Date of This Update: January 9, 2024

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 [1/4/2024]	monograph	Verapamil Injection	R	"The injection complies with the requirements stated under Parenteral Preparations and with the following requirements."	
BP [1/4/2024]	monograph	Salbutamol Injection	R	"The injection complies with the requirements stated under Parenteral Preparations and with the following requirements."	
BP [1/4/2024]	monograph	Propranolol Oral Solution	R	"The oral solution complies with the requirements stated under Oral Liquids and with the following requirements."	
BP [1/4/2024]	monograph	Propranolol Injection	R	"The injection complies with the requirements stated under Parenteral Preparations and with the following requirements."	
BP [1/4/2024]	monograph	Paediatric Paracetamol Oral Suspension	R	"The oral suspension complies with the requirements stated under Oral Liquids and with the following requirements."	
BP [1/4/2024]	monograph	Paediatric Paracetamol Oral Solution	R	"The oral solution complies with the requirements stated under Oral Liquids and with the following requirements."	
BP [1/4/2024]	monograph	Iron Dextran Injection	R	"Bacterial endotoxins The endotoxin limit concentration is 0.50 IU per mg of iron, Appendix XIV C."	
BP [1/4/2024]	monograph	Solifenacin Oral Suspension	N	"The oral suspension complies with the requirements stated under Oral Liquids and with the following requirements."	
BP [1/4/2024]	monograph	Solifenacin Oral Solution	N	"The oral solution complies with the requirements stated under Oral Liquids and with the following requirements."	
BP [1/4/2024]	monograph	Paracetamol Infusion	N	"The infusion complies with the requirements stated under Parenteral Preparations and with the following requirements."	
BP [1/4/2024]	monograph	Marbofloxacin Injection	N	"The contents of the sealed container comply with the requirements for stated under Parenteral Preparations and with the following requirements."	
BP [1/4/2024]	monograph	Marbofloxacin Powder for Injection	N	"The contents of the sealed container comply with the requirements for Powders for Injections or Infusions stated under Parenteral Preparations and with the following requirements."	
BP [1/4/2024]	monograph	Bupivacaine and Fentanyl Injection	R	"The injection complies with the requirements stated under Parenteral Preparations and with the following requirements."	

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Compendium	Proposal Type	Title	New[N] / Revised[R]	Synopsis [requirements or description]	BG
EP 36.1	general chapter	2.6.7. Mycoplasmas	R	Includes sections: 1. Introduction 2. Culture method 2.1 Choice of culture media 2.2 Incubation conditions 2.3. Nutritive properties 2.4. Inhibitory substances 2.5 Test for mycoplasmas in the product to be examined 2.6.Interpretation of results 2.7 Recommended media for the culture method 3. Indicator cell culture method 3.1 Verification of the substrate 3.2 Inhibitory substances 3.3 Test method 3.4.Interpretation of results 4. Nucleic acid amplification techniques (NAT) 4.1. Introduction 4.2. Controls 4.3. Validation 4.4. Inhibitory substances 4.5. Interpretation of results Information section: Validation of nucleic acid amplification techniques (NAT) for the detection of mycoplasmas: guidelines	
EP 36.1	general chapter	5.1.9. Guidelines for Using the Test for Sterility	R	"The revised general chapter allows the use of alternative methods according to general chapter 5.1.6. Alternative methods for control of microbiological quality. In the Precautions against microbial contamination section, requirements about the environment and location in which the sterility test has to be performed have been simplified because this type of information is usually not defined in the Ph. Eur. The line stating that the sterility test is the only analytical method available to the authorities has been removed. Sampling plan considerations have been completed in order to also provide recommendations for terminally sterilised products and lyophilised products. Recommendations for sterility test invalidation are no longer limited to condition (d) of general chapter 2.6.1. Sterility."	
EP 36.1	monograph	Aluminum Hydroxide, Hydrated, for Adsorption	R	“**Bacterial endotoxins** (*2.6.14*): less than 5 IU of endotoxin per milligram of aluminium, if intended for use in the manufacture of an adsorbed product without a further appropriate procedure for the removal of bacterial endotoxins.”	
EP 36.1	monograph	Hemodialysis Solutions, Concentrated, Water for Diluting	R	Section: "**Microbiological monitoring**. During production and subsequent storage, appropriate measures are taken to ensure that the microbial count is adequately controlled and monitored. Appropriate alert and action levels are set so as to detect adverse trends. Under normal conditions, an appropriate action level is a microbial count of 100 CFU/mL, determined by filtration through a membrane with a nominal pore size not greater than 0.45 µm, using R2A agar, and incubating at 20-25 °C for not less than 7 days. The size of the sample is to be chosen in relation to the expected result.” “**Bacterial endotoxins** (2.6.14 or 2.6.32): less than 0.25 IU/mL.”	

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Compendium	Proposal Type	Title	New[N] / Revised[R]	Synopsis [requirements or description]	BG
EP 36.1	monograph	Hemodialysis, Concentrated, Solutions For	R	"**Microbial contamination** TAMC: acceptance criterion 102 CFU/mL (2.6.12). **Sterility** (2.6.1). If the label states that the concentrated haemodialysis solution is sterile, it complies with the test. **Pyrogenicity**. After dilution to obtain the final solution, the solution complies with a suitable test for pyrogenicity. Guidance for selection of a test is given in general chapter 5.1.13. The final solution contains no more than 0.25 endotoxin equivalents per millilitre. Where the test for bacterial endotoxins is selected, this limit is expressed in IU of endotoxin per millilitre."	
EP 36.1	monograph	Hemodialysis, Solutions For	R	**"Microbial contamination** TAMC: acceptance criterion 102 CFU/mL (2.6.12). Sterility (2.6.1). If the label states that the haemodialysis solution is sterile, it complies with the test for sterility. Pyrogenicity. The solution complies with a suitable test for pyrogenicity. Guidance for the selection of a test is given in general chapter 5.1.13. The solution contains not more than 0.25 endotoxin equivalents per millilitre. Where the test for bacterial endotoxins is selected, this limit is expressed in IU of endotoxin per millilitre."	
EP 36.1	monograph	Haemofiltration and Haemodiafiltration, Concentrated Solutions For	R	"**Microbial contamination** TAMC: acceptance criterion 102 CFU/mL (2.6.12). **Sterility** (2.6.1). If the label states that the concentrated solution for haemofiltration or haemodiafiltration is sterile, it complies with the test. **Pyrogenicity**. After dilution to obtain the final solution, this solution complies with a suitable test for pyrogenicity. Guidance for selection of a test is given in general chapter 5.1.13. The final solution contains no more than 0.25 endotoxin equivalents per millilitre. Where the test for bacterial endotoxins is selected, this limit is expressed in IU of endotoxin per millilitre."	
EP 36.1	monograph	Haemofiltration and Haemodiafiltration, Solutions For	R	"**Sterility** (*2.6.1*). The solution complies with the test. **Pyrogenicity.** The solution complies with a suitable test for pyrogenicity. Guidance for the selection of a test is given in general chapter 5.1.13. The solution contains not more than 0.05 endotoxin equivalents per millilitre. Where the test for bacterial endotoxins is selected, this limit is expressed in IU of endotoxin per millilitre."	
EP 36.1	monograph	Hepatitis A Vaccine (Inactivated, Adsorbed)	R	**"Bacterial and fungal contamination.** The single harvest complies with the test for sterility (2.6.1), carried out using 10 mL for each medium. **Mycoplasmas (2.6.7).** The single harvest complies with the test **Sterility** (2.6.1). The inactivated viral harvest complies with the test for sterility, carried out using 10 mL for each medium. **Bacterial endotoxins** (2.6.14): less than 2 IU per single human dose. **Sterility (2.6.1).** The final bulk vaccine complies with the test for sterility, carried out using 10 mL for each medium. **Sterility (2.6.1).** The vaccine complies with the test for sterility."	
EP 36.1	monograph	Influenza Vaccine (Split Virion, Inactivated)	R	"**Bacterial and fungal contamination**. Carry out the test for sterility (*2.6.1*), using 10 mL for each medium. **Mycoplasmas (2.6.7).** The virus seed lot complies with the test. **Sterility (2.6.1).** Carry out the test for sterility, using 10 mL for each medium. **Sterility (2.6.1).** Carry out the test for sterility, using 10 mL for each medium. **Sterility (2.6.1).** It complies with the test. **Bacterial endotoxins (2.6.14):** less than 100 IU per human dose."	

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EP 36.1	monograph	Influenza Vaccine (Surface Antigen, Inactivated, Prepared in Cell Cultures)	R	"**Bacterial and fungal contamination**. Carry out the test for sterility (*2.6.1*), using 10 mL for each medium. **Mycoplasmas (2.6.7).** The single harvest complies with the test. **Sterility (2.6.1).** Carry out the test for sterility, using 10 mL for each medium. **Sterility (2.6.1).** Carry out the test for sterility, using 10 mL for each medium. **Sterility (2.6.1).** It complies with the test. **Bacterial endotoxins (2.6.14):** less than 25 IU per human dose."	
EP 36.1	monograph	Influenza Vaccine (Surface Antigen, Inactivated, Virosome)	R	"**Bacterial and fungal contamination**. Carry out the test for sterility (*2.6.1*), using 10 mL for each medium. **Mycoplasmas** (2.6.7). The virus seed lot complies with the test. **Sterility** (2.6.1). Carry out the test for sterility, using 10 mL for each medium. **Sterility** (2.6.1). Carry out the test for sterility, using 10 mL for each medium. **Sterility** (2.6.1). It complies with the test for sterility **Bacterial endotoxins** (2.6.14): less than 100 IU per human dose."	
EP 36.1	monograph	Influenza Vaccine (Surface Antigen, Inactivated)	R	"**Bacterial and fungal contamination**. Carry out the test for sterility (*2.6.1*), using 10 mL for each medium. **Mycoplasmas** (2.6.7). The virus seed lot complies with the test. **Sterility** (2.6.1). Carry out the test for sterility, using 10 mL for each medium. **Sterility** (2.6.1). Carry out the test for sterility, using 10 mL for each medium. **Sterility (2.6.1).** It complies with the test. **Bacterial endotoxins** (2.6.14): less than 100 IU per human dose."	
EP 36.1	monograph	Influenza Vaccine (Whole Virion, Tnactivated)	R	"**Bacterial and fungal contamination**. Carry out the test for sterility (*2.6.1*), using 10 mL for each medium. **Mycoplasmas** (2.6.7). The virus seed lot complies with the test. **Sterility** (2.6.1). Carry out the test for sterility, using 10 mL for each medium. **Sterility** (2.6.1). Carry out the test for sterility, using 10 mL for each medium. **Sterility (2.6.1).** It complies with the test. **Bacterial endotoxins** (2.6.14): less than 100 IU per human dose."	
EP 36.1	monograph	JK-PSMA-7 (^{18}F) INJECTION3	N	"**Sterility**. It complies with the test for sterility prescribed in the monograph Radiopharmaceutical preparations (0125). The preparation may be released for use before completion of the test. **Bacterial endotoxins** (2.6.14): less than 175/V IU/mL, V being the maximum recommended dose in millilitres. The preparation may be released for use before completion of the test."	
EP 36.1	monograph	Peritoneal Dialysis, Solutions For	R	"**Sterility** (*2.6.1*). The solution complies with the test **Pyrogenicity**. The solution complies with a suitable test for pyrogenicity. Guidance for the selection of a test is given in general chapter 5.1.13. The solution contains no more than 0.05 endotoxin equivalents per millilitre.Where the test for bacterial endotoxins is selected, this limit is expressed in IU of endotoxin per millilitre."	
EP 36.1	monograph	Poliomyelitis Vaccine (Inactivated)	R	"**Bacterial and fungal contamination**. The single harvest complies with the test for sterility (*2.6.1*), carried out using 10 mL for each medium. **Mycoplasmas** (2.6.7). The single harvest complies with the test **Sterility** (2.6.1). The inactivated monovalent harvest complies with the test, carried out using 10 mL for each medium. **Sterility** (2.6.1). The final bulk vaccine complies with the test, carried out using 10 mL for each medium. **Sterility** (2.6.1). It complies with the test. **Bacterial endotoxins** (2.6.14): less than 5 IU per single human dose."	

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EP 36.1	monograph	Smallpox Vaccine (Live)	R	[vaccines produced in eggs] "**Sterility** (*2.6.1*). It complies with the test, carried out using 10 mL for each medium." [vaccines produced in eggs or cell cultures] "**Mycoplasmas** (*2.6.7*). For vaccines produced in eggs, the pooled harvest complies with the test. For vaccines produced in cell cultures, the test carried out on the single harvest may alternatively be performed on the pooled harvest, where justified and authorised." "**Bacterial and fungal contamination**. For vaccines other than those prepared on animal skins, the final bulk complies with the test for sterility (*2.6.1*), using 10 mL for each medium." "**Sterility** (*2.6.1*). Except for skin-derived vaccines, the vaccine complies with the test" [vaccines produced in living animals] "**Total bacterial count**: for vaccines produced on animal skins only, maximum 50 per millilitre, determined by plate count using a suitable volume of the final bulk vaccine. **Escherichia coli.** At least 1 mL samples of a 1:100 dilution of the final bulk vaccine is cultured on plates of a medium suitable for differentiating E. coli from other bacteria. The plates are incubated at 35-37 °C for 48 h. If E. coli is detected the final bulk is discarded or, subject to approval by the competent authority, processed further. **Haemolytic streptococci, coagulase-positive staphylococci or any other pathogenic micro-organisms which are known to be harmful to man by vaccination.** At least 1 mL samples of a 1:100 dilution of the final bulk vaccine are cultured on blood agar. The plates are incubated at 35-37 °C for 48 h. If micro-organisms are detected, the final bulk vaccine is discarded. **Bacillus anthracis.** Any colony seen on any of the plates that morphologically resembles B. anthracis is examined. If the organisms contained in the colony are non-motile, further tests for the cultural character of B. anthracis are carried out, including pathogenicity tests in suitable animals. If B. anthracis is found to be present, the final bulk vaccine and any other associated bulks are discarded. Additional validated molecular testing may be performed. **Clostridium tetani and other pathogenic spore-forming anaerobes.** A total volume of not less than 10 mL of the final bulk vaccine is distributed in equal amounts into 10 tubes, each containing not less than 10 mL of suitable medium for the growth of anaerobic micro-organisms. The tubes are kept at 65 °C for 1 h in order to reduce the content of non-spore-forming organisms, after which they are anaerobically incubated at 35-37 °C for at least 1 week. From every tube or plate showing growth, subcultures are made on plates of a suitable medium. Tubes and plates are incubated anaerobically at the same temperature. All anaerobic colonies are examined and identified and if C. tetani or other pathogenic spore-forming anaerobes are present, the final bulk is discarded." **"Bacterial count.** For skin-derived vaccines, examine the vaccine by suitable microscopic and culture methods for micro-organisms pathogenic for man and, in particular, haemolytic streptococci, staphylococci, pathogenic spore-bearing organisms, especially B. anthracis, and E. coli. The vaccine is free from such contaminants. The total number of non-pathogenic bacteria does not exceed 50 per millilitre." [for all vaccines] **"Bacterial endotoxins** (2.6.14). The vaccine complies with the	

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EP 36.1	monograph	Tick-borne Encephalitis Vaccine (Inactivated)	R	"**Bacterial and fungal contamination**. The single harvest complies with the test for sterility (2.6.1), carried out using 10 mL for each medium.27 **Mycoplasmas** (2.6.7). The single harvest complies with the test. **Sterility** (2.6.1). The purified, inactivated harvest complies with the test, carried out using 10 mL for each medium. **Sterility** (2.6.1). The final bulk vaccine complies with the test, carried out using 10 mL for each medium."	
EP 36.1	monograph	Vaccines for Veterinary Use	R	"3-8. **Bacteria and fungi**. Vaccines comply with the test for sterility (*2.6.1*). Where the volume of liquid in a container is greater than 100 mL, the membrane filtration method is used wherever possible. Where the membrane filtration method cannot be used, the direct inoculation method may be used. Where the volume of liquid in each container is at least 20 mL, the minimum volume to be used for each culture medium is 10 per cent of the contents or 5 mL, whichever is less. The appropriate number of items to be tested (*2.6.1*) is 1 per cent of the batch with a minimum of 4 and a maximum of 10. For live bacterial and for live fungal vaccines, the absence of micro-organisms other than the vaccine strain is demonstrated by suitable methods such as microscopic examination and inoculation of suitable media. For frozen or freeze-dried avian live viral vaccines produced in embryonated eggs, for non-parenteral use only, the requirement for sterility is usually replaced by requirements for absence of pathogenic micro-organisms and for a maximum of 1 non-pathogenic micro-organism per dose. For other vaccines presented in a non-liquid form for non-parenteral use only, in agreement with the competent authority and provided that the product remains stable throughout its shelf life, the requirement for sterility may be replaced by requirements for absence of relevant pathogenic micro-organisms and an appropriately low number of micro-organisms per dose, based on batch data and process validation. **3-11. Mycoplasmas (2.6.7).** Live viral vaccines comply with the test."	
EP 36.1	monograph	Yellow Fever Vaccine (Live)	R	"**Bacterial and fungal contamination**. The single harvest complies with the test for sterility (*2.6.1*), carried out using 10 mL for each medium. **Mycoplasmas** (2.6.7). The single harvest complies with the test. Alternatively, where justified and authorised, the test may be carried out on the pool of single harvests. **Mycobacteria** (2.6.2). A 5 mL sample of the single harvest or pool of single harvests is tested for the presence of Mycobacterium spp. by culture methods known to be sensitive for the detection of these organisms. **Bacterial and fungal contamination**. The final bulk vaccine complies with the test for sterility (2.6.1), carried out using 10 mL for each medium. **Bacterial and fungal contamination**. The reconstituted vaccine complies with the test for sterility (2.6.1). **Bacterial endotoxins** (2.6.14): less than 5 IU per single human dose."	
IP 21/12/2023	monograph	Tilmicosin Injection	N	"Bacterial endotoxins (2.2.3). Not more than 0.5 Endotoxin Unit per ml of tilmicosin. Sterility (2.2.11). Complies with the test for sterility."	
IP 21/12/2023	monograph	Flunixin Meglumine Injection	N	Sterility (2.2.11). Complies with the test for sterility. Bacterial endotoxins (2.2.3). Not more than 4.54 Endotoxin Unit per mg of flunixin.	
JP 32 4	monograph	Oxaliplatin	R	Bacterial endotoxins, microbial enumeration and tests for specified microorganisms	X
JP 32 4	monograph	Oxaliplatin Injection	R	Bacterial endotoxins, sterility	X
	Commenting for PF 49(6) open until January 31, 2024				

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USP 49(6)	general chapter	<86> Bacterial Endotoxins Test Using Recombinant Reagents	N	"This proposed new test chapter provides additional techniques using nonanimal derived reagents to the Bacterial Endotoxins Test 〈85〉. This general chapter is not currently being introduced into a specific monograph or listed in General Notices. It is the responsibility of the user to review the supplier's primary validation package and to verify product suitability for use in testing specific products or materials. This verification must include specific experiments to confirm that the method is suitable for its intended purpose under the conditions of use for the material, drug substance, and/or drug product. The selected verification experiments should be based on an assessment of the complexity of the material to which the method is being applied. The user should refer to Verification of Compendial Procedures 〈1226〉. Regulatory authorities may require supplemental data prior to acceptance. An example of supplemental data may include a comparative study of the material tested by techniques described in this chapter and those in 〈85〉."	
USP 49(6)	general chapter	<1040> Quality Considerations of Plasmid DNA as a Starting Material for Cell and Gene Therapies.	N	Includes: <85> Endotoxins: End use-specific; ≤10–100 EU/mg Bioburden: End use-specific; in general, ≤1 CFU/10 mL <71> Sterility: No growth [Note—Scale of manufacturing may make sampling per <71> difficult. See 5.1.12 Bioburden and Sterility for more details.] Mycoplasma: Should not be present in microbial generated plasmid DNA. Testing is optional depending on application. May be a requirement to rule out human contamination.	
USP 49(6)	monograph	1,2-Distearoyl-sn-glycero-3-phosphocholine	N	"Bacterial Endotoxins Test <85>: Where the label states that 1,2-Distearoyl-sn-glycero-3-phosphocholine must be subjected to further processing during the preparation of injectable dosage forms, the level of bacterial endotoxins is such that the requirement in the relevant dosage form monograph(s) in which 1,2-Distearoyl-sn-glycero-3-phosphocholine is used can be met. Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>: The total aerobic microbial count is NMT 102 cfu/g. The total combined yeasts and molds count is NMT 101 cfu/g. It meets the requirements of the tests for absence of Escherichia coli."	
USP 49(6)	monograph	Brivaracetam	N	"Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>: Where it is intended for use in preparing injectable dosage forms, the total aerobic microbial count is NMT 10^3 cfu/g and the total yeasts and molds count is NMT 10^2 cfu/g. It meets the requirements of the tests for absence of Salmonella species, Escherichia coli, Staphylococcus aureus, Enterobacteriaceae, and Pseudomonas aeruginosa. Bacterial Endotoxins Test <85>: Where the label states that Brivaracetam must be subjected to further processing during the preparation of injectable dosage forms, the level of bacterial endotoxins is such that the requirement in the relevant dosage form monograph(s) in which Brivaracetam is used can be met."	
USP 49(6)	monograph	Brivaracetam Injection	N	"Bacterial Endotoxins Test <85>:Meets the requirements. Sterility Tests <71>:Meets the requirements."	
USP 49(6)	monograph	Brivaracetam Oral Solution	N	"Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>:The total aerobic microbial count is NMT 10^2 cfu/mL, and the total yeasts and molds count is NMT 10^1 cfu/mL. It meets the requirements of the tests for the absence of Escherichia coli and Salmonella species."	
USP 49(6)	monograph	Buprenorphine and Naloxone Sublingual Film	N	"Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>:The total aerobic microbial count is NMT 10^2 cfu/g. The total combined yeasts and molds count is NMT 10^1 cfu/g. It meets the requirements of the tests for absence of Staphylococcus aureus and Pseudomonas aeruginosa."	

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USP 49(6)	monograph	Buspirone Hydrochloride Compounded Oral Suspension	N	"Beyond-Use Date: NMT 90 days after the date on which it was compounded when stored in a refrigerator or at controlled room temperature.[Note—This compounded preparation has met the requirements of Antimicrobial Effectiveness Testing <51>.]"	
USP 49(6)	monograph	Carprofen Compounded Oral Suspension, Veterinary	N	"Beyond-Use Date: NMT 90 days after the date on which it was compounded when stored in a refrigerator or at controlled room temperature.[Note—This compounded preparation has met the requirements of Antimicrobial Effectiveness Testing <51>.]"	
USP 49(6)	monograph	Daunorubicin Hydrochloride Injection.	N	"Sterility Tests 〈71〉:Meets the requirements. Bacterial Endotoxins Test 〈85〉:Meets the requirements."	
USP 49(6)	monograph	European Elder Berry Dry Juice	N	"Microbial Enumeration Tests 〈2021〉:The total aerobic bacterial count does not exceed 10^4 cfu/g, and the total combined molds and yeasts count does not exceed 10^3 cfu/g. Absence of Specified Microorganisms 〈2022, Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli: Meets the requirements."	
USP 49(6)	monograph	European Elder Berry Powder	N	"Microbial Enumeration Tests 〈2021〉:The total aerobic bacterial count does not exceed 10^4 cfu/g, and the total combined molds and yeasts count does not exceed 10^3 cfu/g. Absence of Specified Microorganisms 〈2022, Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli: Meets the requirements."	
USP 49(6)	monograph	Famotidine Compounded Injection	N	"Sterility Tests <71>, Test for Sterility of the Product to Be Examined, Membrane Filtration: It meets the requirements. Bacterial Endotoxins Test <85>: NMT 2.0 of Endotoxin Units/mg of famotidine Beyond-Use Date:In the absence of passing a sterility test and endotoxins test, the beyond-use dates (BUDs) in Pharmaceutical Compounding—Sterile Preparations <797> apply. If prepared as a Category 2 or Category 3 compounded sterile preparation (CSP) and the requirements of a sterility test and endotoxins test are met, NMT 90 days when stored at controlled room temperature or in a refrigerator."	
USP 49(6)	monograph	Fluphenazine Decanoate Injection	R	"Bacterial Endotoxins Test <85>: Meets the requirements. Sterility Tests <71>: Meets the requirements."	
USP 49(6)	monograph	Ibandronate Sodium	N	"Bacterial Endotoxins Test <85>: Where the label states that Ibandronate Sodium must be subjected to further processing during the preparation of injectable dosage forms, the level of bacterial endotoxins are such that the requirement under the relevant dosage form monograph(s) in which Ibandronate Sodium is used can be met."	
USP 49(6)	monograph	Ketamine Compounded Cream	N	"Beyond-Use Date:NMT 90 days after the date on which it was compounded when stored at controlled room temperature. [Note—This compounded preparation has met the requirements of Antimicrobial Effectiveness Testing <51>.]"	
USP 49(6)	monograph	Ketamine Hydrochloride Compounded Injection	N	"Sterility Tests <71>, Test for Sterility of the Product to Be Examined, Membrane Filtration: Meets the requirements. Bacterial Endotoxins Test <85>: NMT 0.4 USP Endotoxin Units/mg of ketamine hydrochloride. Beyond-Use Date:NMT 90 days after the date on which it was compounded when stored at controlled room temperature. [Note—This compounded preparation has met the requirements of Antimicrobial Effectiveness Testing <51>.]"	

Compendial Forum Updates Relevant to Microbiological Issues

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Compendium	Proposal Type	Title	New[N] / Revised[R]	Synopsis [requirements or description]	BG
USP 49(6)	monograph	Kit for Preparation of Technetium Tc 99m Pentetate Injection	R	"Bacterial Endotoxins Test <85>: Meets the requirements. Sterility Tests <71>: Meets the requirements."	
USP 49(6)	monograph	Locust Bean Gum	N	"Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>: The total aerobic microbial count does not exceed 10^4 cfu/g, and the total combined molds and yeasts count does not exceed 10^2 cfu/g. It meets the requirements of the tests for absence of Salmonella species and Escherichia coli. It is recommended that the enrichment broth contains a 1% cellulase solution additive to optimize the recovery of Salmonella from this material."	
USP 49(6)	monograph	Maca Root	N	"Microbial Enumeration Tests <2021>: The total aerobic bacterial count does not exceed 10^5 cfu/g, the total combined molds and yeasts count does not exceed 10^3 cfu/g, and the bile-tolerant Gram-negative bacterial count does not exceed 10^3 cfu/g. Absence of Specified Microorganisms <2022>, Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli: Meets the requirements"	
USP 49(6)	monograph	Maca Root Glucosinolates Dry Extract	N	"Microbial Enumeration Tests <2021>: The total aerobic bacterial count does not exceed 10^4 cfu/g, and the total combined molds and yeasts count does not exceed 10^3 cfu/g. Absence of Specified Microorganisms <2022>, Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli: Meets the requirements."	
USP 49(6)	monograph	Maca Root Powder	N	"Microbial Enumeration Tests <2021>: The total aerobic bacterial count does not exceed 10^5 cfu/g, the total combined molds and yeasts count does not exceed 10^3 cfu/g, and the bile-tolerant Gram-negative bacterial count does not exceed 10^3 cfu/g. Absence of Specified Microorganisms <2022>, Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli: Meets the requirements.	
USP 49(6)	monograph	Mannose	N	"Bacterial Endotoxins Test <85>: If labeled for use in preparing parenteral dosage forms, it also meets the following requirements. The level of bacterial endotoxins is such that the requirement in the relevant dosage form monograph(s) in which Mannose is used can be met. Where the label states that Mannose must be subjected to further processing during the preparation of injectable dosage forms, the level of bacterial endotoxins is such that the requirement in the relevant dosage form monograph(s) in which Mannose is used can be met. Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>: The total aerobic microbial count is NMT 10^3 cfu/g, and the total combined molds and yeasts count is NMT 10^2 cfu/g. If labeled for use in preparing dosage forms, it also meets the following requirements. The level of microorganisms (including specified microorganisms) is such that the requirement in the relevant dosage form monograph(s) in which Mannose is used can be met. It meets the requirements of the tests for absence of Escherichia coli, Salmonella species, Staphylococcus aureus, and Pseudomonas aeruginosa."	
USP 49(6)	monograph	Mesna Injection	N	"Sterility Tests <71>: Meets the requirements. Bacterial Endotoxins Test <85>: Meets the requirements."	
USP 49(6)	monograph	Morphine Sulfate Oral Solution	N	"Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>: The total aerobic microbial count is NMT 10^2 cfu/mL. The total combined yeasts and molds count is NMT 5×10^1 cfu/mL. It meets the requirements of the tests for absence of Escherichia coli and Salmonella species."	

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Compendium	Proposal Type	Title	New[N] / Revised[R]	Synopsis [requirements or description]	BG
USP 49(6)	monograph	Neostigmine Methylsulfate	R	"Bacterial Endotoxins Test <85>: Where the label states that Neostigmine Methylsulfate must be subjected to further processing during the preparation of injectable dosage forms, the level of bacterial endotoxins is such that the requirement in the relevant dosage form monograph(s) in which Neostigmine Methylsulfate is used can be met. Sterility Tests <71>: Where the label states that Neostigmine Methylsulfate is sterile, it meets the requirements. Microbial Enumeration Tests <61>: The total aerobic microbial count is NMT 10^2 cfu/g, and the total combined molds and yeast count is NMT 50 cfu/g."	
USP 49(6)	monograph	Neostigmine Methylsulfate Injection	R	"Sterility Tests <71>: Meets the requirements. Bacterial Endotoxins Test <85>: Meets the requirements."	
USP 49(6)	monograph	Red Clover	R	"'Microbial Enumeration Tests <2021>: The total aerobic microbial count does not exceed 10^6 cfu/g, the total combined molds and yeast count does not exceed 10^4 cfu/g, and the enterobacterial count is NMT 10^3 cfu/g. Absence of Specified Microorganisms <2022>, Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli: Meets the requirements"	
USP 49(6)	monograph	Powdered Red Clover	R	"'Microbial Enumeration Tests <2021>: The total aerobic microbial count does not exceed 10^4 cfu/g, the total combined molds and yeast count does not exceed 10^3 cfu/g.. Absence of Specified Microorganisms <2022>, Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli: Meets the requirements"	
USP 49(6)	monograph	Powdered Red Clover Extract	R	"'Microbial Enumeration Tests <2021>: The total aerobic microbial count does not exceed 10^6 cfu/g, the total combined molds and yeast count does not exceed 10^4 cfu/g, and the enterobacterial count is NMT 10^3 cfu/g. Absence of Specified Microorganisms <2022>, Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli: Meets the requirements"	
USP 49(6)	monograph	Sodium Phosphates Compounded Injection	R	"Sterility Tests <71>: Meets the requirements. Bacterial Endotoxins Test <85>: NMT 1.10 USP Endotoxin Units/mg of sodium phosphates."	
USP 49(6)	monograph	Tazobactam Sodium	N	"Bacterial Endotoxins Test <85>: Where the label states that Tazobactam Sodium must be subjected to further processing during the preparation of injectable dosage forms, the level of bacterial endotoxins is such that the requirement under the relevant dosage form monograph(s) in which Tazobactam Sodium is used can be met. Sterility Tests <71>: Where the label states that Tazobactam Sodium is sterile or that it must be subjected to further processing during the preparation of injectable dosage forms, it meets the requirements."	
USP 49(6)	monograph	Xanthan Gum	R	"Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>: It meets the requirements of the tests for Salmonella species and Escherichia coli."	
	Commenting for PF 50(1) open until March 31, 2024				

Compendial Forum Updates Relevant to Microbiological Issues

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Compendium	Proposal Type	Title	New[N] / Revised[R]	Synopsis [requirements or description]	BG
USP 50(1)	general chapter	<72> Respiration-Based Microbiological Methods for the Detection of Contamination in Short-Life Products	R	Sections include: Introduction Culture Media and Incubation Conditions Method Suitability Test Table 1: Strains of Microorganisms Suitable for Use in the Growth Promotion Test Determination of the Incubation Time in the Product to be Tested Test for Microbial Detection in the Product to be Tested Monitoring and Interpretation of Results	
USP 50(1)	general chapter	<73> ATP BioluminescenseBased—Based Microbiological Methods for the Detection of Contamination in Short-Life Products	R	Sections include: Introduction Culture Media and Incubation Temperatures Growth Promotion Test of Aerobes, Anaerobes, and Fungi Method Suitability Test Nutrient Broth Method Membrane Filtration Method Table 1: Strains of Microorganisms Suitable for Use in the Growth Promotion Test Determination of the Incubation Time of the Product to be Tested Test for Microbial Detection in the Product to be Tested Monitoring and Interpretation of Results	

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Compendium	Proposal Type	Title	New[N] / Revised[R]	Synopsis [requirements or description]	BG
USP 50(1)	general chapter	Rapid Microbial Tests for Release of Sterile Short-Life Products: A Risk-Based Approach	R	Sections include: Introduction Use Requirement Specifications for a Rapid Microbiological Method for the Detection of Contamination in Short-Life Products The Concept of Risk-Based Microbiological Monitoring and Release Testing Critical Operating Parameters to be Used in Determining a Risk-Based Rapid Microbiological Method for the Detection of Contamination in Short-Life Products Table 1: Typical Operational Parameters for Examples of Candidate Rapid Microbiological Technologies Same Size Considerations Table 2: Examples of Detecting Contamination Based on Different Contamination Levels, Product and Sample Volumes Example Technologies for the Detection of Contamination in Short-Life Products Brief Description of the Example Technologies Method Validation and Suitability Testing Glossary References	
USP 50(1)	general chapter	<1119> Bioburden Monitoring	N	Sections include: Introduction Risk-Based Bioburden Monitoring Bioburden Sampling Table 1: Consideration for Bioburden Sampling Bioburden Trest Method Table 2: Considerations for Bioburden Test User Requirements Assessment of Bioburden Monitoring Table 3: Recommended Bioburden Limits References Appendix	

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Compendium	Proposal Type	Title	New[N] / Revised[R]	Synopsis [requirements or description]	BG
USP 50(1)	general chapter	<1119.1> Bioburden Test	N	Sections include: Introduction General Procedures Enumeration Procedures Growth Promotion Test, Negative Controls, and Suitability of the Counting Method Table 1: Preparation and Use of the Test Microorganisms Negative Control Growth Promotion of the Nutrient Culture Media Suitability of the Counting Method in the Presence of Product Testing for Bioburden Membrane Filtration Pour-Plate Method and Surface-Spread Method	
USP 50(1)	general chapter	<1229.3> Monitoring of Bioburden	N	chapter to be omitted	
USP 50(1)	monograph	Amitriptyline Compounded Oral Suspension	N	“Beyond-Use Date:NMT 180 days after the date on which it was compounded when stored in a refrigerator or at controlled room temperature. [Note—This compounded preparation has met the requirements of Antimicrobial Effectiveness Testing <51>.]”	
USP 50(1)	monograph	Atracurium Besylate	R	“Bacterial Endotoxins Test <85>: Where the label states that Atracurium Besylate must be subjected to further processing during the preparation of injectable dosage forms, the level of bacterial endotoxins is such that the requirement in the relevant dosage form monograph(s) in which Atracurium Besylate is used can be met. Sterility Tests <71>: Where the label states that Atracurium Besylate is sterile, it meets the requirements. Microbial Enumeration Tests <61>: The total aerobic microbial count is NMT 10^2 cfu/g, and the total molds and yeast count is NMT 10^1 cfu/g.”	
USP 50(1)	monograph	Atracurium Besylate Injection	R	“Sterility Tests <71>: Meets the requirements Bacterial Endotoxins Test <85>: Meets the requirements”	
USP 50(1)	monograph	Bupivacaine Hydrochloride Compounded Injection	N	“Sterility Tests <71>: Meets the requirements. •Bacterial Endotoxins Tests <85>: NMT 2.5 USP Endotoxin Units/mg of bupivacaine hydrochloride. Beyond-Use Date:In the absence of passing a sterility test and endotoxins test, the beyond-use dates (BUDs) in Pharmaceutical Compounding—Sterile Preparations <797> apply. If prepared as a Category 2 or Category 3 compounded sterile preparation (CSP) and the requirements of a sterility test and endotoxins test are met, NMT 90 days when stored at controlled room temperature or in a refrigerator. [Note—This compounded preparation has met the requirements of Antimicrobial Effectiveness Testing <51>.].”	

Compendial Forum Updates Relevant to Microbiological Issues

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Compendium	Proposal Type	Title	New[N] / Revised[R]	Synopsis [requirements or description]	BG
USP 50(1)	monograph	Colistimethate Sodium	R	"Sterility Tests <71>: Meets the requirements when tested as directed for Test for Sterility of the Product to Be Examined, Membrane Filtration. Bacterial Endotoxins Test <85>: Where the label states that Colistimethate Sodium is sterile or must be subjected to further processing during the preparation of injectable dosage forms, the level of bacterial endotoxins is such that the requirement under the relevant dosage form monograph(s) in which Colistimethate Sodium is used can be met."	
USP 50(1)	monograph	Diazepam Compounded Injection	N	"Sterility Tests <71>: Meets the requirements Bacterial Endotoxins Test <85>: NMT 2.5 USP Endotoxin Units/mg of diazepam Beyond-Use Date:In the absence of passing a sterility test and endotoxins test, the beyond-use dates (BUDs) in Pharmaceutical Compounding—Sterile Preparations <797>a pply. If prepared as a Category 2 or Category 3 compounded sterile preparation (CSP) and a sterility test and endotoxins test are passed, NMT 90 days when stored at controlled room temperature or in a refrigerator. [Note—This compounded preparation has met the requirements in Antimicrobial Effectiveness Testing <51>.]"	
USP 50(1)	monograph	Diclofenac Sodium Compounded Topical Foam	N	"Beyond-Use Date:NMT 180 days after the date on which it was compounded when stored at controlled room temperature. [Note—This compounded preparation has met the requirements of Antimicrobial Effectiveness Testing <51>.]"	
USP 50(1)	monograph	Fentanyl Citrate Compounded Injection	R	"Sterility Tests <71>: Meets the requirements Bacterial Endotoxins Test <85>: NMT 50.0 USP Endotoxin Units/mg of fentanyl (NMT 2 USP Endotoxin Units/mg of fentanyl when administered intrathecally). Beyond-Use Date:In the absence of passing a sterility test and endotoxin test, the beyond-use dates in Pharmaceutical Compounding—Sterile Preparations 〈797〉 apply. If prepared as a Category 2 or Category 3 compounded sterile preparation (CSP) and a sterility test and endotoxins test are passed, NMT 90 days after the date on which it was compounded when stored at controlled room temperature or in a refrigerator."	
USP 50(1)	monograph	Guanidine Hydrochloride	R	"Bacterial Endotoxins Test <85>: If labeled for use in preparing parenteral dosage forms, it also meets the following requirements. The level of bacterial endotoxins is such that the requirement in the relevant dosage form monograph(s) in which Guanidine Hydrochloride is used can be met. Where the label states that Guanidine Hydrochloride must be subjected to further processing during the preparation of injectable dosage forms, the level of bacterial endotoxins is such that the requirement in the relevant dosage form monograph(s) in which Guanidine Hydrochloride is used can be met."	
USP 50(1)	monograph	Hydrocortisone Compounded Oral Suspension	R	"Beyond-Use Date Fomulation in Vehicle A:NMT 90 days after the date on which it was compounded when stored at controlled room temperature or in a refrigerator. [Note—This compounded preparation has met the requirements of Antimicrobial Effectiveness Testing <51>.] Formulation in Vehicle B:NMT 180 days after the date on which it was compounded when stored at controlled room temperature or in a refrigerator. [Note—This compounded preparation has met the requirements of Antimicrobial Effectiveness Testing <51>.]"	
USP 50(1)	monograph	Lacticaseibacillus rhamnosus	R	"Probiotic Tests <64>, Contaminants, Contaminant Microorganisms: The total combined molds and yeasts count does not exceed 102 cfu/g. The total non-lactic acid bacterial count is less than 5 × 103 cfu/g. Probiotic Tests <64>, Contaminants, Specified Microorganisms: It meets the requirements of the test for absence of Escherichia coli in 10 g. It meets the requirements of the test for absence of Salmonella."	

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Compendium	Proposal Type	Title	New[N] / Revised[R]	Synopsis [requirements or description]	BG
USP 50(1)	monograph	Leucovorin Calcium Compounded Injection	N	"Sterility Tests <71>: Meets the requirements. Bacterial Endotoxins Test <85>: NMT 1.95 USP Endotoxin Units/mg of leucovorin calcium. Beyond-Use Date:In the absence of passing a sterility test and endotoxins test, beyond-use dates (BUDs) in Pharmaceutical Compounding—Sterile Preparations <797> apply. If prepared as a Category 2 or Category 3 compounded sterile preparation (CSP) and a sterility test and endotoxins test is passed, NMT 90 days when stored at controlled room temperature or in a refrigerator."	
USP 50(1)	monograph	Lidocaine and Tetracaine Compounded Topical Cream	N	"Beyond-Use Date:NMT 90 days after the date on which it was compounded when stored in a refrigerator or at controlled room temperature. [Note—This compounded preparation has met the requirements of Antimicrobial Effectiveness Testing <51>.]"	
USP 50(1)	monograph	Lidocaine Hydrochloride Compounded Injection	N	"Sterility Tests <71>: Meets the requirements. Bacterial Endotoxins Test <85>: It meets the requirements. Beyond-Use Date:In the absence of passing a sterility test and endotoxins test, the beyond-use dates (BUDs) in <797> apply. If prepared as a Category 2 or Category 3 compounded sterile preparation (CSP) and the requirements of a sterility test and endotoxins test are met, NMT 90 days when stored at controlled room temperature. [Note—This compounded preparation has met the requirements for Antimicrobial Effectiveness Testing <51>]."	
USP 50(1)	monograph	Magnesium Sulfate Compounded Injection	N	"Sterility Tests <71>: Meets the requirements •Bacterial Endotoxins Test <85>: NMT 0.09 USP Endotoxin Units/mg of magnesium sulfateMetronidazole Compounded Oral Suspension •Beyond-Use Date:In the absence of passing a sterility test and endotoxins test, the beyond-use dates (BUDs) in Pharmaceutical Compounding—Sterile Preparations <797> apply. If prepared as a Category 2 or Category 3 compounded sterile preparation (CSP) and a sterility test and endotoxins test are passed, NMT 90 days when stored at controlled room temperature or in a refrigerator. [Note—This compounded preparation has met the requirements of Antimicrobial Effectiveness Testing <51>.]"	
USP 50(1)	monograph	Metronidazole Compounded Oral Suspension	N	"Beyond-Use Date:NMT 180 days after the date on which it was compounded, when stored at refrigerated or at controlled room temperature. [Note—This compounded preparation has met the requirements in Antimicrobial Effectiveness Testing <51>]."	
USP 50(1)	monograph	Mometasone Furoate Cream	R	"Tests for Specified Microorganisms <62>: It meets the requirements of the tests for absence of Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, and Salmonella species."	
USP 50(1)	monograph	Mometasone Furoate Ointment	R	"Tests for Specified Microorganisms <62>: It meets the requirements of the tests for absence of Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, and Salmonella species."	
USP 50(1)	monograph	Mometasone Furoate Topical Solution	R	"Tests for Specified Microorganisms <62>: It meets the requirements of the tests for absence of Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, and Salmonella species."	
USP 50(1)	monograph	Naltrexone Hydrochloride Compounded Oral Suspension	N	"Beyond-Use Date:NMT 90 days after the date on which it was compounded, when stored at controlled room temperature or in a refrigerator. [Note—This compounded preparation has met the requirements of Antimicrobial Effectiveness Testing <51>.]"	
USP 50(1)	monograph	Perilla Fruit	N	"Microbial Enumeration Tests <2021>: The total aerobic bacterial count does not exceed 10^5 cfu/g, the total combined molds and yeasts count does not exceed 10^3 cfu/g, and the bile-tolerant Gram-negative bacteria count does not exceed 10^3 cfu/g. Absence of Specified Microorganisms <2022>, Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli: Meets the requirements."	

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Compendium	Proposal Type	Title	New[N] / Revised[R]	Synopsis [requirements or description]	BG
USP 50(1)	monograph	Perilla Fruit Powder	N	"Microbial Enumeration Tests <2021>: The total aerobic bacterial count does not exceed 10^5 cfu/g, the total combined molds and yeasts count does not exceed 10^3 cfu/g, and the bile-tolerant Gram-negative bacteria count does not exceed 10^3 cfu/g. Absence of Specified Microorganisms <2022>, Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli: Meets the requirements."	
USP 50(1)	monograph	Sildenafil for Oral Suspension	N	"Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>: The total aerobic microbial count is NMT 10^3 cfu/g. The total combined yeasts and molds count is NMT 10^2 cfu/g. It meets the requirements of the tests for absence of Escherichia coli, Salmonella, Staphylococcus aureus, and Pseudomonas aeroginosa."	
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Compendial Forum Updates Relevant to Microbiological Issues

Because some of the proposals of the various forums often rely on linkages to general chapters, at times guesses based on dosage form need to be made as to whether the specific proposal makes a reference to microbiological requirements. When such a guess has been made, this is indicated with an X in the BG column. Remember that no guarantees are made relative to completeness of this update, and you should make reference to the respective pharmacopeial form if in doubt. BP: https://www.pharmacopoeia.com EP: https://pharmeuropa.edqm.eu/home IP: https://ipc.gov.in/#skltbsResponsive2 JP: https://www.pmrj.jp/eng/02/jpf_contents.html USP: https://www.usp.org. Sponsors of the PMF are indicated at the bottom.

Compendium	Proposal Type	Title	New[N] / Revised[R]	Synopsis [requirements or description]	BG
				http://www.sterile.com	
				https://www.rapidmicrobiology.com/subscribe	
		Giles Scientific, Inc.		https://www.biomic.com/trinity-v3.html	
		Special Process Services, LC		https://www.linkedin.com/in/joseph-connaghan-b663929	