

Work Order	3223.3_Rev5
Setup-Code	190109-10290-2801-01



Test Report

JIS Z 2801:2012 (Mod)

Antimicrobial products – Test for antimicrobial activity and efficacy

Test Object:

*BactoAttaQ® against Enterococcus hirae DSM3320
ATCC10541 after one year of artificial aging*

Work Order	3223.3_Rev5
Setup-Code	190109-10290-2801-01

Report on Findings

Client: C.P.S.-Pharma GmbH
Address: Rehlinger Straße 20
66701 Beckingen

Work order no.: 3223.3_Rev5

Test object: BactoAttaQ® against *Enterococcus hirae* DSM3320 ATCC10541 after one year of artificial aging

Sample description: painted plastic films

Date of receipt of sample: 2018-Oct-22

Type of test: JIS Z 2801:2012 Antimicrobial products – Test for antimicrobial activity and efficacy

Test Germ: *Enterococcus hirae* DSM3320 ATCC10541

Test laboratory: QualityLabs BT GmbH

Address: Neumeyerstrasse 46a
90411 Nuremberg, Germany

Setup-Code: 190109-10290-2801-01

Sample material: Leneta foil

No. of pages in report: 7

Report on findings to the client: Place and date of preparation: Nuremberg, 2020-Mar-18
Recipient: C.P.S.-Pharma GmbH
replaces the report from the 18th Mar. 2020

Laboratory Director:



Dr. Gopala Mannala, Technical Director
QualityLabs BT GmbH

Released:



Dr. Peter Steirnücke, Managing Director
QualityLabs BT GmbH

Work Order	3223.3_Rev5
Setup-Code	190109-10290-2801-01

Declaration on Quality Assurance

This investigation was performed and supervised according to the standard operating procedure "SOP zu JIS Z 2801:2012 (Mod)" by QualityLabs BT GmbH. The laboratory and process are continually monitored by independent, external authorities, as well as by internal audits.

Archiving

A copy of the test report, a protocol of the measurement as well as the accompanying correspondence and business records are archived by QualityLabs BT GmbH. The retention period is at least 10 years.

Test description

Anti-bacterial activity is determined in accordance with a modified version of JIS Z 2801:2012.

During the test, a thin liquid-film containing the bacteria (1.25×10^4 CFU / cm²) is applied directly to the test sample (Standard: 5 cm x 5 cm). To avoid desiccation a foil (Standard: 4cm x 4cm, Stomacher Bags) is applied. Immediately after inoculation, the bacteria from the reference sample are separated from the sample and the enveloping foil surfaces using ultrasound and vortex devices and the number of viable germs (CFU – colony-forming units) is determined (t_0 value). A further set of reference samples and samples given anti-microbial treatment is incubated with bacteria in a liquid-film and the enveloping foil in a damp environment at 37°C. After 24 hours, the bacteria are separated from the sample surfaces using ultrasound and vortex devices and the number of viable germs is determined (t_{24} value).

Work Order	3223.3_Rev5
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Assessment of antimicrobial activity

A logarithmic germ reduction of ≥ 3 log scales of the antimicrobial sample in comparison to the respective reference is used as assessment criterion to pass the antimicrobial test.

Germ reduction [log scales]	Antibacterial activity
< 3	Not sufficient antimicrobial activity
≥ 3	Sufficient antimicrobial activity

Work Order	3223.3_Rev5
Setup-Code	190109-10290-2801-01

References to Testconditions

Test conditions		
Sample size	25	cm ²
Foil size	16	cm ²
Volume Inoculum	400	μl
Sample cleaning	-	-

References to deviations, preincubations, special test conditions

The samples have been stored for 56 days at 50 °C, which corresponds to an artificial aging of 1 year according to ASTM F 1980.

Work Order	3223.3_Rev5
Setup-Code	190109-10290-2801-01

Test Results

Sample Name	Sample Code	t ₀ (cells/cm ²)			t ₂₄ (cells/cm ²)			Reduction [%]	Log Reduction
1 Reference sample	102902310180011	1.1 x 10 ⁵	9.4 x 10 ⁴	1.2 x 10 ⁵	1.3 x 10 ⁵	1.4 x 10 ⁵	7.6 x 10 ⁴	-	Reference
2 BactoAttaQ®	102902310180012				< 1.0 x 10 ¹	< 1.0 x 10 ¹	< 1.0 x 10 ¹	> 99.99	> 4

*see "Interpretation of Results", page 6

Test strain	<i>Enterococcus hirae</i> DSM3320 ATCC10541
Initial cell count inoculum / cm ²	1.25 x 10 ⁴
Initials of the editor	CG CG
Measurement ended on	17-01-2019

Work Order	3223.3_Rev5
Setup-Code	190109-10290-2801-01

Comments on test objects

NONE

Interpretation of the results based on the measurements

NONE

Editor: Ms. Görgey 

Crosschecked: Mr. Karimi 

References

JIS Z 2801:2012 Antimicrobial products – Test for antimicrobial activity and efficacy