

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
EP 35.2	chapter	5.31. Phage Therapy Active Substances and Medicinal Products for Human and Veterinary Use	N	Covers bacterial master and working cell banks, microbial purity, bacterial identification, viability, phage sensitivity, sterility, microbiological quality, pyrogenicity.	
EP 35.2	chapter	Additional Information on Gene Therapy Medicinal Products for Human Use	R	Discusses bacterial cells uses for production of plasmid vectors, mycoplasmas, bacterial endotoxins, microbiological examination, sterility, biological activity, bacterial identity,, genetically modified bacterial cells, master and working cell banks	
EP 35.2	monograph	Cholesterol for Parenteral Use	N	Microbial contamination: TAMC 10 ² cfu/g	
EP 35.2	monograph	Enoxaparin Sodium Injection	N	Bacterial endotoxins (2.6.14.) less then 0.01 IU/IU of anti-factor Xa activity	
EP 35.2	monograph	Gallium (⁶⁸ Ga) Chloride (Generator-Produced) Solution for Radiolabelling	R	Bacterial endotoxins (2.6.14.) less than 80 IU/batch	
EP 35.2	monograph	Lutetium (¹⁷⁷ Lu) Zovavotide Guraxetan Injection	N	Sterility (as per monograph Radiopharmaceutical preparations (0125)).	
EP 35.2	monograph	Maize Starch	R	Microbial contamination: TAMC 10 ³ cfu/g, TYMC 10 ² cfu/g, absence of E. coli and Salmonella (2.6.13.)	
EP 35.2	monograph	Sodium Polystyrene Sulfonate	R	Microbial contamination: bile-tolerant gram-negative bacteria: 10 ² cfu/g (2.6.13.)	
EP 35.2	monograph	Lornoxicam	N	listed for your information, no microbial-related information available from JP index	
EP 35.2	monograph	Starch, Hydroxypropyl	R	Microbial contamination: TAMC 10 ³ cfu/g, TYMC 10 ² cru/g, absence of E. coli and Salmonella (2.6.13).	
EP 35.2	monograph	Technetium (^{99m} Tc) Oxidronate Injection	R	Sterility, Bacterial endotoxins (2.6.14.) less than 175/V IU/mL, V being the maximum recommended dose in mL	
EP 35.2	monograph	Vaccines for Veterinary Use	R	Covers bacterial vaccines, bacterial seed lots, sterility, bacterial endotoxins, mycoplasmas, antimicrobial preservatives	
EP 35.2	monograph	Water (¹⁵ O) Injection	R	Sterility, bacterial endotoxins (2.6.14.) less than 175/V IU/mL, V being the maximum recommended dose in mL	

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IP (modified March 29, 2023)	chapter	Substitution of in-vivo Methods by in-vitro Methods for the Quality Control of Vaccines	N	Bacterial vaccines are mentioned.	
IP (uploaded March 17, 2023)	monograph	Lactulose Solution	N	Microbial contamination (2.2.9.) TAMC NMT 100 cfu/g, TCMY NMT 10 cfu/g, absence of E. coli in 1g.	
IP (uploaded March 17, 2023)	monograph	Cellulose Acetate	N	Microbial contamination (2.2.9.) TAMC NMT 1000 cfu/g, TCMY NMT 100 cfu/g, absence of E. coli and Salmonella in 1g.	
IP (uploaded March 17, 2023)	monograph	Thalidomide	N	Microbial contamination (2.2.9.) TAMC NMT 1000 cfu/g, TCMY NMT 100 cfu/g	
IP (uploaded March 17, 2023)	monograph	Thalidomide Capsules	N	Microbial contamination (2.2.9.) TAMC NMT 1000 cfu/g, TCMY NMT 100 cfu/g, absence of E. coli in 1g.	

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				http://www.sterile.com	

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