

Certificate of Analysis



Certificate of Analysis ID: 1052840500_VM1152884_EN

Producer and client: Merck KGaA, Frankfurter Str. 250, 64293 Darmstadt, Germany

Test laboratory: Merck KGaA Qualitätskontrolle für mikrobiologische Produkte
Frankfurter Str. 250, 64293 Darmstadt, Germany

Sample identification: GranuCult® prime
Cetrimide Agar (base)
acc. ISO 22717, FDA-BAM and Ph. Eur./USP/JP

Ordering number: 1.05284.0500

Lot number: VM1152884

Sample ID: 201626637

Accreditation:



Test method: DIN EN ISO 11133:2020
Performance testing of solid culture media:
Qualitative method (streaking method)

Date of analysis: 2025/08/22

Date of release: 2025/08/22

Minimum shelf life: 2030/08/31

Composition (g/l): Pancreatic digest of gelatin 20.0; Magnesium chloride 1.4; Potassium sulfate (Dipotassium sulfate) 10.0; N-Cetyl-N,N,N-trimethylammonium bromide (cetrimide) 0.3; Agar-agar 13.6.

Preparation & sterilization: Dissolve 45.3 g in 1 liter of purified water. Heat in boiling water and agitate frequently until completely dissolved. Add 10 ml/l of Glycerol (CAS No. 56-81-5, e.g. Cat. No. 104057). Autoclave (15 minutes at 121°C). Pour to plates.

Application: For the isolation and identification of Pseudomonas aeruginosa from pharmaceutical, cosmetic and other material.

Storage: Store at +15 °C to +25 °C, dry and tightly closed. Do not use clumped or discolored medium. Protect from UV light (including sun light).

The reported results refer exclusively to the specified medium, see Certificate of Analysis ID.

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Physical parameters

Appearance (clarity):

Specification

slightly opalescent to turbid

Lot value

slightly opalescent

Appearance (color):

light yellowish

light yellowish

pH-value (25 °C):

7.0 – 7.4

7.1

Solidification behaviour (2 h at 45 °C)

liquid

liquid

Microbiological Performance

Qualitative method (streaking method)

Test strain	Specification		Lot value	
	Growth	typical reaction	Growth	typical reaction
Pseudomonas aeruginosa ATCC® 9027 [WDCM 00026]	good to very good	formation of yellowish-green pigment (pyocyanin) with fluorescence under UV light (360 ± 20 nm)	good to very good	passes test formation of yellowish-green pigment (pyocyanin) with fluorescence under UV light (360 ± 20 nm)

Incubation:

24 - 48 hours at 32,5 °C ± 2,5 °C; aerobic.

Microbiological Performance*

Test strain	Specification	Reference 10 – 100 CFU	Test CFU	Recovery rate	Typical reaction
Pseudomonas aeruginosa* ATCC® 9027 [WDCM 00026]	50 – 150 %	61	55	90 %	passes test yellowish-green to blue coloration of the colonies
Pseudomonas aeruginosa* ATCC® 27853 [WDCM 00025]	50 – 150 %	83	108	130 %	passes test yellowish-green to blue coloration of the colonies
Pseudomonas aeruginosa* ATCC® 25668 [WDCM 00114]	50 – 150 %	74	79	107 %	passes test yellowish-green to blue coloration of the colonies

Incubation:

≤ 18 hours at 32,5 °C ± 2,5 °C; aerobic

Test strain	Specification	Reference > 100 CFU	Growth
Escherichia coli* ATCC® 8739 [WDCM 00012]	no growth	8100	no growth
Proteus mirabilis* ATCC® 29906 [WDCM 00023]	no growth	9200	no growth
Staphylococcus aureus* ATCC® 6538 [WDCM 00032]	no growth	4800	no growth

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Test strain	Specification	Reference > 100 CFU	Growth
Salmonella typhimurium* ATCC® 14028 [WDCM 00031]	no growth	8300	no growth

Incubation: ≥ 72 hours at $32,5\text{ }^{\circ}\text{C} \pm 2,5\text{ }^{\circ}\text{C}$; aerobic

Reference medium: Tryptic Soy Agar

Parameters marked with an asterisk have not been tested by an accredited method.

Release: Culture medium released by Approving Officer or delegate LS-SC-PCDQS6

Dr. Lukas Mechler

Responsible Manager of LS-SC-PCDQS6 (Test Laboratory D-PL-15185-01-00)

Certificate of analysis revision history:

Certificate version	Date	Status	Reason for version
01	2025/08/22	effective	Initial version