



Certificate of Analysis

Product Name:	Crystel Platinum RTU Solution CRY110
Reference:	CRY/PLA/032
Batch Number:	P807500
Date of Manufacture:	2018-03-08
Expiry Date:	2020-03-08

This is to certify that Crystel Platinum RTU solution above was tested on 2018-03-09 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	9.3
STERILITY	No growth	Conforms

Completed By:

Reviewed By:

Quality Department: *Sandhu*

Stielinska

Date: *2018-04-20*

Date: *2018-04-20*

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: P807500
ICN: 0318020F
Subcontractor's Report Number: 2018054189

Lab Book Reference: ST03-152
Date Received: 22 Mar 2018
Date Completed: 17 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: 17 APR 2018

Reviewed by:

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

Date: 17 APR 2018

QA Approved by:

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

Date: 17 APR 2018

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	D. Jennings	17 Apr 2018

CONFIDENTIAL
ST03-152

ICN: 0318020F

Page 1 of 1
TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 17 Apr 2018

UK
Dragon Park
Moorgate Road
Knowsley
Liverpool L33 7RX
Tel: +44 (0)151 547 7444
Fax: +44 (0)151 547 7400

USA
124 Bernard E. Saint Jean Drive
East Falmouth
MA 02536-4445
USA
Tel: 001 508 540 3444
Fax: 001 508 540 8680

Germany
PYROQUANT DIAGNOSTIK GmbH
Opelstrasse 14
D-64546 Morfelden-Walldorf
Germany
Tel: 0049 6105 96 10 0
Fax: 0049 6105 96 10 15



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

Certificate of Irradiation

Date Issued: 10-Feb-2018

UK33S12057071-1-2

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

Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1121939
Customer Reference Number:	706514
Product Description:	1000ML T/S BOTTLE DV5171 25-45kGy
Validation Reference:	5171
Quantity Received:	12
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	Bottle 009, B/N: 31012018, 1 plt

Irradiation Data

Date and Time of Irradiation:	10-Feb-2018 10:42
Reference Dose Range kGy:	33.3 - 33.4
Calculated Minimum Dose kGy:	32.0
Calculated Maximum Dose kGy:	36.4

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

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: 09-Mar-2018

UK33S12069394-3-1

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:	1121921
Customer Reference Number:	706678
Product Description:	TRIGGER SPRAY HEAD CRYSTAL-G DV5170 25-45kGy
Validation Reference:	5170
Quantity Received:	20
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	20180221, 1 plt

Irradiation Data

Date and Time of Irradiation:	09-Mar-2018 14:45
Reference Dose Range kGy:	28.7 - 34.9
Calculated Minimum Dose kGy:	26.1
Calculated Maximum Dose kGy:	38.6

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: 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

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