

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 [1/4/03]	monograph	Atenolol Injection	R	sterility, endotoxins	X
BP [1/4/03]	monograph	Atenolol Oral Solution	R	microbial enumeration, tests for specified microorganisms	X
BP [1/4/03]	monograph	Atenolol Tablets	R	microbial enumeration, tests for specified microorganisms	X
BP [1/4/03]	monograph	Biphasic Insulin Aspart Injection	R	sterility, endotoxins	X
BP [1/4/03]	monograph	Biphasic Insulin Lispro Injection	R	sterility, endotoxins	X
BP [1/4/03]	monograph	Co-tenidone Tablets	R	microbial enumeration, tests for specified microorganisms	X
BP [1/4/03]	monograph	Duloxetine Gastro-resistant Capsules	N	microbial enumeration, tests for specified microorganisms	X
BP [1/4/03]	monograph	Enalapril Tablets	R	microbial enumeration, tests for specified microorganisms	X
BP [1/4/03]	monograph	Indapamide Prolonged-release Tablets	R	microbial enumeration, tests for specified microorganisms	X
BP [1/4/03]	monograph	Indapamide Tablets	R	microbial enumeration, tests for specified microorganisms	X
BP [1/4/03]	monograph	Interferon Alfa-2a Injection	R	sterility, endotoxins	X
BP [1/4/03]	monograph	Levetiracetam Infusion	N	sterility, endotoxins	X
BP [1/4/03]	monograph	Levetiracetam Sterile Concentrate	N	sterility, endotoxins	X
BP [1/4/03]	monograph	Levofloxacin Eye Drops	N	sterility, endotoxins	X
BP [1/4/03]	monograph	Levofloxacin Infusion	N	sterility, endotoxins	X
BP [1/4/03]	monograph	Levofloxacin Tablets	N	microbial enumeration, tests for specified microorganisms	X
BP [1/4/03]	monograph	Magnesium Sulfate Paste	R	microbial enumeration, tests for specified microorganisms	X
BP [1/4/03]	monograph	Ofloxacin Eye Drops	N	sterility, endotoxins	X
BP [1/4/03]	monograph	Ofloxacin Infusion	N	sterility, endotoxins	X
BP [1/4/03]	monograph	Ofloxacin Tablets	N	microbial enumeration, tests for specified microorganisms	X
BP [1/4/03]	monograph	Parenteral Nutrition Solutions	R	Sterility Bacterial endotoxins: 0.25 IU/mL	
BP [1/4/03]	monograph	Protamine Sulfate Injection	R	Sterility Bacterial endotoxins: 70 IU/mL	
BP [1/4/03]	general chapter	SC I C. Bacterial Endotoxin Testing	R	“Policy updated and simplified to reflect the addition of BET using recombinant factor C and suppression of Rabbit Pyrogen Testing from BP finished product monographs”	

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BP [1/4/03]	monograph	Salbutamol Injection	R	sterility, endotoxins	X
BP [1/4/03]	monograph	Salbutamol Nebuliser Solution	R	microbial enumeration, tests for specified microorganisms	X
BP [1/4/03]	monograph	Tetracycline Capsules	R	microbial enumeration, tests for specified microorganisms	X
BP [1/4/03]	monograph	Tetracycline Tablets	R	microbial enumeration, tests for specified microorganisms	X
BP [1/4/03]	monograph	Trandolapril Capsules	R	microbial enumeration, tests for specified microorganisms	X
EP [35.2]		[place holder]			
IP [19/12/22]	monograph	Aceclofenac and Paracetamol Tablets	N	2.2.9. Microbial contamination	X
IP [19/12/22]	monograph	Amlodipine Besylate and Olmesartan Medoxomil Tablets	N	2.2.9. Microbial contamination	X
IP [05/01/23]	monograph	Azilsartan Kamedoxomil Tablets	N	2.2.9. Microbial contamination	X
IP [05/01/23]	monograph	Dasatinib Tablets	N	2.2.9. Microbial contamination	X
IP [05/01/23]	monograph	Flunixin Meglumine Injection	N	2.2.11. Sterility 2.2.3. Bacterial endotoxins: NMT 4.54 endotoxin units/mg	
IP [05/01/23]	monograph	Ibuprofen Oral Suspension	N	2.2.9. Microbial contamination	X
IP [19/12/22]	monograph	Ketoconazole Shampoo	N	2.2.9. Microbial contamination Antimicrobial effectiveness test	X
IP [28/11/22]	monograph	Lindane Lotion	N	2.2.9. Microbial contamination	X
IP [28/11/22]	monograph	Molnupiravir Capsules	N	2.2.9. Microbial contamination	X
IP [05/01/23]	monograph	Nepafenac Ophthalmic Suspension	N	2.2.11. Sterility 2.2.3. Bacterial endotoxins Antimicrobial effectiveness test	X
IP [28/11/22]	monograph	Paracetamol and Tramadol Tablets	N	2.2.9. Microbial contamination	X
IP [05/01/23]	monograph	Thalidomide Capsules	N	2.2.9. Microbial contamination	X
IP [05/01/23]	monograph	Vildagliptin Sustained-release Tablets	N	2.2.9. Microbial contamination	X
JP [Dec 2022]		[place holder]			X

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USP PF 49(1)	general chapter	<1151> Pharmaceutical Dosage Forms	R	Microbial Enumeration Tests <61> Tests for Specified Microorganisms <62> Microbiological Examination of Non-sterile Products <1111> Antimicrobial Effectiveness Testing <51> Sterility Tests <71> Endotoxins Tests <85> Pyrogen Test <151>	
USP PF 49(1)	monograph	<i>Bacillus inaquosorum</i>	N	Microbial Characterization, Identification, and Strain Typing <1113> Probiotic Tests <64>, Contaminants, Contaminant Microorganisms: TMYC NMT 10 ² cfu/g Probiotic Tests <6>, Contaminants, Contaminant Microorganisms: Absence of <i>E. coli</i> , <i>Salmonella sp.</i> and <i>S. aureus</i> , all in 10 g Enterobacterial count: NMT 100 cfu/g	
USP PF 49(1)	monograph	Cefoxitin Sodium	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 49(1)	monograph	Cefoxitin for Injection	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 49(1)	monograph	Colistimethate sodium	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 49(1)	monograph	<i>Haematococcus pluvialis</i> Powder	N	Microbial Enumeration Tests <2021>: TAMC NMT 10 ⁵ cfu/g TCMY NMT 10 ³ cfu/g Bile-tolerant Gram-negative count: NMT 10 ³ cfu/g Tests for Specified Microorganisms <2022>: absence of <i>Salmonella sp.</i> , <i>E. coli</i>	
USP PF 49(1)	monograph	Meperidine Hydrochloride Injection	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 49(1)	monograph	Technetium Tc 99m Albumin Aggregated Injection	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 49(1)	monograph	Technetium Tc 99m Bicisate Injection	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 49(1)	monograph	Technetium Tc 99m Exametazime Injection	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 49(1)	monograph	Technetium Tc 99m Mebrofenin Injection	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 49(1)	monograph	Technetium Tc 99m Medronate Injection	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 49(1)	monograph	Technetium Tc 99m Mertiatide Injection	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 49(1)	monograph	Technetium Tc 99m Oxidronate Injection	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 49(1)	monograph	Technetium Tc 99m Pentetate Injection	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	

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USP PF 49(1)	monograph	Sodium Pertechnetate Tc 99m Injection	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 49(1)	monograph	Technetium Tc 99m Pyrophosphate Injection	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 49(1)	monograph	Technetium Tc 99m Red Blood Cells Injection	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 49(1)	monograph	Technetium Tc 99m Sestamibi Injection i	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 49(1)	monograph	Technetium Tc 99m Succimer Injection	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 49(1)	monograph	Technetium Tc 99m Sulfur Colloid Injection	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 49(1)	monograph	Technetium Tc 99m Tetrofosmin Injection	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 49(1)	monograph	Tobramycin	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 49(1)	monograph	Tobramycin Injection	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 49(1)	monograph	Tobramycin for Injection	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 49(1)	monograph	Tobramycin Ophthalmic Ointment	R	Sterility Tests <71>: meets the requirements	
USP PF 49(1)	monograph	Tobramycin Inhalation Solution	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	
USP PF 49(1)	monograph	Tobramycin Ophthalmic Solution	R	Sterility Tests <71>: meets the requirements	
USP PF 49(1)	monograph	Tobramycin and Dexamethasone Ophthalmic Ointment	R	Sterility Tests <71>: meets the requirements	
USP PF 49(1)	monograph	Tobramycin and Dexamethasone Ophthalmic Suspension	R	Sterility Tests <71>: meets the requirements	
USP PF 49(1)	monograph	Tobramycin Sulfate	R	Sterility Tests <71>: meets the requirements Bacterial Endotoxins Test <85>: meets the requirements	

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				<p>Sponsors of the Pharmaceutical Microbiology Forum</p> 	