

Process Run Record

Summary

STERIS AST CZ s.r.o.
Průmyslová zóna Košíkov 80
595 01 Velká Bíteš, Czech Republic
Tel: +420566562145
Fax:

Run ID:	311311	Pallet Count:	18	Batch No.:	22240205
Customer:	routine_MIX cycle-15%	Checksum:	5998	Method:	MIX cycle-15%
Specification:	1.0				

1. Preconditioning

Equipment: **VB Precond G** Config. Rev.: **Pending**
Date Started: **04.02.2024 5:26:46** Date Completed: **04.02.2024 17:01:59** Duration: **11:35:13**

1.1. Preconditioning

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	11:35:13	11:00:00 - 1d 00:00:00	✓
Time-InSpec	Final - P104	11:20:00	11:00:00 - 1d 00:00:00	✓
TE-Min-In-Spec	Min - P101	46,4 °C	45,0 - 55,0 °C	✓
TempAve	Max - P101	52,6 °C	45,0 - 55,0 °C	✓
RH-Min-In-Spec	Min - P22	49,6 %	45,0 - 95,0 %	✓
AT-RH-Avg	Max - P22	69,7 %	45,0 - 95,0 %	✓

1.2. Transfer to Vessel

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
Transfer Duration	Final - P104	00:13:44	n/a - 00:45:00	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
2	0	04.02.2024 5:26:46	04.02.2024 17:15:43	11:35:13

Process Run Record **Summary**

Run ID 311311

2.Vessel Processing

Equipment: **VB Chamber 22** Config. Rev.: **Pending**
 Date Started: **04.02.2024 17:15:43** Date Completed: **05.02.2024 5:07:31** Duration: **11:51:48**

2.1.Start-up Phase

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
TE-CH-Hi	Final - P3	48,5 °C	48,0 - 54,0 °C	✓
TE-CH-Lo	Final - P3	48,5 °C	48,0 - 54,0 °C	✓

2.2.Vacuum

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:13:34	00:10:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:13:34	00:10:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	48,3 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	48,7 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	22,0 kPa	12,0 - 32,0 kPa	✓

2.3.Leak Check

Phase No. 3

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:05:01	00:01:00 - 00:20:00	✓
Total Phase Time	Final - P11	00:05:01	00:01:00 - 00:20:00	✓
TE-CH-Lo	Min - P3	48,6 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,1 °C	40,0 - 55,0 °C	✓
PCurr	Min - P14	22,0 kPa	12,0 - 33,0 kPa	✓
PCurr	Max - P14	22,6 kPa	12,0 - 33,0 kPa	✓

2.4.Vacuum

Phase No. 4

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:00:20	00:00:01 - 00:05:00	✓
Total Phase Time	Final - P11	00:00:20	00:00:01 - 00:05:00	✓
TE-CH-Lo	Min - P3	49,1 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,1 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	22,0 kPa	21,0 - 22,2 kPa	✓

2.5.Steam Inject by Pressure

Phase No. 5

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:02:24	00:01:00 - 00:12:00	✓
Total Phase Time	Final - P11	00:02:24	00:01:00 - 00:12:00	✓
TE-CH-Lo	Min - P3	49,1 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,3 °C	45,0 - 55,0 °C	✓
PCurr	Final - P14	23,1 kPa	23,0 - 26,6 kPa	✓

Process Run Record Summary

Run ID 311311

Stage » Vessel Processing**2.6. Conditioning Dwell by Pressure**

Phase No. 6

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	01:25:01	01:10:00 - 01:40:00	✓
Total Phase Time	Final - P11	01:25:01	01:10:00 - 01:40:00	✓
TE-CH-Lo	Min - P3	49,2 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,2 °C	45,0 - 55,0 °C	✓
PCurr	Min - P14	22,9 kPa	22,0 - 26,6 kPa	✓
PCurr	Max - P14	23,6 kPa	22,0 - 26,6 kPa	✓
RH Reported	Min - P22	66,0 %	N/A - N/A %	
RH Reported	Max - P22	87,9 %	N/A - N/A %	

2.7. Vacuum

Phase No. 7

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:00:43	00:00:01 - 00:05:00	✓
Total Phase Time	Final - P11	00:00:43	00:00:01 - 00:05:00	✓
TE-CH-Lo	Min - P3	50,1 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,2 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	22,0 kPa	21,0 - 22,2 kPa	✓

2.8. EO Inject by Pressure

Phase No. 8

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	01:04:47	00:45:00 - 01:30:00	✓
Total Phase Time	Final - P11	01:04:47	00:45:00 - 01:30:00	✓
TE-CH-Lo	Min - P3	50,1 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	51,1 °C	46,0 - 54,0 °C	✓
PCurr	Final - P1028	215,0 kPa	n/a - N/A kPa	
PCurr	Final - P14	215,0 kPa	200,0 - 225,0 kPa	✓
EO Conc. Reported	Final - P33	414,0 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Final - P33	473,7 mg/l	N/A - N/A mg/l	

Process Run Record Summary

Run ID 311311

Stage » Vessel Processing**2.9. Super-Atmospheric EO Dwell**

Phase No. 9

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	06:00:01	05:55:00 - 07:00:00	✓
Total Phase Time	Final - P11	06:00:01	05:55:00 - 07:00:00	✓
TE-CH-Lo	Min - P3	49,7 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	50,7 °C	46,0 - 54,0 °C	✓
PCurr	Min - P14	209,7 kPa	200,0 - 225,0 kPa	✓
PCurr	Min - P1028	209,7 kPa	N/A - N/A kPa	
PCurr	Max - P1028	215,0 kPa	N/A - N/A kPa	
PCurr	Max - P14	215,0 kPa	200,0 - 225,0 kPa	✓
RH Reported	Min - P22	0,0 %	N/A - N/A %	
RH Reported	Max - P22	0,0 %	N/A - N/A %	
EO Conc. Reported	Min - P33	289,1 mg/l	N/A - N/A mg/l	
EO Conc. Reported	Max - P33	414,0 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Min - P33	473,7 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Max - P33	475,1 mg/l	N/A - N/A mg/l	

2.10. Vacuum

Phase No. 10

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:23:30	00:15:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:23:30	00:15:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	48,1 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,0 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	26,0 kPa	16,0 - 36,0 kPa	✓

2.11. Air Inbleed

Phase No. 11

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:07:26	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:26	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	48,6 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,7 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,0 kPa	90,0 - 103,0 kPa	✓

2.12. Vacuum

Phase No. 12

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:12:01	00:12:00 - 00:28:00	✓
Total Phase Time	Final - P11	00:12:01	00:12:00 - 00:28:00	✓
TE-CH-Lo	Min - P3	48,7 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,5 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	27,0 kPa	17,0 - 37,0 kPa	✓

Process Run Record Summary

Run ID 311311

Stage » Vessel Processing**2.13. Air Inbleed**

Phase No. 13

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:07:20	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:20	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	48,7 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,8 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,0 kPa	90,0 - 103,0 kPa	✓

2.14. Vacuum

Phase No. 14

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:12:01	00:12:00 - 00:28:00	✓
Total Phase Time	Final - P11	00:12:01	00:12:00 - 00:28:00	✓
TE-CH-Lo	Min - P3	48,9 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,7 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	27,0 kPa	17,0 - 37,0 kPa	✓

2.15. Air Inbleed

Phase No. 15

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:07:20	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:20	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	49,0 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,3 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,0 kPa	90,0 - 103,0 kPa	✓

2.16. Vacuum

Phase No. 16

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:12:01	00:12:00 - 00:28:00	✓
Total Phase Time	Final - P11	00:12:01	00:12:00 - 00:28:00	✓
TE-CH-Lo	Min - P3	49,2 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,1 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	27,0 kPa	17,0 - 37,0 kPa	✓

2.17. Air Inbleed

Phase No. 17

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:07:21	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:21	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	49,2 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,5 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,1 kPa	90,0 - 103,0 kPa	✓

Process Run Record Summary

Run ID 311311

Stage » Vessel Processing

2.18.End Phase

Phase No. 18

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	01:30:51	00:00:01 - 05:00:00	✓
Total Phase Time	Final - P11	01:30:51	00:00:01 - 05:00:00	✓
TE-CH-Lo	Min - P3	49,9 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,4 °C	40,0 - 55,0 °C	✓
PCurr	Min - P14	93,0 kPa	90,0 - 103,0 kPa	✓
PCurr	Max - P14	94,7 kPa	90,0 - 103,0 kPa	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
18	0	04.02.2024 17:15:43	05.02.2024 5:07:31	11:51:48

CONFORMING

Krezek, Ales

Digitally signed by Krezek, Ales
Date: 2024.02.05 09:12:31
+01'00'

All dates are expressed in the timezone:

(UTC+01:00) Praha, Bratislava, Budapešť, E

✓ = Pass ✗ = Fail

STERIS: Certificate Of Processing

Prepared for STIRILAB

Ethylene Oxide Run ID 2002-1663

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity (PL)</u>
STIRILAB 03 EQ-15%	202400548	18

Product meets Customer specifications; zero nonconformities occurred during this run.

Other Information

Sterilization Batch Number 22240205

Customer Specification ID: 37

Signature Manifest

Reviewed and E-Signed By: **Sarka Mejzlikova (Quality Analyst)**

Date/Time E-Signed: 05-Feb-2024 9:34 AM

Document Content Revision: 1

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11135.

This Certificate becomes valid only with the Process Run Record Summary and Biological Indicators Incubation Certificate referring to applicable sterilization Batch Number.

Processing Location

STERIS AST CZ s.r.o.
Průmyslová zóna Košíkov 80
Velká Bíteš
595 01

*** End of Ethylene Oxide Certificate of Processing Document ***

Document ID: 8995

Komu: / To **STIRILAB S.R.O.**
TEXTILNÁ 23
03401 RUZOMBEROK SLOVENSKÁ REPUBLIKAANALYSIS CERTIFICATE #1032 - BI208 - 02/12/2024
ČÍSLO CERTIFIKÁTU ANALÝZY 1032 - BI208 - 12/02/2024Page 1 / 1
Strana 1 / 1Our Laboratory Reference Register # BI / 191 - p. 58
Evidenční číslo: BI / 191 - s. 58TITLE: BIOLOGICAL INDICATORS - SPORE STRIP - BACILLUS ATROPHAEUS (B. subtilis var Niger) ATCC #9372
NÁZEV: BIOLOGICKÝ INDIKÁTOR - SPORE STRIP - BACILLUS ATROPHAEUS (B. Subtilis var Niger) ATCC #9372METHOD: ISO 11138-1
METODA: ISO 11138-1
INTERNAL PROCEDURES: LWI-LAB002
VNITŘNÍ PROCEDURA: LWI-LAB002

REFERENCE DATA

REFERENČNÍ ÚDAJESAMPLES DESCRIPTION: ZDRAVOTNICKÉ PROSTŘEDKY-IN VITRO DIAGNOSTIKA
POPIS VZORKŮ: ZDRAVOTNICKÉ PROSTŘEDKY-IN VITRO DIAGNOSTIKA

REFERENCE: STIRILAB S.R.O.

JMÉNO ZÁKAZNÍKA: STIRILAB S.R.O.

WITHDRAWING MADE BY: STERIS

ODPOVĚDNOST ZA VÝBĚR VZORKŮ: STERIS

RECEIVED BY LABORATORY AT: 02/05/2024

DODÁNO DO LABORATOŘE: 05/02/2024

PRODUCTION BATCH: BILL OF DELIVERY: 202400548

PRODUKČNÍ ŠARŽE: BILL OF DELIVERY: 202400548

STERILIZATION BATCH: 22240205 dtd 02/05/2024

STERILIZAČNÍ ŠARŽE: 22240205 dne 05/02/2024

BI BATCH: BATR 485

BI ŠARŽE: BATR 485

POPULATION (ufc/strip): $3.7 \cdot 10^6$ POPULACE (cfu / strip): $3.7 \cdot 10^6$

D-value (min): 2.8

D - hodnota (min): 2.8

ANALYSIS PARAMETERS

PARAMETRY ANALÝZY

POSITIVE CONTROLS N.: 1

POČET POZITIVNÍCH KONTROL: 1

BIOLOGICAL INDICATORS N.: 28

POČET BIOLOGICKÝCH INDIKÁTORŮ: 28

GROWTH EVIDENCE AT THE END OF INCUBATION PERIOD

EVIDENCE RŮSTU NA KONCI INKUBAČNÍ DOBY

BI SAMPLES AFTER 7 DAYS

BI PO SEDMI DNECH

POSITIVE CONTROL BI

POZITIVNÍ KONTROLA BI

negative
negativní
positive
pozitivní

Conclusions

Závěry

EFFECTIVE STERILIZATION CYCLE

ÚČINNÝ STERILIZAČNÍ CYKLUS

LABORATORY RESPONSIBLE
ODPOVĚDNÁ OSOBA

12-02-2024

21

RELEASED BY QUALITY

Šárka Mejzlíková

12.02.2024

Mejzlíková



Transport Document



202400548

STIRILAB s.r.o. a dominique Dutscher company

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034 01
Ružomberok**

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www.stirilab.com, email ekonom@stirilab.com

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CUSTOMER

STERIS AST CZ s.r.o.

Průmyslová zóna Košíkov 80

595 01 Velká Bíteš, ČR

SHIP TO

STERIS AST CZ s.r.o.

Průmyslová zóna Košíkov 80

59501 Velká Bíteš Česká republika

CUST. NO.	VAT CODE	DATE	TD NUMBER	ISSUED BY	PAGE
	CZ27159621	31.01.2024	202400548		1 to 2

CODE	DESCRIPTION	QTY per BOX	MU	QUANTITY
BSC740 order	Fertility collector lotto 23P2001304 exp 30.11.2027	40	40,000	20,00
BSC740 order	Fertility collector lotto 24P2004300 exp 31.01.2028	40	40,000	35,00
BSC740 order	Fertility collector lotto 24P2004301 exp 31.01.2028	40	40,000	10,00
BSV120 order	ANSA 10 uL, PP, peel pack 20 pcs,sterile lotto 23P2020703 exp 30.11.2027	10000	1 000,000	100,00
BSV120 order	ANSA 10 uL, PP, peel pack 20 pcs,sterile lotto 23P2020704 exp 31.12.2027	10000	1 000,000	960,00
BSV120 order	ANSA 10 uL, PP, peel pack 20 pcs,sterile lotto 24P2003400 exp 31.01.2028	10000	1 000,000	200,00
BSV120 order	ANSA 10 uL, PP, peel pack 20 pcs,sterile lotto 24P2003401 exp 31.01.2028	10000	1 000,000	260,00
BSV1200 order	ANSA 10 uL, PP, peel pack 10 pcs,sterile lotto 24P2003300 exp 31.01.2028	12000	1 000,000	192,00
BSV1201 order	ANSA 10 ul , sterile lotto 24P2003700 exp 31.01.2028	2100	2 100,000	8,00
BSV1201 order	ANSA 10 ul , sterile lotto 24P2003701 exp 31.01.2028	2100	2 100,000	7,00
BSV1205 order	Anse jednorázové, 10ul lotto 24P2003200 exp 31.01.2028	4000	1 000,000	16,00
BSV121 order	ANSA 1 uL, PP, peel pack 20 pcs,sterile lotto 23P2020603 exp 31.12.2027	10000	1 000,000	270,00
BSV121 order	ANSA 1 uL, PP, peel pack 20 pcs,sterile lotto 24P2003000 exp 31.01.2028	10000	1 000,000	430,00
BSV1210 order	Anse single-use; volume 1 ul lotto 24P2003500 exp 31.01.2028	12000	1 000,000	120,00
BSV1211 order	ANSA 1 uL, PP,peel pack 1 pcs, sterile lotto 24P2003600 exp 31.01.2028	0	2 100,000	12,00



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STIRILAB s.r.o. a dominique Dutscher company

Textilná 23

034 01

Ružomberok

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CUSTOMER

STERIS AST CZ s.r.o.

Průmyslová zóna Košíkov 80

595 01 Velká Bíteš, ČR

SHIP TO

STERIS AST CZ s.r.o.

Průmyslová zóna Košíkov 80

59501 Velká Bíteš Česká republika

CUST. NO.	VAT CODE	DATE	TD NUMBER	ISSUED BY	PAGE
	CZ27159621	31.01.2024	202400548		2 to 2

CODE	DESCRIPTION	QTY per BOX	MU	QUANTITY
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SHIPPING BY

EXW

ISSUED BY:

Božeková

TRANSPORT

SALE

TRANSPORT START DATE

31.01.2024

DELIVERY TERM

EXW

BOXES

344

PALLETS

18

GROSS WEIGHT KG

2 482,12

NETTO WEIGHT

2 278,13

VOLUME m3

17,96

DRIVER'S SIGNATURE

ANNOTATIONS

RECIPIENT'S SIGNATURE

Any complaint must be made within 8 days after goods receipt. Goods are considered of customer property only after full payment receipt. Any disputes between the are subject to the exclusive jurisdiction of the courts of Slovak republic

ACCEPTANCE
VERIFICATION
1.2.2024