







Compendial Forum Updates Relevant to Microbiological Issues					
Publications referred to in this report all pertain to the respective Forums of the listed compendia. 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. The contents of this report are for educational purposes only.					
Here are links to the respective forums: BP: https://www.pharmacopoeia.com EP: https://pharmeuropa.edqm.eu/home IP: https://ipc.gov.in/#skitbsResponsive2 JP: https://www.pmda.go.jp/english/rs-sb-std/standards-development/jp/0013.html USP: https://www.usp.org . WHO: https://digidigitcollections.net/phint/2025/index.html#p/home .					
An “X” in the Sidecar column indicates that there is a YouTube video associated with the item. “Sidecars” videos are designed to be thought provoking, as per the white paper “Critical Scientific Thinking, SOPs and “Sidecars” at https://microbiologyforum.org/Articles/White_Papers/Critical_Scientific_Thinking_and_SOPs.pdf . Sidecars will be added periodically and listed here, at the PMF web site Training Tab [https://microbiologyforum.org/Training.html], and via online PMF Forum postings [https://microbiologyforum.org/Forum.html].					
Sponsors of the PMF are indicated at the bottom.					
Compendium	Proposal Type	Title	New[N] / Revised[R]	Synopsis [requirements or description]	Side Car
BP	monograph	Marbofloxacin Injection	N	<i>The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.</i>	
BP	monograph	Docetaxel Sterile Concentrate	N	<i>The concentrate complies with the requirements for Concentrates for Injections or Infusions stated under Parenteral Preparations and with the following requirements.</i>	
EP [37.4] [comment deadline 12/31/2025]	monograph	Clindamycin Phosphate	R	Bacterial endotoxins: the test has been deleted in accordance with the Ph. Eur. policy adopted in February 2015 (see Pharmeuropa online, Technical information). [link to February 2015 PE policy: https://assets-us-01.kc-usercontent.com/49d837e7-4c3e-0071-59f0-cb4344fbf121/5993b6dd-bd46-4f7c-be29-4b826cae4ff/Ph_Eur_policy_for_Pharmeuropa_E.pdf	
IP [published 7/24/2024] [no new relevant items as of this report date]					
JP [published 9/30/2024] https://www.pmda.go.jp/files/jp/files/000270298.pdf [no new relevant items as of this report date]					
USP [PF 51(5)]	chapter	Collagenase I	R	Bacterial Endotoxins Test <85>: NMT 50 USP Endotoxin Units/mg of protein Microbial Enumeration Tests <61>: The total bacterial count is NMT 100 cfu/mL.	
USP [PF 51(5)]	chapter	<823> Positron Emission Tomography Drugs for Compounding, Investigational, and Research Uses	R	Microbiologically relevant sections include: Introduction Personnel Training and Qualification Requirements Aseptic Operations Training Aseptic Qualifications Quality Assurance Facilities and Equipment Environmental Monitoring Cleaning and Disinfecting Process and Operational Controls Stability Controls and Acceptance Criteria for Finished PET Drug Products If a PET Drug Product Does Not Conform to Specifications Glossary	
USP [PF 51(5)]	chapter	<1113> Microbial Characterization, Identification, and Strain Typing	R	Chapter includes these sections: Introduction Identification Strategy Isolation of Pure Cultures Morphological Characterization Microbial Identification Methods Qualification of Microbial Identification Methods Microbial Classification Changes Glossary	
USP [PF 51(5)]	chapter	<1117> Microbiological Best Laboratory Practices	R	Chapter includes these sections: Introduction Preparation and Quality Control of Laboratory Media Microbiological Media Incubation Times Incubation Temperature Excursions Maintenance of Microbiological Cultures Laboratory Equipment Laboratory Layout and Operations Sample Handling Competencies and Training of Personnel Considerations for Investigations and Microbiological Risk Assessments Laboratory Resources Method Transfer Enumerative Microbiology Data Integrity of Microbiological Data Interpretation of Assay Results References	
USP [PF 51(5)]	chapter	<2760> Impurities and Contaminants in Dietary Ingredients and Dietary Supplements	N	Includes references to: Microbial Enumeration Tests <2021> Absence of Specified Microorganisms <2022> Microbiological Attributes of Nonsterile Nutritional and Dietary Supplements <2023>	
USP [PF 51(5)]	monograph	Adapalene Cream	N	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 50 ¹ cfu/g. Tests for Specified Microorganisms <62>: It meets the requirements of the tests for absence of <i>Staphylococcus aureus</i> and <i>Pseudomonas aeruginosa</i> .	
USP [PF 51(5)]	monograph	Bacitracin	R	Sterility Tests <71>: Where the label states that the Bacitracin is sterile, it meets the requirements.	
USP [PF 51(5)]	monograph	Bacitracin Zinc	R	Sterility Tests <71>: Where the label states that it is sterile, it meets the requirements. If the membrane filtration test is used, add 20 g of edetate disodium to each liter of Fluid A.	
USP [PF 51(5)]	monograph	Cloxacillin Sodium Intramammary Infusion	proposed for omission	Sterility Tests <71>: Where the label states that it is sterile, it meets the requirements when tested as directed in Test for Sterility of the Product to Be Examined, Direct Inoculation of the Culture Medium, except use Fluid Thioglycollate Medium containing polysorbate 80 solution (1 in 200) and an amount of sterile penicillinase sufficient to inactivate the cloxacillin in each tube, use Soybean–Casein Digest Medium containing polysorbate 80 solution (1 in 200) and an amount of sterile penicillinase sufficient to inactivate the cloxacillin in each tube, and shake the tubes once daily.	
USP [PF 51(5)]	monograph	Formoterol Fumarate Inhalation Solution	N	Sterility Tests <71>: Meets the requirements	
USP [PF 51(5)]	monograph	Karaya Gum	N	Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>: It meets the requirements of the tests for absence of <i>Salmonella</i> species and <i>Escherichia coli</i> .	
USP [PF 51(5)]	monograph	Mate Leaf	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. Absence of Specified Microorganisms <2022>, Test Procedures, Test for Absence of <i>Salmonella</i> Species and Test for Absence of <i>Escherichia coli</i> : Meets the requirements	
USP [PF 51(5)]	monograph	Mate Leaf Aqueous Dry Extract	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 <i>Salmonella</i> Species and Test for Absence of <i>Escherichia coli</i> : Meets the requirements	
USP [PF 51(5)]	monograph	Mate Leaf 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 <i>Salmonella</i> Species and Test for Absence of <i>Escherichia coli</i> : Meets the requirements	
USP [PF 51(5)]	monograph	Teriparatide	R	Bacterial Endotoxins Test <85>: Where the label states that Teriparatide 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 Teriparatide is used can be met. •Microbial Enumeration Tests <61>: For solid Teriparatide, the total aerobic microbial count is NMT 10 ² cfu/g. For aqueous Teriparatide, the total aerobic microbial count is NMT 1 cfu/10 mL, and the yeasts and molds count is NMT 1 cfu/10 mL	
USP [PF 51(5)]	monograph	Tromethamine Hydrochloride	N	Microbial Enumeration Tests <61>: The total aerobic microbial count is NMT 10 ³ cfu/mL. The total combined yeasts and molds count is NMT 10 ² cfu/mL. Tests for Specified Microorganisms <62>: It meets the requirements of the tests for absence of <i>Salmonella</i> species and <i>Escherichia coli</i> . 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 Tromethamine Hydrochloride is used can be met. Where the label states that Tromethamine 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 Tromethamine Hydrochloride is used can be met.	
USP [PF 51(5)]	monograph	Water-Soluble Vitamins Chewable Gels	N	Microbial Enumeration Tests <2021>: The total aerobic microbial count does not exceed 10 ³ cfu/g, and the total combined molds and yeasts count does not exceed 10 ² cfu/g. Absence of Specified Microorganisms <2022>, Test Procedures, Test for Absence of <i>Salmonella</i> Species and Test for Absence of <i>i</i> : Meet the requirements	
WHO [01/2025] [no new relevant items as of this report date]					
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