



Weekly Bulletin

week ending August 4, 2023

Most Recent Topics Covered in PMFList

Bile Tolerant Question

Ubidecarenone Chewable Gel Monograph Revision

Request for PMF List Contributing Consultants to Become Sponsors

Growth promotion of media used for EM

Most Recent Content Added to PMF Website

FDA Regulatory Actions

most recent: <http://www.microbiologyforum.org/content/file/Regulatory%20Actions/RA%20July%2027%202023.pdf>

Compendial Updates

most recent: <http://www.microbiologyforum.org/content/file/Compendial%20Updates/CU%20July%2027%202023.pdf>

Articles/White Papers

most recent: http://www.microbiologyforum.org/content/file/White%20Papers/Trend%20Analysis_2.pdf

Most Recent Content Added to PMF Website

YouTube Videos

most recent: Micro Lab GMP Requirements [<https://youtu.be/cyy-TkFolpQ>]

E-Books/Training

This week: (addresses SOP training using a question and answer approach):

<http://www.microbiologyforum.org/content/file/E-Books/QC-13-07%20V2a.pdf>

Events

This week: [Pharmig Events \(see note at linked page\)](#) [3]

Sponsors page

most recent: Icons and sponsor information added to webpage
<http://www.microbiologyforum.org/sponsors.asp>

PMF “Cartoons” [[click here](#)]

This week: looks at sterilization assurance levels (SAL) and D-values.

New Subscribers: 5

PMF Sponsorship Information and General Information (click link)

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

New Sponsor(s)

no new sponsors this week

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<http://www.microbiologics.com>



<https://ntint.com/>

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<http://www.sterile.com>

Giles Scientific, Inc.

Special Process Services, LC

PMF “Cartoons”



A QC lab manager called me up one day and said that her company was making a product for which there was a compendial monograph with a microbiology-related requirement. The manager indicated that the product was not found to be suitable with the compendial method that was to be used to establish compliance with the compendial requirement. Which of the answers below might I have given (assuming that I had at least some idea what I was talking about) related to the problem:

1. Don't worry about demonstrating method suitability. Just go ahead and use the compendial method as is and report the results.
2. If the compendial method doesn't work, you don't need to worry about demonstrating compliance with the related compendial monograph requirement.
3. Find out what component of your formulation is causing the problem, make a batch without that component, then run the compendial test.
4. You need to either modify the compendial method to make it suitable for use with your product, or else develop and validate another method to evaluate compliance with the compendial requirement.
5. 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:

dporter@microbiologyforum.org

