



Certificate of Analysis

Product Name:	Crystel Platinum RTU Solution CRY110	
Reference:	CRY/PLA/032	
Batch Number:	P700500	
Date of Manufacture:	20-DEC-16	
Expiry Date:	DEC-2018	
This is to certify that Crystel Platinum RTU solution above was tested on 20-DEC-16 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:

Quality Department: E Andrews

Date: 10 Feb 2017

Reviewed By:

[Signature]

Date: 10 FEB 17

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: P700500
ICN: 0117004D
Subcontractor's Report Number: 2017009086

Lab Book Reference: ST03-56
Date Received: 12 JAN 2017
Date Completed: 08 FEB 2017
No. of samples: 10

Sterility Test – Membrane Filtration

Medium	Result
Tryptone Soy Broth	Subculture
Fluid Thioglycollate Medium	Subculture

Subcultured as a precaution due to potential product precipitation

Medium	Result
TSA – 35 Degrees	No growth
TSA – 25 Degrees	No growth

Conclusions:


The samples submitted comply with the test for sterility in accordance with the client's methodology.

Results Reported by:


.....
Laboratory Technician: Charlotte Ray


Date: 08 FEB 2017

Reviewed by:


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

Date: 08 Feb 2017

QA Approved by:


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

Date: 09 FEB 2017

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Page 1 of 2

ST03-56
REVISION NO: 1

ICN: 0117004D
DATE: 08 FEB 2017

TSCTS044-1 Rev 2

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Registered in England and Wales. Company Registration Number: BR002906



Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C RAY	08 FEB 2017

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**ST03-56
REVISION NO: 1**

**ICN: 0117004D
DATE: 08 FEB 2017**

Page 2 of 2

TSCTS044-1 Rev 2



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 25-May-2016

UK33S11630188-2-1

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:	1076147
Customer Reference Number:	702371
Product Description:	1000ml T/S DV4242 25-45kGy
Validation Reference:	4242
Quantity Received:	24
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	Bottle009 1000ml T/S Platinum, 1 Pit

Irradiation Data

Date and Time of Irradiation:	25-May-2016 08:48
Reference Dose Range kGy:	34.1 - 34.7
Calculated Minimum Dose kGy:	32.3
Calculated Maximum Dose kGy:	37.8

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.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 08-Sep-2015

UK33S11452158-1-1

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:	1087391
Customer Reference Number:	700218
Product Description:	Trigger spray head crystal-G DV4286 25-45kGy
Validation Reference:	4286
Quantity Received:	10
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	1plt

Irradiation Data

Date and Time of Irradiation:	08-Sep-2015 04:53
Reference Dose Range kGy:	31.1 - 32.1
Calculated Minimum Dose kGy:	28.1
Calculated Maximum Dose kGy:	34.8

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.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 19-Sep-2016

UK33S11702145-2-1

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:	1087393
Customer Reference Number:	703090
Product Description:	BAG 001-G DV4285 25-45kGy
Validation Reference:	4285
Quantity Received:	4
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BAG001-G, 1PLT

Irradiation Data

Date and Time of Irradiation:	19-Sep-2016 11:35
Reference Dose Range kGy:	34.2 - 34.2
Calculated Minimum Dose kGy:	26.4
Calculated Maximum Dose kGy:	36.1

Irradiation Release Authorised By Synergy Health plc

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