



## Certificate of Analysis

Product Name:	<b>Crystel Platinum RTU Solution CRY110</b>	
Reference:	CRY/PLA/032	
Batch Number:	P804000	
Date of Manufacture:	2017-10-03	
Expiry Date:	2019-10	
This is to certify that Crystel Platinum RTU solution above was tested on 2017-10-03 and found to comply with all requirements as set out in the specifications and method of analysis.		
PROPERTIES	SPECIFICATION	RESULTS
APPEARANCE	Clear Solution free of matter	Conforms
SPECIFIC GRAVITY	0.995 – 1.005	1.000
pH	8.50 – 10.00	9.17
STERILITY	No growth	No growth

Completed By:

Reviewed By:

Quality Department: *E. Andrews*

*S. Mellinck*

Date: *2018-03-09*

Date: *2018-03-09*

DRF1500 CRY/PLA/033/Issue3/June 2012

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**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:** CRY110 Platinum  
**Lot No:** P804000  
**ICN:** 0218009D  
**Subcontractor's Report Number:** 2018029072

**Lab Book Reference:** ST03-133  
**Date Received:** 13 Feb 2018  
**Date Completed:** 07 Mar 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: 07 MAR 2018

**Reviewed by:**

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

Date: 07 MAR 2018

**QA Approved by:**

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

Date: 07 MAR 2018

**Revision History:**

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	D. Jennings	07 Mar 2018

**CONFIDENTIAL**  
ST03-133

ICN: 0218009D

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TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 07 Mar 2018

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

## Certificate of Irradiation

Date Issued: 18-Jan-2018

UK33S12041486-4-1

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:	1121939
Customer Reference Number:	706279
Product Description:	1000ML T/S BOTTLE DV5171 25-45kGy
Validation Reference:	5171
Quantity Received:	16
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	02112017, 1 PLT

### Irradiation Data

Date and Time of Irradiation:	18-Jan-2018 17:22
Reference Dose Range kGy:	29.6 - 30.4
Calculated Minimum Dose kGy:	28.4
Calculated Maximum Dose kGy:	33.1

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



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## Certificate of Irradiation

Date Issued: 07-Feb-2018

UK33S12051056-1-2

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

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### Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1121938
Customer Reference Number:	706435
Product Description:	BAG 001-G DV5194 25-48kGy
Validation Reference:	5194
Quantity Received:	4
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	48.0
Customer Unit Lot/Batch Number:	26012018, 1 PLT

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### Irradiation Data

Date and Time of Irradiation:	06-Feb-2018 18:58
Reference Dose Range kGy:	39.0 - 39.0
Calculated Minimum Dose kGy:	27.9
Calculated Maximum Dose kGy:	43.5

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## Certificate of Irradiation

Date Issued: 11-Jan-2018

UK33S12037910-2-1

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  
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Suffolk CB8 7NY  
UNITED KINGDOM

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### Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1121921
Customer Reference Number:	706246
Product Description:	TRIGGER SPRAY HEAD CRYSTAL-G DV5170 25-45kGy
Validation Reference:	5170
Quantity Received:	8
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	B/N: 21122017, EXP: 20191230, 1 pit

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### Irradiation Data

Date and Time of Irradiation:	11-Jan-2018 07:30
Reference Dose Range kGy:	31.3 - 31.4
Calculated Minimum Dose kGy:	28.5
Calculated Maximum Dose kGy:	34.7

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

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