



Certificate of Analysis-CRY 119

PRODUCT batch number: P702602
 BASE batch number: P702600
 ACTIVATOR batch number: P702500

Product Name:		Cry-Spore Working Solution
Product batch number:		P702602
Reference:		CRY/SPO/021
This is to certify that Cry-Spore Working Solution bearing the batch no's: P702600 and P702500 were tested on 15-NOV-16 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	1.002
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:		15-NOV-16
Date of Expiry:		NOV-2018
This is to certify that Cry-Spore Base Solution P702600 was tested on 15-NOV-16 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	1.024
pH	1.5 – 3.5	1.8
STERILITY	No growth	Conforms





Product Name:	Cry-Spore Activator Solution	
Reference:	CRY/SPO/019	
Date of Manufacture:	14-NOV-16	
Date of Expiry:	NOV-2018	
This is to certify that Cry-Spore Activator Solution P706500 was tested on 14-NOV-16 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	1.015
pH	11.5 – 13.0	11.5
SODIUM CHLORITE	2.10% +/- 0.1%	2.14%
STERILITY	No growth	CONFORMS

Completed By:

Reviewed By:

Quality Department: E Andrews


.....

Date: 7 MAR 2017

Date: 07th MARCH 2017



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: CRY119 Cryspore Base	Lab Book Reference: ST03-61
Lot No: P702600	Date Received: 02 Feb 2017
ICN: 0217005D	Date Completed: 28 Feb 2017
Subcontractor's Report Number: 2017023893	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: Sophie Hughes

Date: 28 Feb 2017

Reviewed by:


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

Date: 02 Mar 2017

QA Approved by:


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

Date: 02 MAR 2017

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	S. Hughes	28 Feb 2017

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ST03-61
REVISION NO: 1

ICN: 0217005D
DATE: 28 Feb 2017

TSCTS044-1 Rev 2

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PYROQUANT DIAGNOSTIK GmbH
Opelstrasse 14
D-64546 Morfelden-Walldorf
Germany
Tel: 0049 6105 96 10 0
Fax: 0049 6105 96 10 15

Web: www.accjuk.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: CRY119 Cryspore Activator Lot No: P702500 ICN: 0217005D Subcontractor's Report Number: 2017023944	Lab Book Reference: ST03-60 Date Received: 02 Feb 2017 Date Completed: 28 Feb 2017 No. of samples: 10
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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: Sophie Hughes

Date: 28 Feb 2017

Reviewed by:

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

Date: 02 Mar 2017

QA Approved by:

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

Date: 02 Mar 2017

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	S. Hughes	28 Feb 2017

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ST03-60
REVISION NO: 1

ICN: 0217005D
DATE: 28 Feb 2017

TSCTS044-1 Rev 2

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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 26-Nov-2016

UK33S11753022-3-1

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:	1075628
Customer Reference Number:	703612
Product Description:	BOTTLE 100ML DV4224 25-45kGy
Validation Reference:	4224
Quantity Received:	19
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	10112016, 1 plit

Irradiation Data

Date and Time of Irradiation:	26-Nov-2016 06:56
Reference Dose Range kGy:	33.2 - 33.4
Calculated Minimum Dose kGy:	31.6
Calculated Maximum Dose kGy:	36.4

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: 29-Sep-2016

UK33S11712941-1-1

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:	703172
Product Description:	BOTTLE 100ML DV4224 25-45kGy
Validation Reference:	4224
Quantity Received:	23
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	014, 2 plts

Irradiation Data

Date and Time of Irradiation:	28-Sep-2016 12:21
Reference Dose Range kGy:	32.8 - 33.2
Calculated Minimum Dose kGy:	31.2
Calculated Maximum Dose kGy:	36.2

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: 11-Oct-2016

UK33S11712941-4-1

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:	1108122
Customer Reference Number:	703172
Product Description:	CAP030-G 25-45kGy SINGLE VAL
Quantity Received:	11
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	VALIDATION, 1 pit
Other Process Details:	Actual min dose: 29.1kGy Actual max dose: 34.7ky

Irradiation Data

Date and Time of Irradiation:	11-Oct-2016 11:41
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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: 25-Mar-2016

UK33S11583580-1-1

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:	701795
Product Description:	BOTTLE 100ML DV4224 25-45kGy
Validation Reference:	4224
Quantity Received:	24
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	1075628, CRY/ACT/1 x 12, CRY/BASE x 12, 3 PLTS

Irradiation Data

Date and Time of Irradiation:	24-Mar-2016 22:50
Reference Dose Range kGy:	33.6 - 33.8
Calculated Minimum Dose kGy:	32.0
Calculated Maximum Dose kGy:	36.9

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: 14-Sep-2016

UK33S11705020-2-1

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:	1075628
Customer Reference Number:	703128
Product Description:	BOTTLE 100ML DV4224 25-45kGy
Validation Reference:	4224
Quantity Received:	8
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	Irradiation of Bottle 012, 1 pit

Irradiation Data

Date and Time of Irradiation:	13-Sep-2016 19:31
Reference Dose Range kGy:	33.9 - 34.0
Calculated Minimum Dose kGy:	32.3
Calculated Maximum Dose kGy:	37.1

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: 04-Oct-2016

UK33S11715571-4-1

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:	703200
Product Description:	CAP 001-G DV1.4225 25-45kGy
Validation Reference:	1.4225
Quantity Received:	4
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	CAP001-G, 1 pit

Irradiation Data

Date and Time of Irradiation:	03-Oct-2016 23:41
Reference Dose Range kGy:	32.2 - 32.2
Calculated Minimum Dose kGy:	28.0
Calculated Maximum Dose kGy:	36.1

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: 04-Aug-2016

UK33S11669509-2-1

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:	1096575
Customer Reference Number:	702752
Product Description:	BAG004 DV4398 25-40kGy
Validation Reference:	4398
Quantity Received:	3
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BAG 004, 1PLT

Irradiation Data

Date and Time of Irradiation:	28-Jul-2016 00:05
Reference Dose Range kGy:	32.2 - 32.2
Calculated Minimum Dose kGy:	25.2
Calculated Maximum Dose kGy:	36.2

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