



Certificate of Analysis-CRY 119

PRODUCT batch number: P808003
BASE batch number: P807801
ACTIVATOR batch number: P808002

| Product Name: | Cry-Spore Working Solution | |
|---|---|----------|
| Product batch number: | P808003 | |
| Reference: | CRY/SPO/021 | |
| This is to certify that Cry-Spore Working Solution bearing the batch no's: P807801 and P808002 were tested on 2018-03-15 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: | 2018-03-14 | |
| Date of Expiry: | 2020-03-14 | |
| This is to certify that Cry-Spore Base Solution was tested on 2018-03-15 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: | 2018-03-14 | |
| Date of Expiry: | 2020-03-14 | |
| This is to certify that Cry-Spore Activator Solution was tested on 2018-03-15 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 | 1.017 |
| pH | 11.5 – 13.0 | 11.8 |
| SODIUM CHLORITE | 2.10% +/- 0.1% | 2.15% |
| STERILITY | No growth | Conforms |

Completed By:

Reviewed By:

Quality Department: E. Andrews

[Signature]

Date: 2018-04-24

Date: 2018-04-24



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: P807801
ICN: 0318030D
Subcontractor's Report Number: 2018057332

Lab Book Reference: ST03-155
Date Received: 27 Mar 2018
Date Completed: 18 Apr 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: Daniel Jennings

Date: 18 APR 2018

Reviewed by:


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

Date: 19 APR 2018

QA Approved by:


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

Date: 19 APR 2018

Revision History:

| DCCF No: | Revision: | Description: | Originator: | Effective Date: |
|----------|-----------|------------------------|-------------|-----------------|
| N/A | 1 | Revision 1, no changes | D. Jennings | 18 Apr 2018 |

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ST03-155

ICN: 0318030D

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REVISION NO: 1

DATE: 18 Apr 2018

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124 Bernard J. Saint Jean Drive
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Germany
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: P808002
ICN: 0318030D
Subcontractor's Report Number: 2018057333

Lab Book Reference: ST03-156
Date Received: 27 Mar 2018
Date Completed: 18 Apr 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: Daniel Jennings

Date: 19 APR 2018

Reviewed by:


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

Date: 19 APR 2018

QA Approved by:


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

Date: 19 APR 2018

Revision History:

| DCCF No: | Revision: | Description: | Originator: | Effective Date: |
|----------|-----------|------------------------|-------------|-----------------|
| N/A | 1 | Revision 1, no changes | D. Jennings | 18 Apr 2018 |

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ST03-156

ICN: 0318030D

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REVISION NO: 1

DATE: 18 Apr 2018

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

Certificate of Irradiation

Date Issued: 11-Jan-2018

UK33S12034059-1-4

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: | 706219 |
| Product Description: | BOTTLE 100ML DV5155 25-45kGy |
| Validation Reference: | 5155 |
| Quantity Received: | 4 |
| Customer Minimum Specification kGy: | 25.0 |
| Customer Maximum Specification kGy: | 45.0 |
| Customer Unit Lot/Batch Number: | 07122017, 1 pt |

Irradiation Data

| | |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 10-Jan-2018 21:40 |
| Reference Dose Range kGy: | 33.3 - 33.3 |
| Calculated Minimum Dose kGy: | 31.3 |
| 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: 25-Feb-2018

UK33S12061299-2-1

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: | 1121930 |
| Customer Reference Number: | 706585 |
| Product Description: | 100ML BOTTLE CAP DV5165 25-45kGy |
| Validation Reference: | 5165 |
| Quantity Received: | 6 |
| Customer Minimum Specification kGy: | 25.0 |
| Customer Maximum Specification kGy: | 45.0 |
| Customer Unit Lot/Batch Number: | 07022018, 1 PLT |

Irradiation Data

| | |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 24-Feb-2018 19:32 |
| Reference Dose Range kGy: | 33.5 - 33.5 |
| Calculated Minimum Dose kGy: | 30.7 |
| Calculated Maximum Dose kGy: | 37.3 |

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: 04-Feb-2018

UK33S12053399-1-1

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: | 706465 |
| Product Description: | BOTTLE 100ML DV5155 25-45kGy |
| Validation Reference: | 5155 |
| Quantity Received: | 14 |
| Customer Minimum Specification kGy: | 25.0 |
| Customer Maximum Specification kGy: | 45.0 |
| Customer Unit Lot/Batch Number: | BN: 16012018, 1 pit |

Irradiation Data

| | |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 04-Feb-2018 18:17 |
| Reference Dose Range kGy: | 31.7 - 32.0 |
| Calculated Minimum Dose kGy: | 29.8 |
| Calculated Maximum Dose kGy: | 34.7 |

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 |
|-------------------------------|-------------------|

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: 15-Jan-2018

UK33S12041486-1-1

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: | 1121936 |
| Customer Reference Number: | 706279 |
| Product Description: | BAG 004-G DV5175 25-45kGy |
| Validation Reference: | 5175 |
| Quantity Received: | 4 |
| Customer Minimum Specification kGy: | 25.0 |
| Customer Maximum Specification kGy: | 45.0 |
| Customer Unit Lot/Batch Number: | 06112017, 1 PLT |

Irradiation Data

| | |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 15-Jan-2018 21:52 |
| Reference Dose Range kGy: | 33.7 - 33.7 |
| Calculated Minimum Dose kGy: | 25.9 |
| 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

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