



## Certificate of Analysis

Product Name:	Crystel Platinum RTU Solution
Reference:	CRY/PLA/032
Batch Number:	P720600
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: E Andrews

Date: 2017-08-24

Reviewed By:

[Signature]

Date: 2017-08-24

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:** CRY111 Platinum  
**Lot No:** P720600  
**ICN:** 0717024D  
**Subcontractor's Report Number:** 2017138638

**Lab Book Reference:** ST03-88  
**Date Received:** 28 Jul 2017  
**Date Completed:** 16 Aug 2017  
**No. of samples:** 3

#### 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

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ST03-88

ICN: 0717024D

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TSCS044-1 Rev 3

REVISION NO: 1

DATE: 16 Aug 2017

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Registered in England and Wales. Company Registration Number: BR002906



<http://www.synergyhealthplc.com>

## Certificate of Irradiation

Date Issued: 01-Mar-2016

UK33S11568178-1-1

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

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### Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1075875
Customer Reference Number:	701451
Product Description:	BOTTLE 5LT DV4232 25-45kGy
Validation Reference:	4232
Quantity Received:	14
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	bottle 046 5l platinum, 1 plt

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### Irradiation Data

Date and Time of Irradiation:	01-Mar-2016 01:18
Reference Dose Range kGy:	30.7 - 31.5
Calculated Minimum Dose kGy:	29.2
Calculated Maximum Dose kGy:	33.7

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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: 09-Mar-2016

UK33S11555976-2-1

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

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### Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1078033
Customer Reference Number:	701467
Product Description:	BAG002 DV4268 25-70kGy
Validation Reference:	4268
Quantity Received:	8
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	70.0
Customer Unit Lot/Batch Number:	BAG 002-G, 1 plt

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### Irradiation Data

Date and Time of Irradiation:	09-Mar-2016 09:29
Reference Dose Range kGy:	55.7 - 56.3
Calculated Minimum Dose kGy:	37.8
Calculated Maximum Dose kGy:	60.8

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Irradiation Release Authorised By Synergy Health plc

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