



Certificate of Analysis

Product Name:	Crystel Platinum RTU Solution	
Reference:	CRY/PLA/032	
Batch Number:	P720501	
Date of Manufacture:	2017-07-18	
Expiry Date:	2019-07	
This is to certify that Crystel Platinum RTU solution above was tested on 2017-07-19 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	9.28
STERILITY	No growth	Conforms

Completed By:

Quality Department: Sanatous

Date: 2017-08-23

Reviewed By:

[Signature]

Date: 2017-08-23

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: P720501
ICN: 0717021D
Subcontractor's Report Number: 2017138637

Lab Book Reference: ST03-87
Date Received: 26 Jul 2017
Date Completed: 16 Aug 2017
No. of samples: 8

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: Sophie Hughes

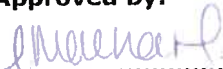
Date: 16 Aug 2017

Reviewed by:


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

Date: 18 Aug 2017

QA Approved by:


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

Date: 18 Aug 2017

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	S. Hughes	16 Aug 2017

CONFIDENTIAL
ST03-87

ICN: 0717021D

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TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 16 Aug 2017

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Registered in England and Wales. Company Registration Number: 11002906



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date issued: 23-Jul-2016

UK33S11669509-1-1

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:	1076147
Customer Reference Number:	702752
Product Description:	1000ml T/S DV4242 25-45kGy
Validation Reference:	4242
Quantity Received:	49
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BOTTLE 009-PLATINUM, 2 PLTS

Irradiation Data

Date and Time of Irradiation:	23-Jul-2016 07:35
Reference Dose Range kGy:	31.6 - 32.2
Calculated Minimum Dose kGy:	30.0
Calculated Maximum Dose kGy:	35.0

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

UK33S11455485-1-1

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:	700363
Product Description:	Trigger spray head crystal-G DV4286 25-45kGy
Validation Reference:	4286
Quantity Received:	15
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 04:54
Reference Dose Range kGy:	31.3 - 32.0
Calculated Minimum Dose kGy:	28.3
Calculated Maximum Dose kGy:	34.7

Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

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



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 29-Aug-2016

UK33S11678232-3-1

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:	702828
Product Description:	BAG 001-G DV4285 25-45kGy
Validation Reference:	4285
Quantity Received:	3
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BAG 001-G, 1 pit

Irradiation Data

Date and Time of Irradiation:	29-Aug-2016 05:43
Reference Dose Range kGy:	37.6 - 37.6
Calculated Minimum Dose kGy:	29.0
Calculated Maximum Dose kGy:	39.6

Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

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