



Weekly Bulletin

week ending July 7, 2023

Most Recent Topics Covered in PMFList

[*indicates associated YouTube video]

- RECOVERIES IN WATER FOR INJECTION
- Sterility Test

Most Recent Content Added to PMF Website

- **FDA Regulatory Actions**
 - most recent: <http://www.microbiologyforum.org/content/file/Regulatory%20Actions/RA%20June%202022%202023.pdf>
- **Compendial Updates**
 - most recent: <http://www.microbiologyforum.org/content/file/Compendial%20Updates/CU%20June%202021%202023.pdf>
- **Articles/White Papers**
 - most recent: http://www.microbiologyforum.org/content/file/White%20Papers/Trend%20Analysis_2.pdf
- **YouTube Videos**

- most recent: Micro Lab GMP Requirements [<https://youtu.be/cyy-TkFolpQ>]
- E-Books
 - **This week**: (addresses PMFList EM Q&A): <http://www.microbiologyforum.org/content/file/E-Books/EM%20ebbok%201.pdf>
- Events
 - most recent: [Pharmig Events \(see note at linked page\)](#) [3]
- Sponsors page
 - **This week**: Icons and sponsor information added to webpage <http://www.microbiologyforum.org/sponsors.asp>
- PMF “Cartoons” [[click here](#)]
 - **This week**: looks at antimicrobial effectiveness test versus chemical testing.

New Subscribers: 2

PMF Sponsorship Information and General Information (click link)

<http://www.microbiologyforum.org/content/file/PMF%20Sponsorship%202023%20April%208%202023.pdf>

New Sponsor



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PMF “Cartoons”



I heard about a company that made a product with a polymeric antimicrobial preservative that they had on a stability program. The preservative did not have a compendial monograph, so the lab developed and validated a chemical assay for the agent. The company also did the USP chapter <51> Antimicrobial Effectiveness test. Over time, the chemical test indicated almost 100% stability, whereas chapter <51> testing showed a steady decrease in efficacy over time, eventually resulting in testing failure. What explanation provided below might you provide for this situation?

1. The chemists didn't validate the test correctly.
2. The microbiologists don't know how to properly perform the chapter <51> test.
3. The test used from chapter <51> was not properly validated.
4. The product was not suitable for use with the test in chapter <51>.
5. Something is happening with the preservative agent such that the chemical test sees it but the bacterial/fungal cells do not see it the same way over time.
6. None of the above. My answer would be.....

Feel free to email serious or humorous answers you might like to have posted in next week's PMF Weekly Bulletin, with or without attribution (your call) to: