ThermoFisher SCIENTIFIC MBD-BT-SPEC-0096

Rev 03

Page 1 of 4

# OXOID QUALITY ASSURANCE PRODUCT SPECIFICATION

### POTATO DEXTROSE AGAR (CM0139)

#### POTATO DEXTROSE AGAR

(EP, USP, JP, BP)

#### **Typical Formula\***

Potato extract	grams per litre	4.0**
Glucose		20.0
Agar		15.0
**4.0g of potato extract are eq	uivalent to 200g of infusion from potatoe	es

\* adjusted as required to meet performance standards

#### Directions

Suspend 39g in 1 litre of water (purified, as required). Bring to the boil to dissolve completely. Sterilize by autoclaving at 121°C for 15 minutes. Mix well and pour into sterile Petri dishes.

If necessary, after sterilization adjust the medium to pH 3.5 by adding Lactic Acid 10% (SR0021) at 50°C. Do not reheat after acidification.

#### **Physical Characteristics**

Off-white, free-flowing powder Colour on reconstitution - straw 1 Moisture level - less than or equal to 7% pH 5.6 ± 0.2 at 25°C (without adjustment) pH 3.5 ± 0.1 at 25°C (after adjustment) Clarity - clear Gel strength - firm, comparable to 15.0g/litre of agar CM0139

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MBD-BT-SPEC-0096

Rev 03

Page 2 of 4

# OXOID QUALITY ASSURANCE PRODUCT SPECIFICATION

## POTATO DEXTROSE AGAR (CM0139)

#### **Microbiological Tests Using Optimum Inoculum Dilution**

Control Medium: Potato Dextrose Agar

Reactions after incubation at 25°C for 5 days

Tested using acidified medium

Medium is challenged with 10-100 colony-forming units

Candida krusei	ATCC <sup>®</sup> 6258	1-4mm cream colonies
Candida albicans	ATCC®10231	1-4mm cream colonies

A satisfactory result is represented by recovery of positive strains equal to or greater than 70% of the control medium.

Medium is challenged with 1E+04 to 1E+06 colony-forming units

Bacillus subtilis	ATCC <sup>®</sup> 6633	No growth
Escherichia coli	ATCC <sup>®</sup> 8739	No growth
Staphylococcus aureus	ATCC <sup>®</sup> 6538	No growth

Negative strains are inhibited.

Inoculation using stab technique

Aspergillus fumigatus	ATCC <sup>®</sup> 9197	>15mm cream mycelia, blue/green spores
Aspergillus brasiliensis	ATCC®16404	> 15mm white mycelia, black spores
Fusarium culmorum	FMH-2407W	> 15mm white mycelia, orange/red spores
Fusarium oxysporum	FYH-2386W	> 15mm white mycelia, pink/red spores

For mould species, a satisfactory result is represented by typical colonial morphology.



MBD-BT-SPEC-0096

Rev 03

Page 3 of 4

## OXOID QUALITY ASSURANCE PRODUCT SPECIFICATION

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#### Testing performed in accordance with USP/EP/BP.JP

#### Reactions after incubation at 25°C for 5 to 7 days

Medium is challenged with 10-100 colony-forming units

Aspergillus brasiliensis ATCC®16404 > 10mm white mycelia, black spores

A satisfactory result is represented by recovery of positive strains equal to or greater than 70% of the control medium

The Microbiological Quality Control of this product complies with the following pharmacopoeia;

- 1. European Pharmacopoeia: Current version.
  - 2.6.12 Microbiological Examination of Non-Sterile Products: Harmonised Method: Microbial Enumeration tests
  - 2.6.13 Microbiological Examination of Non-Sterile Products: Tests for Specified Microorganisms. B. Harmonised Method
- 2. United States Pharmacopoeia: Current version.
  - 61 Microbiological Examination of Non-Sterile Products: Microbial Enumeration tests.
  - 62 Microbiological Examination of Non-Sterile Products: Tests for Specified Microorganisms
- 3. Japanese Pharmacopoeia: Current version.

ThermoFisher SCIENTIFIC MBD-BT-SPEC-

0096 Rev 03

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Page 4 of 4

# OXOID QUALITY ASSURANCE PRODUCT SPECIFICATION POTATO DEXTROSE AGAR (CM0139)

### **Revision History**

Section / Step	Description of Change	Reason for Change	Reference
Directions	Remove the amount of Lactic Acid required to do the pH adjustment.	Change control	MOC-2024-1258