

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 | Vaccines for Veterinary Use | R | Antimicrobial preservatives 5.1.3 Sterility 2.6.1 Mycoplasmas 2.6.7 | |
| EP 35.2 | chapter | 5.31. PHAGE THERAPY ACTIVE SUBSTANCES AND MEDICINAL PRODUCTS FOR HUMAN AND VETERINARY USE | N | “ Microbial purity. The absence of microbial contaminants is determined by plating or other suitable methods.” Bacterial identification. Microbiological examination (2.6.12) Sterility (2.6.1). Microbiological quality: 5.1.4. Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use. Pyrogenicity (5.1.13). | |
| EP 35.2 | chapter | 5.34. ADDITIONAL INFORMATION ON GENE THERAPY MEDICINAL PRODUCTS FOR HUMAN USE | R | Mycoplasmas 2.6.7 Microbiological examination: 2.6.1 Sterility or 2.6.12 bio burden Bacterial endotoxins 2.6.14 or 2.6.32 Sterility 2.6.1 Strain characterization Pyrogenicity Microbial purity | |
| EP 35.2 | monograph | Enoxaparin Sodium Injection | N | Bacterial endotoxins 2.6.14 | |
| EP 35.2 | monograph | Gallium (⁶⁸ Ga) Chloride (Generator-Produced) Solution for Radiolabelling | R | Sterility 2.6.1 Bacterial endotoxins 2.6.14 | |
| EP 35.2 | monograph | LUTETIUM (177LU) ZADAVOTIDE GURAXETAN INJECTION | N | Sterility Radiopharmaceutical preparations (0125) | |
| EP 35.2 | monograph | Maize Starch | R | Microbial contamination 2.6.12 and 2.6.13 | |
| EP 35.2 | monograph | Sodium polystyrene sulfonate | R | Bile-tolerant gram-negative: 10 ² cfu/g; 2.6.13 | |
| EP 35.2 | monograph | Starch, Hydroxypropyl | R | Microbial contamination 2.6.12 and 2.6.13 | |
| EP 35.2 | monograph | TECHNETIUM (^{99m} Tc) OXIDRONATE INJECTION | R | Sterility 2.6.1 Bacterial endotoxins 2.6.14 | |

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|---------------|---------------|------------------------------------|---------------------|--|----|
| EP 35.2 | monograph | Water (¹⁵ O) Injection | R | Sterility 2.6.1 Bacterial endotoxins 2.6.14 | |
| IP 5/25/2023 | monograph | Atropine Ophthalmic Solution | N | Sterility (2.2.11) | |
| IP 5/25/2023 | monograph | Azilsartan Kamedoxomil | N | Microbial contamination (2.2.9) | |
| IP 14/06/2023 | monograph | Brivaracetam Oral Solution | N | Microbial contamination (2.2.9) | |
| IP 12/06/2023 | monograph | Miltefosine Capsules | N | Microbial contamination (2.2.9) | |
| IP 12/06/2023 | monograph | Nepafenac Ophthalmic Suspension | N | Sterility (2.2.11) | |
| IP 12/06/2023 | monograph | Perampanel | N | Microbial contamination (2.2.9) | |
| IP 12/06/2023 | monograph | Perampanel Tablets | N | Microbial contamination (2.2.9) | |
| IP 18/5/2023 | monograph | Tilmicosin Injection | N | Sterility (2.2.11) Bacterial endotoxins (2.2.3) | |
| IP 23/5/2023 | monograph | Flunixin Meglumine Injection | N | Sterility (2.2.11) Bacterial endotoxins (2.2.3) | |
| JP June 2023 | monograph | Clindamycin Phosphate | R | Sterility Bacterial Endotoxins | X |

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