



Certificate of Analysis

Product Name:	Crystel Platinum RTU Solution CRY110
Reference:	CRY/PLA/032
Batch Number:	P804001
Date of Manufacture:	2018-01-17
Expiry Date:	2020-01-17

This is to certify that Crystel Platinum RTU solution above was tested on 2018-01-18 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	9.22
STERILITY	No growth	No growth

Completed By:

Reviewed By:

Quality Department: Carolews

Helinda

Date: 2018-03-09

Date: 2018-03-09

DRF1500 CRY/PLA/033/Issue3/June 2012



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: P804001
ICN: 0218009D
Subcontractor's Report Number: 2018029071

Lab Book Reference: ST03-134
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

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ST03-134

ICN: 0218009D

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REVISION NO: 1

DATE: 07 Mar 2018

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

Certificate of Irradiation

Date Issued: 18-Jan-2018

UK33S12041486-4-2

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

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 17:24
Reference Dose Range kGy:	30.2 - 30.4
Calculated Minimum Dose kGy:	29.0
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



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

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
Newmarket
Suffolk CB8 7NY
UNITED KINGDOM

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 plt

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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Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069



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

Certificate of Irradiation

Date Issued: 07-Feb-2018

UK33S12051056-1-1

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:	1121938
Customer Reference Number:	706435
Product Description:	BAG 001-G DV5194 25-48kGy
Validation Reference:	5194
Quantity Received:	5
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	48.0
Customer Unit Lot/Batch Number:	20171017, 1 PLT

Irradiation Data

Date and Time of Irradiation:	06-Feb-2018 18:57
Reference Dose Range kGy:	38.4 - 38.4
Calculated Minimum Dose kGy:	27.5
Calculated Maximum Dose kGy:	42.8

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