

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/#skitbsResponsive2> 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
EP 35.2	monograph	Aprotinin concentrated solution	R	Bacterial endotoxins (2.6.14.) less than 0.14 IU per European Pharmacopoeia Unit of aprotinin	
EP 35.2	monograph	Cholesterol for parenteral use	R	Microbial contamination (2.6.12.): TAMC 10 ² cfu/g	
EP 35.2	monograph	Gallium (⁶⁸ Ga) Chloride (Accelerator-Produced) Solution for Radiolabelling	R	Bacterial endotoxins (2.6.14.) less than 80 IU/batch. Sterility (as per monograph Radiopharmaceutical preparations (0125)).	
USP 49(3)	chapter	<2> Oral Drug Products— Product Quality Tests	R	Specific tests for liquids: Tests for Burkholderia Cepacia Complex <60> , Microbial Enumeration Tests <61> , and Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use <1111> .	
USP 49(3)	chapter	<1568> Quality Considerations for Cannabis and Cannabis-Derived Products for Clinical Research	N	Microbial contaminants section includes Microbial Enumeration Tests <61> , Tests for Specified Microorganisms <62> ,Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use <1111>	
USP 49(3)	monograph	Aminopentamide Sulfate Injection	to be omitted	included bacterial endotoxins and sterility tests	
USP 49(3)	monograph	Azelaic Acid Topical Gel	N	Microbial Enumeration Tests <61>: TAMC NMT 10 ² cfu/g, TYMC NMT 10 ¹ cfu/g. Tests for Specified Microorganisms <62>: absence of <i>Staphylococcus aureus</i> and <i>Pseudomonas aeruginosa</i>	
USP 49(3)	monograph	Clobetasol Propionate Shampoo	N	Microbial Enumeration Tests <61>: TAMC NMT 10 ² cfu/g, TYMC NMT 10 ¹ cfu/g. Tests for Specified Microorganisms <62>: absence of <i>Staphylococcus aureus</i> and <i>Pseudomonas aeruginosa</i> . Meets requirements for Microbiological Examination of Nonsterile Products—Tests for Burkholderia Cepacia Complex <60>	
USP 49(3)	monograph	Gamma cyclodextran	R	Microbial Enumeration Tests <61>: TAMC NMT 1000 cfu/g, TYMC NMT 100 cfu/g. Tests for Specified Microorganisms <62>: absence of <i>Salmonella</i> species and <i>Escherichia coli</i> .	
USP 49(3)	monograph	Dexmedetomidine Hydrochloride	R	Microbial Enumeration Tests <61>: TAMC NMT 10 ² cfu/g, TYMC NMT 10 ¹ cfu/g. Bacterial Endotoxins Test <85>: meets the requirements	
USP 49(3)	monograph	European Elder Berry Aqueous Dry Extract	N	Microbial Enumeration Tests <2021>:TAMC NMT 10 ⁴ cfu/g, TCMC NMT 10 ³ cfu/g. Absence of Specified Microorganisms <2022>: absence of <i>Salmonella</i> species and <i>Escherichia coli</i> .	
USP 49(3)	monograph	European Elder Berry Dry Extract	R	Microbial Enumeration Tests <2021>:TAMC NMT 10 ⁴ cfu/g, TYMC NMT 10 ³ cfu/g. Absence of Specified Microorganisms <2022>: absence of <i>Salmonella</i> species and <i>Escherichia coli</i> .	
USP 49(3)	monograph	Gonadorelin Acetate	R	Microbial Enumeration Tests <61>: TAMC NMT 10 ² cfu/g, TYMC NMT 10 ² cfu/g. Bacterial Endotoxins Test <85>: meets the requirements	

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USP 49(3)	monograph	Ofloxacin Otic Solution	N	Sterility Tests <71>: meets the requirements	
USP 49(3)	monograph	Procaine Hydrochloride	R	Bacterial Endotoxins Test <85>: meets the requirements. Sterility Tests <71>: meets the requirements	
USP 49(3)	monograph	Silodosin Capsules	N	Microbial Enumeration Tests <61>:TAMC NMT 10 ³ cfu/g, TYMC NMT 10 ² cfu/g. Tests for Specified Microorganisms <62>: absence of <i>Escherichia coli</i> .	
USP 49(3)	monograph	Soybean Phosphatidylcholine	N	Microbial Enumeration Tests <61>: TAMC NMT 10 ³ cfu/g, TYMC NMT 10 ² cfu/g. Tests for Specified Microorganisms <62>: absence of <i>Salmonella</i> species and <i>Escherichia coli</i> . Bacterial Endotoxins Test <85>: meets the requirements.	
USP 49(3)	monograph	Corn Starch	R	Microbial Enumeration Tests <61>: TAMC NMT 10 ³ cfu/g, TYMC NMT 10 ² cfu/g. Tests for Specified Microorganisms <62>: absence of <i>Staphylococcus aureus</i> and <i>Pseudomonas aeruginosa</i> .	

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		Special Process Services, LC		https://www.linkedin.com/in/joseph-connaghan-b663929	