MIRACLE Academy

التعقيم والتصنيع المعقم

لجان الدُّفعات

اللهم وفقني في دراستي، ونوّر بالكتاب بصري، واشرح به صدري، واستعمل به بدني، واطلق به لساني، وقوِّ به عزمي بحولك وقوتك، فإنّه لا حول ولا قوة إلّا بك يا أرحم الراحمين.

وفقكم الله...

بكون حاطط كمان بالشابتر كيف نعمل Sample preparation وكيف نعمل Aseptic testing with sterile media
وكمان بكون حاطط كيف نحصل على Homogenous mixture حيث انه العينة ممكن يكون فيها highly water soluble compound or Fatty product or Aerosol or transdermal patch فهدول كلهم موجود بال Pharmacopeia كيف نتعامل معهم و كيف نعمل للعينة بوجودهم Total viable count

Microbiology Testing for Non-sterile Products
https://www.youtube.com/watch?v=2RsuPBZK058&t=966s

- USP <61>
- Three testing methods
  - Filtration
  - Pour plate
  - Surface spread
- Incubation, enumeration, results

متذكرين بالفيرست حكينا حتى نعمTVC يا بنعمل:

1) Pour plate
2) Spread plate
3) Filtration

طبعا احنا النا حرية الاختيار شو نستخدم اي طريقة

TVC: Total Viable Count

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*بدنا نعرف اي test بأي مكان اله Limitation يعني مش بس بال Microbiological test

Limitation for enumeration techniques (contamination test or bioburden determination) انه :

Not all organism present in the product will grow under testing condition

يعني وارد يكون عندي بالعينة MO لكن لن تنمو بال condition المحطوطة فيها و الموجودة في pharmacopeia فبنحسبهم viable but not culturable ، فمش كل ال MO اللي بنشوفهم و بنحسبهم viable بروح ازرعهم و احسب اكم عندي منهم بالعينة لانه مش كلهم رح ينمو تحت ال test condition

- USP <61> - Limitations
  - Not all organisms present in the product will grow under testing conditions
    - Viable but non-culturable
  - Microorganisms in samples are not homogenous.
    - Sink to the bottom or create a film on the top
    - Fungal balls floating in different areas

ليش not homogenous ؟
لأنه ما عم نحكي عن ملح ذائب بماء لأن هون في MO او Spores أو Fungus هاي بتكون بجانب العينة او بنص العينة او بالقاع عايشين او بتعمل film بس ما بنقدر نطلعهم بالعينة تاعتنا عشان هيك بناخد عينة من اماكن مختلفة عشان نوصل لهي ال Spores و ممكن نوصل و ممكن لا فهي من ال limitation

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بشابتر 62 رح نحكي عن :
Test for specific organisms

هسا بشابتر 62 رح نحتاج Agar media خاصة و media خاصة و incubation خاص حتى نحصل على ال Objectionable MO

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– Limitations

Limitation for test specific organism techniques

- Screen for specific organisms only
  - Additional specific organism screens may need to be created
  - Identify any growth recovered - Any growth recovered could mean a quality issue

يعني مثلا عم نعمل test for prescence of E.coli لما طلع لون ال Culture طلع ال E.coli مش موجودة و طلع Culture آخر لكن ال USP ما حكالنا لو طلع Culture آخر شو نعمل

يعني ما في تعليمات لو آخر Culture طلع معنا (زي ما حكينا بالنقطة الأولى)

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USP <51> - Antimicrobial Effectiveness Testing (AET)

- USP <51> - Antimicrobial Effectiveness Testing (AET)
  - Purpose of the test:
  - Testing performed to determine the effectiveness of antimicrobial preservatives by inoculating the sample with a set of challenge organisms and the number of CFU surviving at different time points is recorded.
    - Testing must be performed on sterile and non-sterile products that contain antimicrobial preservatives, even if the active drug intrinsically is antimicrobial.

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الشرح بالسلايد اللي بعد هاي

To determine the effectiveness of antimicrobial preservation, how?

By inculcating the sample with a set of 6 challenge organism , then we choose 5 from these 6 , after that the number of CFU survival of different times point recorded

على 7 ايام و 14 يوم و 21 يوم و 28 يوم
و نحدد ال survival و نرسم ال time with survival
لنشوف ال log reduction .

- USP <51>
  - Sterile - Multi-dose products that contain preservatives to inhibit growth during the withdrawing of individual doses
  - Non-sterile - Products that contain preservatives which are used to protect the product from microbiological growth during usage and manufacturing.
  - Testing is performed on the product as it is distributed by the manufacture (finished product)
  - Preservatives used should be below the level that is toxic to the user

لازم يكون تركيز المادة الحافظة ضمن التركيز المسموح فيه بحيث يكون
test the preservative for finish product in finish container

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***Sterile: مثل قطرة اول ما تنزل عالسوق هي sterile لكن فيها preservative system فلازم نتأكد انه بشتغل صح عشان اي بكتيريا تدخل يقتلها.**
***Non sterile: مثل oral solution أو Creams**

You have to test the preservative system even for sterile or non-sterile dosage form

- USP <51> - Product categories – Based on route of administration

Category	Product description
1	Injections, parenterals including emulsions, otic, sterile nasal and ophthalmic products made with aqueous bases or vehicles
2	Topical (aqueous bases or vehicles), non-sterile nasal and emulsions, including those applied to the mucous membranes
3	Oral products other than antacids with aqueous bases or vehicles
4	Antacids made with an aqueous base

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We have to know the category of products to the preservative efficacy test that we have to do and to interpret the result.

هسا اول شي كل product عنا ينتمي الى category معينة و موضحين شو كل category بتضم بالجدول السابق و معرفة ال category بتهمني لأعرف هل result اللي حصلت عليها لمنتجي هي pass or fail فمعرفتي اي category المنتج تاعي رح تساعدني اعرف شو العدد المسموح بنتيجة ال test .

* فـ احنا عنا regulation حسب المنطقة .

هسا لو كان المنتج هو category 1 فلازم نعمل :

Test for bacteria and test for yeast

واكم ال result المسموحة موجودة بالجدول اللي بعد هي السلايد لهي ال category ولباقي ال categories .

Category	Organism Type	Result Criteria Acceptance critiria
1	Bacteria	Not less than 1.0 log reduction from the initial calculated count at 7 days, not less than 3.0 log reduction from the initial count at 14 days, and no increase from the 14 days count at 28 days.
2	Bacteria	Not less than 2.0 log reduction from the initial count at 14 days, and no increase from the 14 days count at 28 days.
3	Bacteria	Not less than 1.0 log reduction from the initial count at 14 days, and no increase from the 14 days count at 28 days.
1-4	Mold and yeast	No increase from the initial calculated count at 14 and 28 days

- Additional criteria required for EP testing for parenteral, ophthalmic, topical and oral liquid based preparations.

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- USP <51> - How is testing performed?
  - Inoculum is prepared per USP instructions
  - Sample is inoculated with tested organisms
    - *S. aureus, P. aeruginosa, E. coli, C. albicans* and *A. brasiliensis*
    - Categories 1, 2, and 3 – final inoculum concentration is between 1 x 10^5 and 1 x 10^6 CFU/ mL
    - Category 4 – final inoculum concentration is between 1 x 10^3 and 1 x 10^4 CFU/ mL
  - Incubated and plated on specific days per product category requirements

بنعمل challenge
اقل لأنه ال
Antacids very basic

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بهالشابتر بكون حاكيلك كيف تعمل incoluating
اللي همه :
3 bacteria & 2 fungus (5MO)

- Determining Acceptance criteria
  - USP <1111> - Non-sterile products: Acceptance criteria for pharmaceutical preparations
  - Chapter recommendations for acceptance criteria
    - –Cutaneous–
      - » TAMC <200 CFU/g/mL Like creams
      - » TYMC <20 CFU/g/mL
      - » Absent of *S. aureus* and *P. aeruginosa*

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شابتر 1111 يعطي acceptance critiria لل non sterile products.
فيعني عملنا ال enumeration حسب شابتر 61 كيف رح نتأكد من ال Acceptance critiria؟ من شابتر 1111