



Certificate of Analysis-CRY 119

PRODUCT batch number: P628501

BASE batch number: P628500

ACTIVATOR batch number: P628000

Product Name:	Cry-Spore Working Solution	
Product batch number:	P628501	
Reference:	CRY/SPO/021	
This is to certify that Cry-Spore Working Solution bearing the batch no's: P628500 and P628000 were tested on 07-NOV-2016 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	3.5
CLO ₂ Concentration – after 10 minutes (ppm)	230 – 280	238 ppm

Product Name:	Cry-Spore Base Solution	
Reference:	CRY/SPO/020	
Date of Manufacture:	18-JUL-2016	
Date of Expiry:	JUL-2018	
This is to certify that Cry-Spore Base Solution was tested on 18-JUL-2016 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	1.022
pH	1.5 – 3.5	1.8
STERILITY	No growth	Conforms





Product Name:	Cry-Spore Activator Solution	
Reference:	CRY/SPO/019	
Date of Manufacture:	16-SEP-2016	
Date of Expiry:	SEP-2018	
This is to certify that Cry-Spore Activator Solution was tested on 16-SEP-2016 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	11.7
SODIUM CHLORITE	2.10% +/- 0.1%	2.1%
STERILITY	No growth	Conforms

Completed By:

Quality Department: E Andrews

Date: 8 Nov 2016

Reviewed By:

[Signature]

Date: 8 Nov 16



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 Lot No: P628500 ICN: 1016014F Subcontractor's Report Number: 2016241950	Lab Book Reference: ST03-34 Date Received: 13 OCT 2016 Date Completed: 04 NOV 2016 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: Charlotte Ray

Date: 04 NOV 2016

Reviewed by:

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

Date: 04 NOV 2016

QA Approved by:

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

Date: 04 NOV 2016

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C. Ray	04 NOV 2016

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ST03-34
REVISION NO: 1

ICN: 1016014F
DATE: 04 NOV 2016

TSCTS044-1 Rev 2

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PYROQUANT DIAGNOSTIK GmbH
Opelstrasse 13
D-61516 Mülfelden-Waldhof
Germany
Tel: 0049 6105 96 10 0
Fax: 0049 6105 96 10 15

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	Lab Book Reference: ST03-35
Lot No: P628000	Date Received: 13 OCT 2016
ICN: 1016014F	Date Completed: 04 NOV 2016
Subcontractor's Report Number: 2016241951	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: Charlotte Ray

Date: 04 NOV 2016

Reviewed by:

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

Date: 04 NOV 2016

QA Approved by:

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

Date: 04 NOV 2016

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C. Ray	04 NOV 2016

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ST03-35
REVISION NO: 1

ICN: 1016014F
DATE: 04 NOV 2016

TSCTS044-1 Rev 2

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Registered in England and Wales. Company Registration Number: BR002906



<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: 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 plt

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: 30-Jul-2016

UK33S11673290-1-1

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:	702783
Product Description:	BOTTLE 100ML DV4224 25-45kGy
Validation Reference:	4224
Quantity Received:	14
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BOTTLE 012, 1PLT

Irradiation Data

Date and Time of Irradiation:	30-Jul-2016 01:08
Reference Dose Range kGy:	31.5 - 31.9
Calculated Minimum Dose kGy:	30.0
Calculated Maximum Dose kGy:	34.8

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-Aug-2016

UK33S11678232-2-1

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:	1075625
Customer Reference Number:	702828
Product Description:	CAP 001-G DV1.4225 25-45kGy
Validation Reference:	1.4225
Quantity Received:	3
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	1 plt

Irradiation Data

Date and Time of Irradiation:	11-Aug-2016 02:38
Reference Dose Range kGy:	33.4 - 33.4
Calculated Minimum Dose kGy:	29.0
Calculated Maximum Dose kGy:	37.5

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: 31-Aug-2016

UK33S11690237-2-1

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:	702993
Product Description:	BAG004 DV4398 25-40kGy
Validation Reference:	4398
Quantity Received:	5
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BAG004-G, 1 plt

Irradiation Data

Date and Time of Irradiation:	31-Aug-2016 03:00
Reference Dose Range kGy:	32.0 - 32.0
Calculated Minimum Dose kGy:	25.0
Calculated Maximum Dose kGy:	36.0

Irradiation Release Authorised By Synergy Health plc

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

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