Stress certificate

ComASP Vancomycin/Teicoplanin
Réf : 068008

Réf : PR-711219
Validé : 21/11/23

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Microbiology products since 1983

Stability StudyReport **75005_SS-Rev.01**

STABILITY AND TRANSPORTATION STUDIES

Liofilchem's Antimicrobial Susceptibility Panels: Validation of Shelf Life and Stability Outside Specified Temperatures

Product details	
Catalogue Number (Ref.)	75005
Name	ComASP Vancomycin/Teicoplanin
Description	System for susceptibility testing of vancomycin and teicoplanin with the broth microdilution method
Storage Temperature	2-8°C
Shelf Life	485 days

Introduction

The aim of the study is to demonstrate the stability of the parameters of the finished products over time.

The study is carried out according to the recommendations of the EN ISO 23640 − *In vitro* diagnostic medical devices − Evaluation of stability testing of *in vitro* diagnostic reagents.

Stability testing is performed as real-time study with the product stored at the recommended temperature for the length of its proposed shelf life.

Stress environmental conditions are implemented to simulate in a short period of time changes that may occur in the long-term. Such thermal stresses are also included to mimic unfavorable conditions that may be encountered during transportation (simulation of the delivery process) and in the laboratory use.

Operating Procedure

The study is carried out on three (3) batches. Examinations are performed in triplicate. For storage temperature and time see Table 1.

Table 1.

Temperature	Time
2-8°C	The entire test period
15-25°	4 days
35-39°C	2 days

Temperature-stressed products are then placed in the recommended conditions until time of testing. The frequency testing, status of the investigation and the entire study length is presented in Table 2.

Table 2.

Initial (t0)	1M	3M	6M	12M	18M
X	X	X	X	X	X

The batches used for stability testing are listed in Table 3.

Table 3.

Ref.	Batch
$75005	062518054 113018001 012919001

Acceptance criteria

The product is considered acceptable for its intended use when all analytical results meet set acceptance limits. Well-content is examined for appearance, homogeneity and dehydration before substrata are reconstituted.
Microbiological performance is monitored using the quality control strains and incubation conditions, as indicated in the product's Certificate of Analysis (CoA).

Discussion / Conclusion

Product stressed intentionally did not show any sign of deterioration, nor effects on performance characteristics were observed during the study. Storage for up to eighteen (18) months at the label storage condition had no significant effects on the stability of the product (since little or no variability was registered over time, statistical analysis has been considered unnecessary).

Data support the labelled shelf life of the product.

Date 11.09.2020

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