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Webinar Wednesday:
Microbial Examination
of Non Sterile Products

Microbiology

Assessment:

Recommendations for
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(1 of 6) Mar. 15, 2017

Microbiology Testing:

USP requirements for

Sterile and Nonsterile

Preparations CosPET-

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~~Preservation Challenge
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Method of testing
Scharlau :: Analysis of
Water ICMSF 2017 02

\ "Microbiological
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L. Buchanan

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~~Practices, Media Fill and~~
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Bacterial endotoxin test
/Limulus amebocyte
lysate test (BET/LAL)

~~What is (Microbial Limit~~
~~Test)?~~

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MILK SAMPLE Air

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Development ICH
Q8(R2) Microbiological
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EXAMINATION OF

NONSTERILE Use

standardized stable

suspensions of test strains

or prepare as stated

below. Seed-lot culture

maintenance techniques

(seed-lot sys-

PRODUCTS:

MICROBIAL items) are

used so that the viable

microorganisms used for

inoculation are not

more than 5 passages

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Microbiological Examination Of

removed from the original master

Nonsterile

~~<61> Microbiological Examination Of Nonsterile Products ...~~

USP Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests. USP tests allow quantitative enumeration of mesophilic bacteria and fungi that may grow

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Products
under aerobic conditions. The tests are designed primarily to determine whether a substance or preparation complies with an established specification for microbiological quality.

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Examination of
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USP ...

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Examination of Non-
Sterile Products: I.
Microbiological
Examination of Non-
Sterile Products:
Microbial Enumeration
Tests, and USP <61>
Microbiological
Examination of
Nonsterile Products:
Microbial ...

~~Annex 4A(R1)~~
Microbiological

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Microbiological Examination Of Nonsterile ...

Microbial examination of nonsterile products is performed according to the methods given in the texts on Microbial Enumeration Tests 61 and Tests for Specified Microorganisms 62. Acceptance criteria for nonsterile pharmaceutical products based upon the total

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Products
aerobic microbial count
(TAMC) and the total
combined yeasts and
molds count (TYMC)
are given in Tables 1 and
2.

1111

~~MICROBIOLOGICAL
EXAMINATION OF
NONSTERILE
PRODUCTS ...~~

Microbiological
examination of nonsterile

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Cannabis products. ...
cannabis is consumed via
vaporizing or smoking
oils and flowers while the
other half is consumed in
Marijuana Infused
Products or ...

~~(PDF) Microbiological
examination of nonsterile
Cannabis ...~~

biological Examination
of Nonsterile Products:
Microbial Enumer-

Read Online Microbiological

Examination Of
Nonsterile
Products 61 .

suspension of vegetative cells of *Cl. sporogenes*, a stable spore sus- If the product to be examined has antimicrobial activity, this suspension is used for test inoculation.

~~62~~ Microbiological
Examination Of

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~~Nonsterile Products ...~~
Examination Of
NonSterile
Products
GUIDANCE
DOCUMENT. Q4B
Annex 4C:
Microbiological
Examination of Non-
Sterile Products:
Acceptance Criteria for
Pharmaceutical
Preparations and
Substances for
Pharmaceutical Use
General Chapter ...

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~~Q4B Annex 4C:
Examination Of
Microbiological
Nonsterile
Examination of Non-
Sterile ...~~

MICROBIOLOGICAL
EXAMINATION OF
NON-STERILE
PRODUCTS: TEST
FOR SPECIFIED
MICRO-ORGANISMS

This general chapter presents 2 sets of tests.

The 1st set gives the reference methods for

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determining compliance
with monographs.
Nonsterile
Products

~~2.6.13.~~

~~MICROBIOLOGICAL
EXAMINATION OF
NON-STERILE~~

Non-fatty products
insoluble in
water. Suspend 10g or 10
ml of the product to be
examined in buffered
sodium chloride-
peptone solution pH 7.0

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or in another suitable

liquid. In general a one in ten

suspension is prepared, but

the characteristics of

some products may

necessitate the use of

larger volumes. A suitable

surface-active agent such

as 1 g/l

2.6.12.

~~MICROBIOLOGICAL~~

~~EXAMINATION OF~~

~~NON-STERILE ...~~

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Total of 1285 samples of non-sterile drugs manufactured by different pharmaceutical plants in Polish were taken into study. The microbiological quality of drugs was assessed in accordance with the criteria included in the European Pharmacopoeia (EP). An analysis of test results demonstrated that the

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Microbiological Examination Of Nonsterile Products

percentage of non-compliant samples was 1.87%.

~~Microbiological quality of non-sterile pharmaceutical products~~

Microbiological Examination of Non-Sterile products: Tests for Specified

Microorganisms provide protocols that allow quantitative enumeration

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Microbiological Examination Of Nonsterile Products

of the presence of bacteria and fungi. The tests help determine whether a nonsterile product complies with an established specification for microbiological quality. Additionally, these two USP chap-

~~Quality Control:
Microbial Limit Tests for
Nonsterile ...~~

On December 1, 2019,
Page 24/33

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Microbiological
USP <60>
Examination Of
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Products

MICROBIOLOGICAL EXAMINATION OF NONSTERILE

PRODUCTS - Tests for
Burkholderia Cepacia
Complex (BCC), will
become official. Testing
for BCC was developed
due to numerous adverse
events reported,
especially in aqueous
product where BCC may
be associated with

Read Online Microbiological manufacturing water Of Examination Of systems. Nonsterile

~~What FDA Considers
When Assessing
Microorganisms in Non~~

...

However, on December 1, 2019 the United States Pharmacopoeia (USP) new published chapter <60> Microbiological Examination of Non-Sterile Products Tests for

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Burkholderia Cepacia
Complex became official
as a means for testing
drug components and/or
final preparations for the
presence of Bcc.

~~USP Microbiological
Examination of Non-
sterile Products ...~~

Microbial examination of
non-sterile products is
performed according to
the methods given in the

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texts on 3.3.1 Microbial
enumeration tests and
3.3.2 Tests for specified
microorganisms.

Acceptance criteria for
non-sterile
pharmaceutical products

~~Microbiological quality
of non-sterile products ...~~

Microbiological
Examination of
Nonsterile Products
Microbial Enumeration

Read Online
Microbiological
Examination Of
and Test for Specified
Organisms for Nonsterile
Products Microbial
Enumeration tests for
nonsterile products,
following test procedures
outlined in USP <61>,
provides an evaluation of
the microbial content of
a product also known as
bioburden testing.

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Examination of

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Microbiological Examination Of Nonsterile Products

~~Nonsterile Products~~

As described in USP <61>, this microbial enumeration test provides a quantitative evaluation of the microbial content of a sample, also known as microbial bioburden testing or microbial limits testing. USP <62> is the method used to determine the presence or absence of

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Microbiological Examination Of Nonsterile Products

objectionable organisms or pathogens within a sample.

~~Microbiological Examination of Nonsterile Products~~

The presence of certain microorganisms in nonsterile preparations may have the potential to reduce or even inactivate the therapeutic activity of the product and has a

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Examination Of
potential to adversely
affect the health of the
patient. Manufacturers
have therefore to ensure a
low bioburden of
finished dosage forms

~~Change to read—
United States
Pharmacopeia~~

MICROBIOLOGICAL
EXAMINATION OF
NON-STERILE
PRODUCTS: TOTAL

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VIABLE AEROBIC

COUNT This general chapter presents 2 sets of tests.

The 1st set gives the reference methods for determining compliance with monographs.

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