

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 [3/7/2023]	monograph	Acetylcysteine Injection	R	Test for bacterial endotoxins, Appendix XIV C: NMT 0.3 IU/mL	
EP 35.3	monograph	Charcoal, Activated	R	Microbial contamination: TAMC: acceptance criterion 10 ³ cfu/g, TYMC: acceptance criterion 10 ² cfu/g	
EP 35.3	monograph	Pharmaceutical Preparations	R	Includes section on microbiological quality.	
EP 35.3	monograph	Sorbitol , Liquid, Partially Dehydrated	R	Microbial contamination: TAMC: acceptance criterion 10 ³ cfu/g (2.6.12), TYMC: acceptance criterion 10 ² cfu/g (2.6.12), absence of <i>E. coli</i> (2.6.13), absence of <i>Salmonella</i> (2.6.13)	
IP 19/07/2023	monograph	Azacidine for Injection	N	Sterility (2.2.11). Complies with the test for sterility. Bacterial endotoxins (2.2.3). Not more than 1.0 Endotoxin Units per mg of azacidine.	
IP 19/07/2023	monograph	Brivaracetam Injection	N	Sterility (2.2.11). Complies with the test for sterility. Bacterial endotoxins (2.2.3). Not more than 2 Endotoxin Units per mg of brivaracetam.	
IP 12/06/2023	monograph	Miltefosine Capsules	N	Microbial contamination (2.2.9). Total aerobic viable count is not more than 10 ³ cfu per g and total fungal count not more than 10 ² cfu per g. 1g is free from <i>Escherichia coli</i> .	
IP 13/06/2023	monograph	Nepafenac Ophthalmic Suspension	N	Sterility (2.2.11). Complies with the test for sterility.	
IP 19/07/2023	monograph	Saline Nasal Solution	N	Microbial contamination (2.2.9). Total aerobic viable count is not more than 10 ² CFU per ml and total combined mold and yeasts count is not more than 10 CFU per ml and 1 ml is free from <i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> and <i>Burkholderia cepacia</i> .	
USP 49(4)	chapter	Multi-Ingredient Dietary Supplement Products— Product Quality Tests	R	Microbial Enumeration Tests <2021>, Absence of Specified Microorganisms <2022> and Microbiological Attributes of Nonsterile Nutritional and Dietary Supplements <2023>	
USP 49(4)	monograph	Ajowan Fruit	R	Microbial Enumeration Tests <2021>: total aerobic bacteria count < 10 ⁵ cfu/g, TCMY < 10 ³ cfu/g, bile-tolerant Gram-negative bacteria count < 10 ³ cfu/g. Absence of Specified Microorganisms <2022>: absence of <i>Salmonella</i> sp. and <i>E. coli</i> .	
USP 49(4)	monograph	Ajowan Fruit Oil	R	Microbial Enumeration Tests <2021>: total aerobic bacteria count < 10 ⁴ cfu/g, TCMY < 10 ³ cfu/g. Absence of Specified Microorganisms <2022>: absence of <i>Salmonella</i> sp. and <i>E. coli</i> .	
USP 49(4)	monograph	Ajowan Fruit Powder	R	Microbial Enumeration Tests <2021>: total aerobic bacteria count < 10 ⁵ cfu/g, TCMY < 10 ³ cfu/g, bile-tolerant Gram-negative bacteria count < 10 ³ cfu/g. Absence of Specified Microorganisms <2022>: absence of <i>Salmonella</i> sp. and <i>E. coli</i> .	
USP 49(4)	monograph	Broccoli Seed Dry Extract	R	Microbial Enumeration Tests <2021>: total aerobic bacteria count < 10 ⁴ cfu/g, TCMY < 10 ³ cfu/g. Absence of Specified Microorganisms <2022>: absence of <i>Salmonella</i> sp. and <i>E. coli</i> .	

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USP 49(4)	monograph	Dimethyl Sulfoxide Irrigation	R	Sterility Tests <71>: meets the requirements, Bacterial Endotoxins Test <85>: meets the requirements	
USP 49(4)	monograph	Fluphenazine Decanoate	R	Bacterial Endotoxins Test <85>: meets the requirements	
USP 49(4)	monograph	Fondaparinux Sodium Injection	R	Sterility Tests <71>: meets the requirements, Bacterial Endotoxins Test <85>: meets the requirements	
USP 49(4)	monograph	Rice Protein	N	Microbial Enumeration Tests <2021>: total aerobic bacteria count < 10 ⁵ cfu/g, TCMY < 10 ³ cfu/g. Absence of Specified Microorganisms <2022>: absence of <i>Salmonella</i> sp. and <i>E. coli</i> .	
USP 49(4)	monograph	Sirolimus	N	Microbial Enumeration Tests <61>: TAMC does not exceed 10 ³ cfu/g. TYMC does not exceed 10 ² cfu/g.	
USP 49(4)	monograph	Sour Jujube Seed	R	Microbial Enumeration Tests <2021>: total aerobic bacteria count < 10 ⁵ cfu/g, TCMY < 10 ³ cfu/g, bile-tolerant Gram-negative bacteria count < 10 ³ cfu/g. Absence of Specified Microorganisms <2022>: absence of <i>Salmonella</i> sp. and <i>E. coli</i> .	
USP 49(4)	monograph	Sour Jujube Seed Dry Extract	R	Microbial Enumeration Tests <2021>: total aerobic bacteria count < 10 ⁴ cfu/g, TCMY < 10 ³ cfu/g. Absence of Specified Microorganisms <2022>: absence of <i>Salmonella</i> sp. and <i>E. coli</i> .	
USP 49(4)	monograph	Sour Jujube Seed Dry Powder	R	Microbial Enumeration Tests <2021>: total aerobic bacteria count < 10 ⁵ cfu/g, TCMY < 10 ³ cfu/g, bile-tolerant Gram-negative bacteria count < 10 ³ cfu/g. Absence of Specified Microorganisms <2022>: absence of <i>Salmonella</i> sp. and <i>E. coli</i> .	
USP 49(4)	monograph	Ubidecarenone Chewable Gels	N	Microbial Enumeration Tests <2021>: total aerobic bacteria count < 10 ³ cfu/g, TCMY < 10 ² cfu/g. Absence of Specified Microorganisms <2022>: absence of <i>Salmonella</i> sp. and <i>E. coli</i> .	

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				http://www.sterile.com	
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