

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 PF 49(2)	stimuli article	Comparison of Four Endotoxin Detection Reagents in Measuring Autochthonous Endotoxin Levels in Four Representative Parenteral Products	N	Discusses naturally occurring endotoxins, reference endotoxins, with analysis by two kinetic and two recombinant assay products.	
USP PF 49(2)	monograph	Acetylcysteine Solution	R	includes Sterility Tests <71>	
USP PF 49(2)	monograph	Antithrombin III Human	R	includes Pyrogen Test <151>	
USP PF 49(2)	monograph	Clobetasol Propionate Topical Spray	N	Microbial Enumeration Tests <61>: the TAMC does not exceed 10 ² cfu/g, the TMYC does not exceed 10 ¹ cfu/g. Tests for Specified Microorganisms <62>: absence of <i>Staphylococcus aureus</i> and <i>Pseudomonas aeruginosa</i>	
USP PF 49(2)	monograph	Eptifibatide	N	Bacterial Endotoxins Test <85> Microbial Enumeration Tests <61>: the TAMC does not exceed 10 ² cfu/g, the TMYC does not exceed 10 ² cfu/g.	
USP PF 49(2)	monograph	Sargramostim for Injection	R	includes Bacterial Endotoxins Test <85>, Sterility Tests <71>	

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				http://www.sterile.com	

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