



Certificate of Analysis-CRY 119

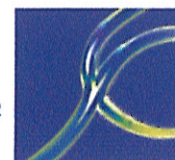
PRODUCT batch number: P822001

BASE batch number: P821402

ACTIVATOR batch number: P822000

Product Name:	Cry-Spore Working Solution	
Product batch number:	P822001	
Reference:	CRY/SPO/021	
This is to certify that Cry-Spore Working Solution bearing the batch no's: P821402 and P822000 were tested on 2018-07-25 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
CIO ₂ Concentration – after 10 minutes (ppm)	230 – 280	230 ppm

Product Name:	Cry-Spore Base Solution	
Reference:	CRY/SPO/020	
Date of Manufacture:	2018-07-24	
Date of Expiry:	2020-07-24	
This is to certify that Cry-Spore Base Solution was tested on 2018-07-25 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	1.020
pH	1.5 – 3.5	1.9
STERILITY	No growth	Conforms





Product Name:	Cry-Spore Activator Solution	
Reference:	CRY/SPO/019	
Date of Manufacture:	2018-07-24	
Date of Expiry:	2020-07-24	
This is to certify that Cry-Spore Activator Solution was tested on 2018-07-24 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	12.0
SODIUM CHLORITE	2.10% +/- 0.1%	2.01%
STERILITY	No growth	Conforms

Completed By:

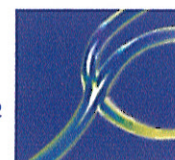
Reviewed By:

Quality Department: Eandrews

Stielinska

Date: 2018-09-13

Date: 2018-09-13



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: P821402
ICN: 0818016F
Subcontractor's Report Number: 2018153823

Lab Book Reference: ST03-187
Date Received: 14 AUG 2018
Date Completed: 07 SEP 2018
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: L. Ellis

Date: 07 SEP 2018


Reviewed by:



 Quality Assurance Manager
 UK General Manager
 Technical Manager
 Laboratory Manager

Date: 07 SEP 2018

QA Approved by:



 Quality Assurance
 UK General Manager
 Technical Manager

Date: 07 SEP 2018

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
NA	1	Revision 1, no changes	L Ellis	07 SEP 2018

CONFIDENTIAL
ST03-187

ICN: 0818016F

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TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 07 SEP 2018

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PYROQUANT DIAGNOSTIK GmbH
Opelstrasse 14
D-64546 Mörfelden-Walldorf
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
Lot No: P822000
ICN: 0818016F
Subcontractor's Report Number: 2018153824

Lab Book Reference: ST03-186
Date Received: 14 AUG 2018
Date Completed: 07 SEP 2018
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: L. Ellis

Date: 07 SEP 2018

Reviewed by:



 Quality Assurance Manager
 UK General Manager
 Technical Manager
 Laboratory Manager

Date: 07 SEP 2018

QA Approved by:



 Quality Assurance
 UK General Manager
 Technical Manager

Date: 07 SEP 2018

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
NA	1	Revision 1, no changes	L Ellis	07 SEP 2018

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ST03-186

ICN: 0818016F

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TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 07 SEP 2018

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<http://www.steris-ast.com>

Certificate of Irradiation

Date Issued: 19-Mar-2018

UK33S12073738-1-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 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:	1121497
Customer Reference Number:	706717
Product Description:	BOTTLE 100ML DV5155 25-45kGy
Validation Reference:	5155
Quantity Received:	17
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BN: 01032018, 1 PLT

Irradiation Data

Date and Time of Irradiation:	19-Mar-2018 07:24
Reference Dose Range kGy:	32.8 - 33.2
Calculated Minimum Dose kGy:	30.8
Calculated Maximum Dose kGy:	36.0

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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 plt
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.steris-ast.com>

Certificate of Irradiation

Date Issued: 27-May-2018

UK33S12111134-1-3

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 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:	1121497
Customer Reference Number:	707232
Product Description:	BOTTLE 100ML DV5155 25-45kGy
Validation Reference:	5155
Quantity Received:	20
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	20180516, 1 plt

Irradiation Data

Date and Time of Irradiation:	27-May-2018 02:37
Reference Dose Range kGy:	33.2 - 33.3
Calculated Minimum Dose kGy:	31.2
Calculated Maximum Dose kGy:	36.1

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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.steris-ast.com>

Certificate of Irradiation

Date Issued: 17-Mar-2018

UK33S12073738-3-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 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:	1121930
Customer Reference Number:	706717
Product Description:	100ML BOTTLE CAP DV5165 25-45kGy
Validation Reference:	5165
Quantity Received:	3
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BN: 05032018, 1 PLT

Irradiation Data

Date and Time of Irradiation:	17-Mar-2018 11:03
Reference Dose Range kGy:	32.2 - 32.2
Calculated Minimum Dose kGy:	29.5
Calculated Maximum Dose kGy:	35.9

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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.steris-ast.com>

Certificate of Irradiation

Date Issued: 08-May-2018

UK33S12098540-2-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 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:	1121936
Customer Reference Number:	707064
Product Description:	BAG 004-G DV5175 25-45kGy
Validation Reference:	5175
Quantity Received:	6
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	20180423, 1 plt

Irradiation Data

Date and Time of Irradiation:	08-May-2018 07:49
Reference Dose Range kGy:	35.8 - 35.8
Calculated Minimum Dose kGy:	27.5
Calculated Maximum Dose kGy:	38.4

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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

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