

**REF AEB400100****Cryobilles****THERMAL SHOCK VALIDATION STATEMENT****Introduction**

These studies are performed during the product development on one batch including thermal shocks. Thermal shocks are test temperature cycles to which products are subjected to simulate the cold chain rupture that may occur during the delivery process. These studies support product performance during shelf-life.

**Summary of the stability study**

The studies were performed according to the following protocol: PCQ 610/A.

The following protocol has been implemented for the product, before its storage at the recommended conditions:

Cycle	Temperature	Storage Time
1	2-8°C	5 days
2	18-23°C	5 days
3	37°C	5 days
4	50°C	1 day
5	-20°C	1 day

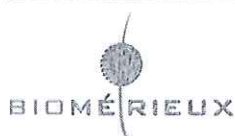
The study consists in verifying the conformity of appearance, pH, fertility/growth promotion and selectivity of the media.


Tests were performed on batch 215651.

The results obtained are described in the following report: Stability Study Report EN/389/A.

The performance are maintained until the expiry date.

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**REF** AEB400100**Cryobilles****THERMAL SHOCK VALIDATION STATEMENT**

Results for Cycle 1

Test		Theoretical results	Results
Appearance		Amber, Fluid + beads	Conform
pH		7.4 +/- 0.2	7.3
<b>Fertility – Specificity - Selectivity</b>		Inoculation of 100µ of calibrated inoculi (100 to 1000CFU). Calculation of a survival rate RS at room T° =(enul.T2 hours/enum.T0)x100 on TSA in 100µ of cryobeads fluid.	
<i>Candida albicans</i> – ATCC 10231 // UMIP 48.72 (CAN1.1)	48h 22.5°C	50% < RS < 200 %	Conform
<i>Escherichia coli</i> – ATCC 8739 / CIP 53.126 (ESC.1.2)	24h 32.5°C	50% < RS < 200 %	Conform
<i>Staphylococcus epidermis</i> – ATCC 12228 / CIP 68.21 (STA.2.3)	24h 32.5°C	50% < RS < 200 %	Conform

Results for Cycle 2

Test		Theoretical results	Results
Appearance		Amber, Fluid + beads	Conform
pH		7.4 +/- 0.2	7.2
<b>Fertility – Specificity - Selectivity</b>		Inoculation of 100µ of calibrated inoculi (100 to 1000CFU). Calculation of a survival rate RS at room T° =(enul.T2 hours/enum.T0)x100 on TSA in 100µ of cryobeads fluid.	
<i>Candida albicans</i> – ATCC 10231 // UMIP 48.72 (CAN1.1)	48h 22.5°C	50% < RS < 200 %	Conform
<i>Escherichia coli</i> – ATCC 8739 / CIP 53.126 (ESC.1.2)	24h 32.5°C	50% < RS < 200 %	Conform
<i>Staphylococcus epidermis</i> – ATCC 12228 / CIP 68.21 (STA.2.3)	24h 32.5°C	50% < RS < 200 %	Conform

Results for Cycle 3

Test		Theoretical results	Results
Appearance		Amber, Fluid + beads	Conform
pH		7.4 +/- 0.2	7.3
<b>Fertility – Specificity - Selectivity</b>		Inoculation of 100µ of calibrated inoculi (100 to 1000CFU). Calculation of a survival rate RS at room T° =(enul.T2 hours/enum.T0)x100 on TSA in 100µ of cryobeads fluid.	
<i>Candida albicans</i> – ATCC 10231 // UMIP 48.72 (CAN1.1)	48h 22.5°C	50% < RS < 200 %	Conform
<i>Escherichia coli</i> – ATCC 8739 / CIP 53.126 (ESC.1.2)	24h 32.5°C	50% < RS < 200 %	Conform
<i>Staphylococcus epidermis</i> – ATCC 12228 / CIP 68.21 (STA.2.3)	24h 32.5°C	50% < RS < 200 %	Conform

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**Cryobilles**

## THERMAL SHOCK VALIDATION STATEMENT

Results for Cycle 4

Test		Theoretical results	Results
Appearance		Amber, Fluid + beads	Conform
pH		7.4 +/- 0.2	7.3
Fertility – Specificity - Selectivity		Inoculation of 100µ of calibrated inoculi (100 to 1000CFU). Calculation of a survival rate RS at room T° =(enul.T2 hours/enum.T0)x100 on TSA in 100µ of cryobeads fluid.	
<i>Candida albicans</i> – ATCC 10231 // UMIP 48.72 (CAN1.1)	48h 22.5°C	50% < RS < 200 %	Conform
<i>Escherichia coli</i> – ATCC 8739 / CIP 53.126 (ESC.1.2)	24h 32.5°C	50% < RS < 200 %	Conform
<i>Staphylococcus epidermis</i> – ATCC 12228 / CIP 68.21 (STA.2.3)	24h 32.5°C	50% < RS < 200 %	Conform

Results for Cycle 5

Test		Theoretical results	Results
Appearance		Amber, Fluid + beads	Conform
pH		7.4 +/- 0.2	7.4
Fertility – Specificity - Selectivity		Inoculation of 100µ of calibrated inoculi (100 to 1000CFU). Calculation of a survival rate RS at room T° =(enul.T2 hours/enum.T0)x100 on TSA in 100µ of cryobeads fluid.	
<i>Candida albicans</i> – ATCC 10231 // UMIP 48.72 (CAN1.1)	48h 22.5°C	50% < RS < 200 %	Conform
<i>Escherichia coli</i> – ATCC 8739 / CIP 53.126 (ESC.1.2)	24h 32.5°C	50% < RS < 200 %	Conform
<i>Staphylococcus epidermis</i> – ATCC 12228 / CIP 68.21 (STA.2.3)	24h 32.5°C	50% < RS < 200 %	Conform

### Revision history:

Revision	Application date	Revision description
00	06/04/2017	Document creation

### Approval:

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