

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	monograph	Aprotinin Concentrated Solution	R	Bacterial endotoxins (2.6.14): less than 0.14 IU per EPU of aprotinin	
EP 35.2	monograph	Gallium (⁶⁸ Ga) Chloride (Accelerator-Produced) Solution for Radiolabeling	R	Sterility [monograph on Radiopharmaceutical preparations (0125)] Bacterial endotoxins (2.6.14): less than 80 IU per batch	
EP 35.2	monograph	Water (150) Injection	R	Sterility [monograph on Radiopharmaceutical preparations (0125)] Bacterial endotoxins (2.6.14): less than 175/V IU/mL V is the maximum recommended dose in mL.	
JP 32 1	monograph	Oxaliplatin	N	Bacterial endotoxins, microbial enumeration and tests for specified microorganisms	X
JP 32 1	monograph	Oxaliplatin Injection	N	Bacterial endotoxins, sterility	X
JP 32 1	monograph	Febuxostat	N	listed for your information, no microbial-related information available from JP index	
JP 32 1	monograph	Febuxostat Tablets	N	listed for your information, no microbial-related information available from JP index	
JP 32 1	monograph	Gefitinib Tablets	N	listed for your information, no microbial-related information available from JP index	
JP 32 1	monograph	Lornoxicam	N	listed for your information, no microbial-related information available from JP index	
JP 32 1	monograph	Lornoxicam Tablets	N	listed for your information, no microbial-related information available from JP index	
JP 32 1	monograph	Tolvaptan	N	listed for your information, no microbial-related information available from JP index	
JP 32 1	monograph	Tolvaptan Tablets	N	listed for your information, no microbial-related information available from JP index	
JP 32 1	monograph	Shin'iseihaito Extract	N	listed for your information, no microbial-related information available from JP index	
JP 32 1	monograph	Gentian	R	listed for your information, no microbial-related information available from JP index	
JP 32 1	monograph	Powdered Gentian	R	listed for your information, no microbial-related information available from JP index	
JP 32 1	monograph	Ophiopogon Root	R	listed for your information, no microbial-related information available from JP index	
JP 32 1	monograph	Uncaria Hook	R	listed for your information, no microbial-related information available from JP index	
JP 32 1	monograph	Yokukansankachi mpihange Extract	R	listed for your information, no microbial-related information available from JP index	

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				http://www.acciusa.com/	
				http://www.microbiologics.com	
				https://ntint.com/	
				http://www.sterislifesciences.com/	
				http://www.sterile.com	

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