Date of This Update: March 5, 2024

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
BP [comments due March 31, 2024]	monograph	Iron Dextran Injection	R	"Bacterial endotoxins The endotoxin limit concentration is 0.50 IU per mg of iron, Appendix XIV C."	
BP [comments due March 31, 2024]	monograph	Verapamil Injection	R	"The injection complies with the requirements stated under Parenteral Preparations and with the following requirements."	
BP [comments due March 31, 2024]	monograph	Salbutamol Injection	R	"The infusion complies with the requirements stated under Parenteral Preparations and with the following requirements."	
BP [comments due March 31, 2024]	monograph	Paracetamol Infusion	N	"The injection complies with the requirements stated under Parenteral Preparations and with the following requirements."	
BP [comments due March 31, 2024]	monograph	Marbofloxacin Injection	N	"The contents of the sealed container comply with the requirements for stated under Parenteral Preparations with the following requirements.	
BP [comments due March 31, 2024]	monograph	Bupivacaine and Fentanyl Injection	R	"The injection complies with the requirements stated under Parenteral Preparations and with the following requirements."	
EP 36.2	monograph	Nasal Preparations	R	"Unless otherwise justified and authorised, aqueous nasal preparations supplied in multidose containers contain a suitable preservative at a suitable concentration, except where the preparation itself has adequate antimicrobial properties. Preparations for administration to the injured nose, particularly when the mucosa is damaged, or prior to surgery are sterile and, unless otherwise justified and authorised, free from preservatives and supplied in single-dose containers." "TESTS Sterility (2.6.1). Where the label states that the preparation is sterile, it complies with the test.34 STORAGE If the preparation is sterile, store in a sterile, airtight, tamper-evident container." "LABELLING The label states: –the name of any added preservative; –where applicable, that the preparation is sterile; …"	

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EP 36.2	general chapter	Ear Preparations	R	"They are liquid, semi-solid or solid preparations containing one or more active substances in a suitable vehicle. They may contain excipients, for example to adjust the tonicity or viscosity of the preparation, to adjust or stabilise the pH, to increase the solubility of the active substances, to stabilise the preparation or to provide adequate antimicrobial properties. The excipients do not adversely affect the intended medicinal action of the preparation or, at the concentrations used, cause toxicity or undue local irritation. Preparations for administration to the injured ear, particularly where the eardrum is perforated, or prior to surgery are sterile and, unless otherwise justified and authorised, free from preservatives and supplied in single-dose containers. Ear preparations are supplied in multidose or single-dose containers provided, if necessary, with a suitable administration device which may be designed to avoid the introduction of contaminants. Unless otherwise justified and authorised, aqueous ear preparations supplied in multidose containers contain a suitable preservative at a suitable concentration, except where the preparation itself has adequate antimicrobial properties." "Sterility (2.6.1). Where the label states that the preparation is sterile, it complies with the test."	
EP 36.2	monograph	Pressurized Pharmaceutical Preparations	R	"Sterility (2.6.1). Where the label indicates states that the preparation is sterile, it complies with the test for sterility."	
IP 18/1/2024	monograph	Carbamazepine Oral Suspension	N	"Microbial contamination (2.2.9). Total microbial count is not more than 102 CFU per g. 1 g is free from Salmonella species and Escherichia coli."	
IP 18/1/2024	monograph	Ciprofloxacin for Oral Suspension	N	"Microbial contamination (2.2.9). Total aerobic viable count is not more than 10^3 CFU per g and total fungal count is not more than10^2 CFU per g determined by plate count. 1 g is free from Escherichia coli."	
IP 18/1/2024	monograph	Dihydroergotamine Injection	N	"Bacterial endotoxins (2.2.3). Not more than 175.0 Endotoxin units per mg of dihydroergotamine mesylate. Other tests. Comply with the test stated under Parenteral Preparations (Injections)."	
IP 18/1/2024	monograph	Ferric Carboxymaltose Injection	N	"Sterility (2.2.11). Complies with the test for sterility. Bacterial endotoxins (2.2.3). Not more than 3.7 Endotoxins Unit per mg of iron. Other tests. Comply with the tests stated under Parenteral Preparations (Injections)."	

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IP 1/3/2024 [comments due April 15, 2024]	general chapter	Disinfectants and Antiseptics Available at: https://ipc.gov.in/images/Disinfectant_and_Antiseptics.pdf	N	Includes the following sections: 1.0 Introduction 2.0 Classification of Disinfectant 3.0 Selection of an Antiseptic for Hand and Surgical Site Disinfection 4.0 Selection of a Disinfectant for Use in a Pharmaceutical Manufacturing Environment 5.0 Theoretical Discussion of Disinfectant Activity 6.0 Mechanism of Disinfectant Activity 7.0 Microbial Resistance to Disinfectants 8.0 Disinfectant Challenge Testing 9.0 Determination of Bactericidal, Fungicidal and Yeasticidal Activity of Antiseptic Medicinal Products 9.1 Principal 9.2 Test Organisms and Growth Conditions 9.2.1 Preparation of Test Strain 9.2.2 Preparation of Antiseptic Product Test Solution 9.2.3 Neutralizing Agents 9.3 Methods 9.3.1 Dilution Neutralization Method 9.3.1.1 Suitability of Test/Control 9.3.1.1.1 Experimental conditions control 9.3.1.1.2 Neutralising agent control 9.3.1.1.3 Dilution-neutralisation method control 9.3.2 Membrane Filtration Method 9.3.2.1 Verification of the selected experimental conditions and of the membrane filtration method 9.3.2.1.1 Experimental Conditions Control 9.3.2.1.2 Membrane Filtration Method Control 9.4 Acceptance Criteria 10 Disinfectants in a Cleaning and Sanitization Program 11 Definitions	
USP 50(2)	monograph	Argatroban in Sodium Chloride Injection	N	“Sterility Tests <71>: Meets the requirements Bacterial Endotoxins Test <85>: Meets the requirements”	
USP 50(2)	monograph	Cisatracurium Besylate	R	changes made: “6. Add the Bacterial Endotoxins Test, Microbial Enumeration Tests, Tests for Specified Microorganisms, Sterility Tests, and a Labeling section to support preparation of sterile drug products.”	
USP 50(2)	monograph	Cumin 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 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 50(2)	monograph	Cumin Fruit Dry Extract	N	“Microbial Enumeration Tests <2021>: The total aerobic bacterial count does not exceed 10^4 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”	

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USP 50(2)	monograph	Cumin 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 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 50(2)	monograph	Metronidazole Vaginal Gel	N	"Microbiological Examination of Nonsterile Products—Tests for Burkholderia Cepacia Complex <60>: Meets the requirements Microbial Enumeration Tests <61>: The total aerobic microbial count does not exceed 10^2 cfu/g. The total molds and yeasts count does not exceed 10^1 cfu/g. Tests for Specified Microorganisms <62>: It meets the requirements of the tests for absence of Staphylococcus aureus, Pseudomonas aeruginosa, and Candida albicans."	
USP 50(2)	monograph	Norepinephrine Bitartrate Injection	R	changes made: "Revise the requirement in the Bacterial Endotoxins Test to remove the numerical limit and refer to Bacterial Endotoxins Test <85> for the calculation of limits."	
USP 50(2)	monograph	Sodium Oleate	N	"Microbial Enumeration Tests <61>: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. Tests for Specified Microorganisms <62>:It meets the requirements of the test for absence of Escherichia coli. Bacterial Endotoxins Test <85> For Sodium Oleate intended for use in the manufacture of injectable dosage forms:The level of bacterial endotoxins is such that the requirement in the relevant dosage form monograph(s) in which Sodium Oleate is used can be met. Where the label states that Sodium Oleate 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 Sodium Oleate is used can be met."	
USP 50(2)	monograph	Sunitinib Capsules	N	"Microbial Enumeration Tests <61> :The total aerobic microbial count is NMT 10^3cfu/g. The total combined yeasts and molds count is NMT 10^2 cfu/g. Tests for Specified Microorganisms <62>: It meets the requirements of the tests for absence of Escherichia coli."	
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	NOVATEK INTERNATIONAL			https://ntint.com/	
	Rapidmicro biosystems®			https://www.rapidmicrobio.com	
	STERIS®			http://www.sterislifesciences.com/	
	vai VELTEK ASSOCIATES, INC.			http://www.sterile.com	
	rapid microbiology FOCUSED ON MICROBIOLOGY			https://www.rapidmicrobiology.com/subscribe	
	Giles Scientific, Inc.			https://www.biomic.com/trinity-v3.html	
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