

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 [10/5/2023]	monograph	Flucloxacillin for Injection	R	Test for bacterial endotoxins, Appendix XIV C: less than 0.35 IU/mg	
EP 35.4	general chapter	2.7.24. Flow Cytometry	R	“5-8. CONTROL OF MICROBIOLOGICAL QUALITY Flow cytometry can be used for the control of microbiological quality. Their use as alternative methods suitable for rapid detection of micro-organisms are described in general chapters 2.6.27. Microbiological examination of cell-based preparations and 5.1.6. Alternative methods for control of microbiological quality.”	
EP 35.4	monograph	Dicloxacillin Sodium Monohydrate	R	Pyrogens requirement removed.	
EP 35.4	monograph	Starches, Hydroxyethyl	R	Microbial contamination: TAMC: acceptance criterion 10 ² cfu/g (2.6.12.), Bacterial endotoxins: less than 2.5 IU/g (2.6.14.)	
EP 35.4	monograph	Teriparatide injection	N	Bacterial endotoxins: less than 100 IU in the volume that contains 1 mg of teriparatide (2.6.14.)	
IP 18/08/2023	monograph	Lactulose Solution	N	Microbial contamination (2.2.9). Total aerobic viable count is not more than 10 ² cfu per g. 1g is free from <i>Escherichia coli</i> and 10 g is free from <i>Salmonella</i> .	
IP 09/10/2023	monograph	Morphine Sulphate Injection	R	Bacterial Endotoxins (2.2.3) Change From: Not more than 17.0 Endotoxins Units per mg of morphine; if labelled for intrathecal use it contains not more than 14.29 Endotoxins Units per mg of morphine. To: Not more than 17.0 Endotoxins Units per mg of morphine sulphate; if labelled for intrathecal use it contains not more than 14.29 Endotoxins Units per mg of morphine sulphate.	
IP 09/10/2023	monograph	Ceftriaxone Sodium	R	Bacterial Endotoxins (2.2.3) Change From: Not more than 0.20 Endotoxins Units per mg of ceftriaxone sodium. To: Not more than 0.08 Endotoxins Units per mg of ceftriaxone sodium.	
IP 09/10/2023	monograph	Ceftriaxone Injection	R	Bacterial Endotoxins (2.2.3) Change From: Not more than 0.20 Endotoxins Units per mg of ceftriaxone. To: Not more than 0.08 Endotoxins Units per mg of ceftriaxone.	
USP 49(5)	general chapter	<64> Probiotic Tests	R	Microbial Enumeration Tests <2021>, Absence of Specified Microorganisms <2022> and Validation of Alternative Microbiological Methods <1223>	
USP 49(5)	monograph	Bendamustine Hydrochloride	R	Bacterial Endotoxins Test <85> :Meets the requirements. Where the label states that Bendamustine Hydrochloride 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 Bendamustine Hydrochloride 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. The total combined molds and yeasts count is NMT 10 ² cfu/g.	
USP 49(5)	monograph	Bendamustine Hydrochloride for Injection	R	Bacterial Endotoxins Test <85> :Meets the requirements Sterility Tests <71> :Meets the requirements	

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
USP 49(5)	monograph	Bexarotene Capsules	R	Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62> :The total aerobic microbial count is NMT 10 ² cfu/g and the total combined yeasts and molds count is NMT 10 ² cfu/g. They meet the requirements of the test for absence of Escherichia coli.	
USP 49(5)	monograph	dl-Lactide and Glycolide (50:50) Copolymer 46000 Acid	N	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. •Bacterial Endotoxins Test <85> :Where the label states that dl-Lactide and Glycolide (50:50) Copolymer 46000 Acid 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 dl-Lactide and Glycolide (50:50) Copolymer 46000 Acid is used can be met.	
USP 49(5)	monograph	Gastrodia Rhizome	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 •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(5)	monograph	Gastrodia Rhizome 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 bacteria do 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(5)	monograph	Gastrodia Rhizome 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 •Absence of Specified Microorganisms <2022> , Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli: Meets the requirements	

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
USP 49(5)	monograph	Hard Gelatin Capsule Shells	N	<p>Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62></p> <p>For oral use: The total aerobic microbial count does not exceed 10^3 cfu/g, and the total combined yeasts and molds count does not exceed 10^2 cfu/g. They meet the requirements of the test for absence of Escherichia coli.</p> <p>For inhalation use: The total aerobic microbial count does not exceed 10^2 cfu/g, and the total combined yeasts and molds count does not exceed 10^1 cfu/g. They meet the requirements of the tests for absence of Staphylococcus aureus, Pseudomonas aeruginosa, and bile-tolerant Gram-negative bacteria.</p> <p>For nasal use: The total aerobic microbial count does not exceed 10^2 cfu/g, and the total combined yeasts and molds count does not exceed 10^1 cfu/g. They meet the requirements of the tests for absence of Staphylococcus aureus and Pseudomonas aeruginosa.</p> <p>For vaginal use: The total aerobic microbial count does not exceed 10^2 cfu/g, and the total combined yeasts and molds count does not exceed 10^1 cfu/g. They meet the requirements of the tests for absence of Staphylococcus aureus, Pseudomonas aeruginosa, and Candida albicans.</p>	
USP 49(5)	monograph	Hard Hypromellose Capsule Shells	N	<p>Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62></p> <p>For oral use: The total aerobic microbial count does not exceed 10^3 cfu/g, and the total combined yeasts and molds count does not exceed 10^2 cfu/g. They meet the requirements of the test for absence of Escherichia coli.</p> <p>For inhalation use: The total aerobic microbial count does not exceed 10^2 cfu/g, and the total combined yeasts and molds count does not exceed 10^1 cfu/g. They meet the requirements of the tests for absence of Staphylococcus aureus, Pseudomonas aeruginosa, and bile-tolerant Gram-negative bacteria.</p> <p>For nasal use: The total aerobic microbial count does not exceed 10^2 cfu/g, and the total combined yeasts and molds count does not exceed 10^1 cfu/g. They meet the requirements of the tests for absence of Staphylococcus aureus and Pseudomonas aeruginosa.</p> <p>For vaginal use: The total aerobic microbial count does not exceed 10^2 cfu/g, and the total combined yeasts and molds count does not exceed 10^1 cfu/g. They meet the requirements of the tests for absence of Staphylococcus aureus, Pseudomonas aeruginosa, and Candida albicans.</p>	
USP 49(5)	monograph	Krill Oil Capsules	R	<p>Microbial Enumeration Tests <2021> : The total aerobic microbial count does not exceed 10^3 cfu/g, and the combined molds and yeasts count does not exceed 10^2 cfu/g.</p> <p>Absence of Specified Microorganisms <2022> , Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli: Meet the requirements</p>	


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
USP 49(5)	monograph	Anhydrous Lactose	R	Microbial Enumeration Tests <61> ,Tests for Specified Microorganisms <62> ,and Tests for Burkholderia Cepacia Complex <60> For non-inhalation and non-injection grades: The total aerobic microbial count is NMT 1×10^2 cfu/g and the total combined molds and yeasts count is NMT 5×10^1 cfu/g. It meets the requirements of the test for absence of Escherichia coli. For inhalation grades and injection grades:The total aerobic microbial count is NMT 1×10^1 cfu/g and the total combined molds and yeasts count is NMT 1×10^1 cfu/g. It meets the requirements of the tests for the absence of Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Salmonella species, and Burkholderia cepacia. Add the following: Bacterial Endotoxins Test <85> :NMT 5 EU/g, if intended for use in the manufacture of parenteral or inhalation products	
USP 49(5)	monograph	Lactose Monohydrate	R	Bacterial Endotoxins Test <85> :NMT 5 EU/g, if intended for use in the manufacture of parenteral or inhalation products.	
USP 49(5)	monograph	Ligilactobacillus salivarius	R	Probiotic Tests <64> , Contaminants, Contaminant Microorganisms:The total combined molds and yeasts count does not exceed 10^2 cfu/g. The total non-lactic acid bacteria count is less than 5×10^3 cfu/g. Probiotic Tests <64> , Contaminants, Specified Microorganisms:It meets the requirements of the tests for the absence of Escherichia coli in 10 g and for the absence of Salmonella species in 40 g. •Listeria:(See Food Chemicals Codex, Appendix XV.) It meets the requirements of the test for absence of Listeria in 25 g.	
USP 49(5)	monograph	Meloxicam Injection	N	Bacterial Endotoxins Test <85> :Meets the requirements Sterility Tests <71> :Meets the requirements	
USP 49(5)	monograph	Phenol 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 0.4 USP Endotoxin Units/mg of phenol	







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
USP 49(5)	monograph	Hard Pullulan Capsule Shells	N	<p>Microbial Enumeration Tests 〈61〉 and Tests for Specified Microorganisms 〈62〉</p> <p>For oral use: The total aerobic microbial count does not exceed 10³ cfu/g, and the total combined yeasts and molds count does not exceed 10² cfu/g. They meet the requirements of the test for absence of Escherichia coli.</p> <p>For inhalation use: The total aerobic microbial count does not exceed 10² cfu/g, and the total combined yeasts and molds count does not exceed 10¹ cfu/g. They meet the requirements of the tests for absence of Staphylococcus aureus, Pseudomonas aeruginosa, and bile-tolerant Gram-negative bacteria.</p> <p>For nasal use: The total aerobic microbial count does not exceed 10² cfu/g, and the total combined yeasts and molds count does not exceed 10¹ cfu/g. They meet the requirements of the tests for absence of Staphylococcus aureus and Pseudomonas aeruginosa.</p> <p>For vaginal use: The total aerobic microbial count does not exceed 10² cfu/g, and the total combined yeasts and molds count does not exceed 10¹ cfu/g. They meet the requirements of the tests for absence of Staphylococcus aureus, Pseudomonas aeruginosa, and Candida albicans.</p>	
USP 49(5)	monograph	Streptococcus salivarius	N	<ul style="list-style-type: none"> • Probiotic Tests 〈64〉, Contaminants, Contaminant Microorganisms: The total combined molds and yeasts count does not exceed 10² cfu/g. • Absence of Specified Microorganisms 〈2022〉, Test Procedures, Test for Absence of Escherichia coli, Test for Absence of Salmonella Species, and Test for Absence of Staphylococcus aureus: It meets the requirements of the tests for absence of Escherichia coli in 10 g, for absence of Salmonella species in 25 g, and for absence of Staphylococcus aureus in 10 g. • Coliforms: (See Food Chemicals Codex, Appendix XV.) It meets the requirements of the tests for absence of coliforms in 1 g. <p>[Note—In addition to the testing for the microorganisms listed above, the probiotic ingredient should be tested for mesophilic aerobic endospore forming bacilli depending on the risk of contamination based on formal risk assessment programs such as Hazard Analysis and Critical Control Points (HACCP). The method used for testing mesophilic aerobic endospore forming bacilli must be officially accepted or appropriately validated.]</p>	
Current Sponsors of the PMF					
				http://www.acciusa.com/	

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.microbiologics.com	
				https://ntint.com/	
				https://www.rapidmicrobio.com	
				http://www.sterislifesciences.com/	
				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	