enumeration Tests <61>: TAMC NMT 10 ² cfu/g TCMY NMT 10 ¹ cfu/g Tests for Specified Microorganisms <62>: absence of <i>S. aureus</i> , <i>P. aeruginosa</i>	
USP PF 48(6)	monograph	dl-Lactide and Glycolide (50:50) Copolymer 12000 Ethyl Ester	N	Microbial Enumeration Tests <61>: TAMC NMT 10 ³ cfu/g TCMY NMT 10 ² cfu/g Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 48(6)	monograph	Fludeoxyglucose F 18 Injection	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 48(6)	monograph	Hard Gelatin Capsule Shells	N	Microbial Enumeration Tests <61>: TAMC NMT 10 ³ cfu/g TCMY NMT 10 ² cfu/g [oral use] Tests for Specified Microorganisms <62>: absence of <i>E. coli</i> [oral use] Microbial Enumeration Tests <61>: TAMC NMT 10 ² cfu/g TCMY NMT 10 ¹ cfu/g [inhalation] Tests for Specified Microorganisms <62>: absence of <i>S. aureus</i> , <i>P. aeruginosa</i> and bile-tolerant Gram-negative bacteria [inhalation] Microbial Enumeration Tests <61>: TAMC NMT 10 ² cfu/g TCMY NMT 10 ¹ cfu/g [nasal use] Tests for Specified Microorganisms <62>: absence of <i>S. aureus</i> , <i>P. aeruginosa</i> [nasal use]	
USP PF 48(6)	monograph	Hydrocodone Bitartrate and Acetaminophen Oral Solution	N	Microbial Enumeration Tests <61>: TAMC NMT 10 ² cfu/mL TCMY NMT 10 ¹ cfu/mL Tests for Specified Microorganisms <62>: absence of <i>E. coli</i> Microbiological Examination of Nonsterile Products—Tests for <i>Burkholderia Cepacia</i> Complex <60>: Meets the requirements	

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USP PF 48(6)	monograph	Hard Hypromellose Capsule Shells	N	Microbial Enumeration Tests <61>: TAMC NMT 10 ³ cfu/g TCMY NMT 10 ² cfu/g [oral use] Tests for Specified Microorganisms <62>: absence of <i>E. coli</i> [oral use] Microbial Enumeration Tests <61>: TAMC NMT 10 ² cfu/g TCMY NMT 10 ¹ cfu/g [inhalation] Tests for Specified Microorganisms <62>: absence of <i>S. aureus</i> , <i>P. aeruginosa</i> and bile-tolerant Gram-negative bacteria [inhalation] Microbial Enumeration Tests <61>: TAMC NMT 10 ² cfu/g TCMY NMT 10 ¹ cfu/g [nasal use] Tests for Specified Microorganisms <62>: absence of <i>S. aureus</i> , <i>P. aeruginosa</i> [nasal use]	
USP PF 48(6)	monograph	Ioxilan Injection	delete	sterility, bacterial endotoxins	
USP PF 48(6)	monograph	Levofloxacin Ophthalmic Solution	N	Sterility Tests <71>: meets the requirements	
USP PF 48(6)	monograph	Levofloxacin oral Solution	R	Microbial Enumeration Tests <61>: TAMC NMT 10 ² cfu/mL TCMY NMT 10 ¹ cfu/mL Tests for Specified Microorganisms <62>: absence of <i>E. coli</i>	
USP PF 48(6)	monograph	Liothyronine Sodium Injection	N	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 48(6)	monograph	Menaquinone-7 Preparation	R	Microbial Enumeration Tests <2021>: TAMC NMT 10 ³ cfu/g TCMY NMT 10 ² cfu/g Tests for Specified Microorganisms <2022>: absence of <i>Salmonella sp.</i> , <i>E. coli</i> , <i>S. aureus</i>	
USP PF 48(6)	monograph	Mesalamine Suppositories	N	Microbial Enumeration Tests <61>: TAMC NMT 10 ³ cfu/g TCMY NMT 10 ² cfu/g	
USP PF 48(6)	monograph	pea protein	N	Microbial Enumeration Tests <2021>: TAMC NMT 10 ⁵ cfu/g TCMY NMT 10 ³ cfu/g Tests for Specified Microorganisms <2022>: absence of <i>Salmonella sp.</i> , <i>E. coli</i>	
USP PF 48(6)	monograph	Plerixafor	N	Microbial Enumeration Tests <61>: TAMC NMT 10 ² cfu/g TCMY NMT 10 ² cfu/g Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 48(6)	monograph	Plerixafor injection	N	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 48(6)	monograph	Hard Pullulan Capsule Shells	N	Microbial Enumeration Tests <61>: TAMC NMT 10 ³ cfu/g TCMY NMT 10 ² cfu/g [oral use] Tests for Specified Microorganisms <62>: absence of <i>E. coli</i> [oral use] Microbial Enumeration Tests <61>: TAMC NMT 10 ² cfu/g TCMY NMT 10 ¹ cfu/g [inhalation] Tests for Specified Microorganisms <62>: absence of <i>S. aureus</i> , <i>P. aeruginosa</i> and bile-tolerant Gram-negative bacteria [inhalation] Microbial Enumeration Tests <61>: TAMC NMT 10 ² cfu/g TCMY NMT 10 ¹ cfu/g [nasal use] Tests for Specified Microorganisms <62>: absence of <i>S. aureus</i> , <i>P. aeruginosa</i> [nasal use]	
USP PF 48(6)	monograph	Sodium Nitroprusside.	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 48(6)	monograph	Sodium Nitroprusside injection	N	sterility, bacterial endotoxins Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 48(6)	monograph	Red Yeast Dry Extract	N	Microbial Enumeration Tests <2021>: TAMC NMT 10 ⁴ cfu/g TCMY NMT 10 ² cfu/g, bile-tolerant Gram-negative bacteria NMT 10 ³ cfu/g Tests for Specified Microorganisms <2022>: absence of <i>Salmonella sp.</i> , <i>E. coli</i> , <i>S. aureus</i>	

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USP PF 48(6)	monograph	red yeast rice powder	N	Microbial Enumeration Tests <2021>: TAMC NMT 10 ⁴ cfu/g TCMY NMT 10 ² cfu/g, bile-tolerant Gram-negative bacteria NMT 10 ³ cfu/g Tests for Specified Microorganisms <2022>: absence of <i>Salmonella</i> sp., <i>E. coli</i> , <i>S. aureus</i>	

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