What Makes An Objectionable Organism

PRESENTED BY PAUL YEATMAN Bsc

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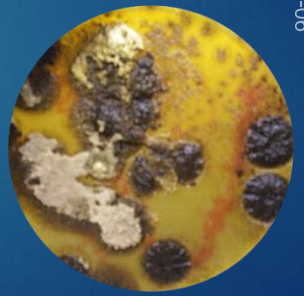
Introduction

- Who Am I?
- What's in it for you?
- This presentation applies to products not required to be sterile.
- As not all microbes specified are objectionable, and not all objectionable microbes are specified, it is important to be able to determine if any microbes recovered during routine and specified TMAC and TYMC testing are objectionable.



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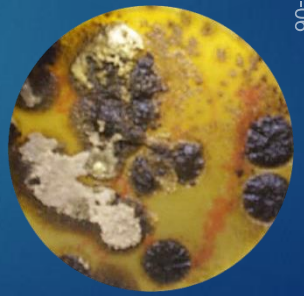
Presentation Aims/Outcomes

This presentation will provide you with the following knowledge:

- What makes a specified organism
- What makes an objectionable organism
- How to determine if a microbe is objectionable
- Risk assessment considerations
- The benefits of knowing the differences between specified & objectionable organisms



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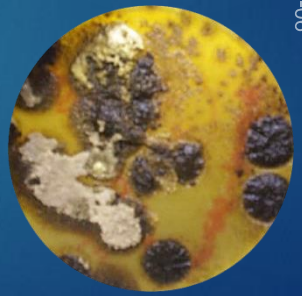
What Is A Specified Organism?

A specified organism is one that according to the pharmacopeia, cannot be present in a sample (usually 10g). These microbes are specified either as they may be an indicator organism or they may actually pose product safety concerns.

USP <1111> Microbiological Examination of Nonsterile Products lists several organisms which, depending on the route of administration, can be objectionable in a drug:

- Staphylococcus aureus
- Escherichia coli
- Pseudomonas aeruginosa
- Candida albicans
- bile-tolerant gram-negative bacteria



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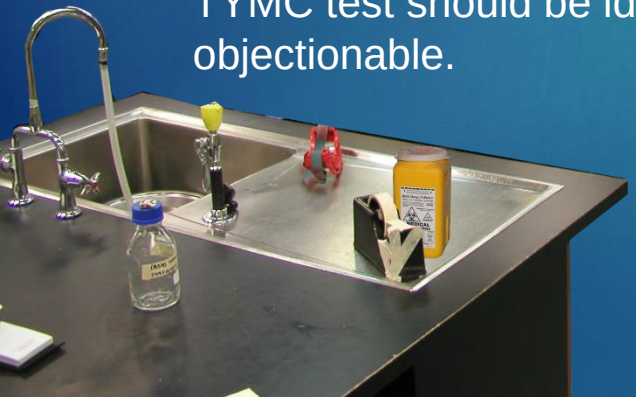
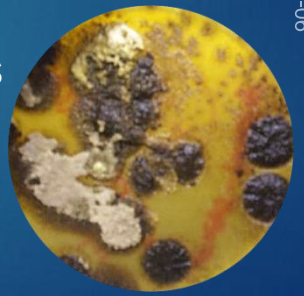
What Is An Objectionable Organism?

An objectionable organism is one that we do not want to see in our product based on:

- what the microbe is
- how many microbes were recovered
- how the product is used
- who the end user is

It can be argued that a specified microbe is not necessarily objectionable. Any microbe recovered from any TAMC and TYMC test should be identified and examined to determine if it is objectionable.





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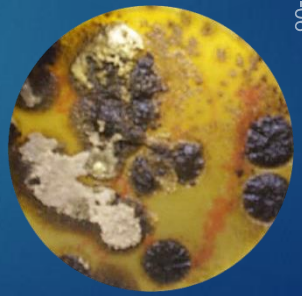
Determining If A Recovered Microbe Is Objectionable

A non sterile manufacturer should be concerned if microbes that are not specified are recovered during the specified test and they should determine if microbes recovered by the TAMC and TYMC tests are potentially objectionable. This can be evaluated by reviewing:

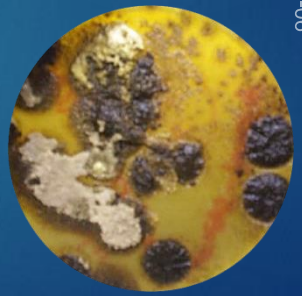
- Microbe pathogenicity
- Microbe source
- Potential product spoilage
- Results of the AMC test
- The product's target user and mode of application



Risk Assessment Considerations

When you recover a microbe your training and experience will give you a good idea if the microbe might cause issues. Here, as part of your risk assessment and investigation you need to consider such things as:

- Recovered microbe count
- Preservatives and antimicrobials in the product
- Validation data
- Intended use of product
- Where the recovered microbe typically causes disease
- Historical data of product



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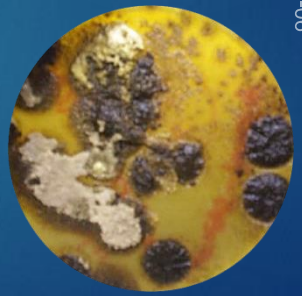
The Benefits of Knowing The Differences Between Specified & Objectionable Organisms

- Being aware that any microbe recovered during TMAC and TYMC is potentially objectionable is important as people tend to assume specified = objectionable and all other microbes are acceptable.
- By examining microbes recovered during TAMC and TYMC testing one may determine if they are detrimental to the product or patient. This ensures we release quality products that do not have unexpected (negative) impacts to us or the customer



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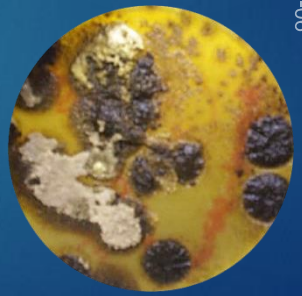
Conclusion

You will now know the following:

- What a specified organism is.
- What an objectionable organism is.
- How to determine if a microbe is objectionable.
- Some things to consider as part of your risk assessment.
- The benefits of knowing all of the above.



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References / Appendix

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