

### 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](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	Gallium ( <sup>68</sup> Ga) Chloride (Accelerator-Produced) Solution for Radiolabelling	R	Sterility (Radiopharmaceutical preparations 0125), Bacterial endotoxins (2.6.14)	
IP [24/1/23]	monograph	Vildagliptin Prolonged-release Tablets	N	2.2.9. Microbial contamination: Total microbial count not more than 1000 cfu per g, total yeast and mould count not more than 100 cfu per g, 1g is free from Escherichia coli,	X
IP [20/1/23]	general chapter	General Chapter Guidelines on the Bacterial Endotoxins Tests	R	various revisions to text	
JP [Dec 2022]		[place holder]			X
USP PF 49(1)		[place holder]	R		

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				<a href="http://www.sterile.com">http://www.sterile.com</a>	

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