



Certificate of Analysis-CRY 119

PRODUCT batch number: P723401
 BASE batch number: P723400
 ACTIVATOR batch number: P723301

Product Name:	Cry-Spore Working Solution	
Product batch number:	P723401	
Reference:	CRY/SPO/021	
This is to certify that Cry-Spore Working Solution bearing the batch no's: 722900 and 722600 were tested on 2017-08-18 and found to comply with all requirements as set out in the specifications and method of analysis.		
PROPERTIES	SPECIFICATION	RESULTS
APPEARANCE	Clear pale yellow liquid free of matter	Conforms
SPECIFIC GRAVITY	0.995 – 1.005	1.000
pH	2.5 – 5.5	3.0
ClO ₂ Concentration – after 10 minutes (ppm)	230 – 280	236

Product Name:	Cry-Spore Base Solution	
Reference:	CRY/SPO/020	
Date of Manufacture:	2017-08-17	
Date of Expiry:	2019-08	
This is to certify that Cry-Spore Base Solution was tested on 2017-08-18 and found to comply with all requirements as set out in the specifications and method of analysis.		
PROPERTIES	SPECIFICATION	RESULTS
APPEARANCE	Clear blue liquid free of matter	Conforms
SPECIFIC GRAVITY	1.020 – 1.060	1.002
pH	1.5 – 3.5	2.8
STERILITY	No growth	Conforms

DRF1589 CRY/SPO/007/Issue6/October 2012






Product Name:	Cry-Spore Activator Solution	
Reference:	CRY/SPO/019	
Date of Manufacture:	2017-08-14	
Date of Expiry:	2019-08	
This is to certify that Cry-Spore Activator Solution was tested on 2017-08-14 and found to comply with all requirements as set out in the specifications and method of analysis.		
PROPERTIES	SPECIFICATION	RESULTS
APPEARANCE	Clear and free of matter	Conforms
SPECIFIC GRAVITY	1.015 – 1.035	1.016
pH	11.5 – 13.0	11.6
SODIUM CHLORITE	2.10% +/- 0.1%	2.06%
STERILITY	No growth	Conforms

Completed By:

Reviewed By:

Quality Department: E. Andrews

..... 

Date: 2017-09-26

Date: 2017-09-26



Sterility Testing Analytical Report

Please note the results below are not generated at Associates of Cape Cod Int. Inc., but reported from a subcontractor's final report.

Sample ID: Cryspore Base	Lab Book Reference: ST03-95
Lot No: P723400	Date Received: 30 Aug 2017
ICN: 0817022D	Date Completed: 18 Sep 2017
Subcontractor's Report Number: 2017159795	No. of samples: 10

Sterility Test – Membrane Filtration

Medium	Result
Tryptone Soy Broth	No growth
Fluid Thioglycollate Medium	No growth

Conclusions:

The samples submitted comply with the test for sterility in accordance with the client's methodology.

Results Reported by:


.....
Laboratory Technician/Designee: Caroline Thornton


Date: 22 SEP 2017

Reviewed by:


.....
 Quality Assurance Manager
 UK General Manager
 Technical Manager
 Laboratory Manager

Date: 22 SEP 2017

QA Approved by:


.....
 Quality Assurance
 UK General Manager
 Technical Manager

Date: 22 SEP 2017

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C. Thornton	20 Sep 2017

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ST03-95ICN: 0817022D

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TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 18 Sep 2017

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Germany
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Fax: 0049 6103 96 10 15

Web: www.accituk.co.uk

Registered in England and Wales. Company Registration Number: BR002906

Sterility Testing Analytical Report

Please note the results below are not generated at Associates of Cape Cod Int. Inc., but reported from a subcontractor's final report.

Sample ID: Cryspore Activator
Lot No: P723301
ICN: 0817022D
Subcontractor's Report Number: 2017159793

Lab Book Reference: ST03-93
Date Received: 30 Aug 2017
Date Completed: 18 Sep 2017
No. of samples: 10

Sterility Test – Membrane Filtration

Medium	Result
Tryptone Soy Broth	No growth
Fluid Thioglycollate Medium	No growth

Conclusions:

The samples submitted comply with the test for sterility in accordance with the client's methodology.

Results Reported by:

.....
Laboratory Technician/Designee: Caroline Thornton

Date: 22 SEP 2017

Reviewed by:

-
 Quality Assurance Manager
 UK General Manager
 Technical Manager
 Laboratory Manager

Date: 22 SEP 2017

QA Approved by:

-
 Quality Assurance
 UK General Manager
 Technical Manager

Date: 22 SEP 2017

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C. Thornton	20 Sep 2017

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ST03-93ICN: 0817022D

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REVISION NO: 1

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Registered in England and Wales. Company Registration Number: BR002906



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 15-Mar-2017

UK33S11829406-1-1

This is to certify that AST Daventry Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 Sterilisation of Health Care Products
 EN ISO 9001:2008 Quality Management System
 EN ISO 13485:2012 Quality System - Medical Devices

The Tristel Company Ltd
 Unit 4C Lynx Bus Park, Fordham Rd
 Newmarket
 Suffolk CB8 7NY
 UNITED KINGDOM

Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1075875
Customer Reference Number:	704369
Product Description:	BOTTLE 5LT DV4232 25-45kGy
Validation Reference:	4232
Quantity Received:	40
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	01032017, 2 pils

Irradiation Data

Date and Time of Irradiation:	14-Mar-2017 16:39
Reference Dose Range kGy:	32.5 - 33.2
Calculated Minimum Dose kGy:	30.9
Calculated Maximum Dose kGy:	35.5

Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM
 Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 24-Apr-2017

UK33S11858352-1-1

This is to certify that AST Daventry Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 Sterilisation of Health Care Products
 EN ISO 9001:2008 Quality Management System
 EN ISO 13485:2012 Quality System - Medical Devices

The Tristel Company Ltd
 Unit 4C Lynx Bus Park, Fordham Rd
 Newmarket
 Suffolk CB8 7NY
 UNITED KINGDOM

Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1075875
Customer Reference Number:	704663
Product Description:	BOTTLE 5LT DV4232 25-45kGy
Validation Reference:	4232
Quantity Received:	20
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	11042017, 1 PLT

Irradiation Data

Date and Time of Irradiation:	24-Apr-2017 12:23
Reference Dose Range kGy:	32.1 - 32.7
Calculated Minimum Dose kGy:	30.5
Calculated Maximum Dose kGy:	35.0

Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM
 Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 19-Apr-2017

UK33S11854017-1-1

This is to certify that AST Daventry Synergy Health PLC has where appropriate delivered an Irradiation process in accordance with:

EN ISO 11137-1:2015 Sterilisation of Health Care Products
 EN ISO 9001:2008 Quality Management System
 EN ISO 13485:2012 Quality System - Medical Devices

The Tristel Company Ltd
 Unit 4C Lynx Bus Park, Fordham Rd
 Newmarket
 Suffolk CB8 7NY
 UNITED KINGDOM

Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1075628
Customer Reference Number:	704631
Product Description:	BOTTLE 100ML DV4224 25-45kGy
Validation Reference:	4224
Quantity Received:	10
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	07042017

Irradiation Data

Date and Time of Irradiation:	19-Apr-2017 01:02
Reference Dose Range kGy:	32.1 - 32.6
Calculated Minimum Dose kGy:	30.6
Calculated Maximum Dose kGy:	35.6

Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM
 Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 06-Mar-2017

UK33S11824859-3-1

This is to certify that AST Daventry Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 Sterilisation of Health Care Products
 EN ISO 9001:2008 Quality Management System
 EN ISO 13485:2012 Quality System - Medical Devices

The Tristel Company Ltd
 Unit 4C Lynx Bus Park, Fordham Rd
 Newmarket
 Suffolk CB8 7NY
 UNITED KINGDOM

Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1075625
Customer Reference Number:	704309
Product Description:	CAP 001-G DV1.4225 25-45kGy
Validation Reference:	1.4225
Quantity Received:	2
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	22022017, 1 plt

Irradiation Data

Date and Time of Irradiation:	06-Mar-2017 00:44
Reference Dose Range kGy:	35.2 - 35.2
Calculated Minimum Dose kGy:	30.6
Calculated Maximum Dose kGy:	39.5

Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM
 Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 15-Mar-2017

UK33S11829406-2-1

This is to certify that AST Daventry Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 Sterilisation of Health Care Products
 EN ISO 9001:2008 Quality Management System
 EN ISO 13485:2012 Quality System - Medical Devices

The Tristel Company Ltd
 Unit 4C Lynx Bus Park, Fordham Rd
 Newmarket
 Suffolk CB8 7NY
 UNITED KINGDOM

Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1078033
Customer Reference Number:	704369
Product Description:	BAG002 DV4268 25-70kGy
Validation Reference:	4268
Quantity Received:	6
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	70.0
Customer Unit Lot/Batch Number:	21022017, 1 PLT

Irradiation Data

Date and Time of Irradiation:	14-Mar-2017 18:57
Reference Dose Range kGy:	54.6 - 54.6
Calculated Minimum Dose kGy:	37.0
Calculated Maximum Dose kGy:	59.0

Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM
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