Rapid Sterility Strategies for Compounded Sterile Preparations

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Webinar Q&A - Rapid Sterility Benefits and Usage

1. **Have you seen the benefits of using rapid sterility testing during the COVID-19 pandemic?**
   During the COVID-19 pandemic, using rapid sterility testing on certain protocols have proved to be beneficial. For reduced staffing times, using rapid sterility testing has allowed our organization to check sterile compound batches on fewer days and send 1 or 2 shipments a week to ARL for testing compared to sending them everyday. With the reduced quarantine time from 14-days (using traditional methods) to 6-days (rapid testing) we were able to continue producing medications without sacrificing beyond-use date time beyond what we would expect from a normal USP <71> sterility test. As staffing returns to normal, we will continue to send shipments on a more routine basis. Rapid sterility testing has given us some flexibility in these difficult times.
   Kevin Hansen, PharmD, MS, BCPS, Moses H. Cone Memorial Hospital

2. **When freezing products to reduce waiting time to see if the test passes, is there a rule of thumb for which products can be frozen for stability? If a product while shipping defrost, can we re-freeze when it arrives ?**
   You should only use the storage conditions for each specific compounded sterile preparation based on the stability indicating method study used for that specific protocol. For each of our protocols, only room temperature storage was used, thus we do not freeze or refrigerate our samples sent to ARL. To minimize any environmental 'impact' on the samples, we only use overnight shipping as an option. Freezing a sample may prohibit growth of a microorganisms in your sample; the purpose of a doing a sterility test is to detect microbial growth. Therefore, it may not be beneficial to freeze samples for shipping.
   Kevin Hansen, PharmD, MS, BCPS, Moses H. Cone Memorial Hospital

3. **Do you anticipate any of the USP 797 revisions regarding extending BUDs for CSPs affecting your current practice, the products you produce, and the BUDs that you assign?**
   It is important to define 'extended beyond-use dates' especially when comparing the 2008 version of USP <797> with the proposed revised version. The 2008 version allowed for 'extended BUD's' beyond the listed table IF a sterility test was performed. The proposed revised version now includes sterility testing beyond-use dates within the table. The change between the two versions is now with the proposed revised version, there is now a maximum date identified for BUDs with a sterility test, that the 2008 version did not address. I encourage you to participate in the upcoming USP Beyond-Use Date Open Forum where thoughts from the compounding community can be shared to influence the revising of the chapter on BUDs.
   Kevin Hansen, PharmD, MS, BCPS, Moses H. Cone Memorial Hospital

4. **With respect to assignment of BUD for a preparation, when doing your method suitability workup, are you also performing USP 788 Particulate testing and/or USP 1207 Container closure integrity testing initially?**
   The scope of this presentation was focused solely on microbiological/sterility testing of compounded sterile preparations. With this, we know that in assigning a beyond-use date we need to consider not only the sterility of our compounds but also myriad of other stability factors as indicated for the specific preparation (i.e. stability, particulate matter, pH, endotoxins, etc.). Further the container used for the final preparation should undergo a container closure integrity study to ensure the product can maintain its characteristics throughout its BUD and identified storage conditions. These specific requirements will be identified when performing the method suitability using stability indicating methods with forced degradation. A great resource to use for certain compounds is a 'USP Compounded Monograph'. This resource will outline the specific required tests that need to be performed to be able to assign the listed beyond-use date. The use of 'extended beyond-use dates' is an evolving topic that is currently be discussed within USP and the community with the recent appeals with USP <797>.
   Kevin Hansen, PharmD, MS, BCPS, Moses H. Cone Memorial Hospital

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Webinar Q&A - Rapid Sterility Method

1. **What is the cost difference between a rapid test and traditional growth based USP <71> sterility test?**
   A rapid sterility test is approximately $100-$150 more than a traditional sterility test.
   Brian Kelley, ARL Bio Pharma

2. **How long did it take to validate the Celsis instrument?**
   The validation took approximately 11 months. Click here to view the validation.
   Brian Kelley, ARL Bio Pharma

3. **How long does it take for a product-specific validation to be performed and what is the sample requirement?**
   Rapid sterility method suitability takes 10 business days. ARL requires 4x sterility test volume to complete method suitability.

   3x the sterility volume is used for inhibition testing (similar to USP <71> method suitability testing), and an additional full sterility test volume is used for sample effects testing, which ensures the product formulation does not interfere with the Celsis Rapid Sterility assay itself.
   Brian Kelley, ARL Bio Pharma

4. **How much does rapid sterility method suitability cost?**
   • Method Suitability: $1,500
   • Method Suitability (Antimicrobial Actives and Metered Devices): $1,750
   • Method Verification: $750 - available if method suitability is already on file
   • Omnicell IV station users may be eligible for $50 method suitability if a method suitability was performed during a Beyond Use Dating (BUD) study. Check with your Omnicell representative.

   ARL is currently running a promotion for $500 off rapid sterility method suitability through September 30, 2020.
   Brian Kelley, ARL Bio Pharma

5. **Can you update the group where USP is with regards to the use of Rapid Test for release of products?**
   USP <797> states that, when required, sterility testing "must be performed according to <71> or a validated alternative method that is non-inferior to <71> testing". Chapter <1223> is referenced for the validation of alternative microbiological methods.
   Brian Kelley, ARL Bio Pharma