



Certificate of Analysis

Product Name:	Crystel Platinum RTU Solution CRY111	
Reference:	CRY/PLA/032	
Batch Number:	P704700	
Date of Manufacture:	01-FEB-17	
Expiry Date:	FEB-2019	
This is to certify that Crystel Platinum RTU solution above was tested on 03-FEB-17 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	0.999
pH	8.50 – 10.00	9.2
STERILITY	No growth	Conforms

Completed By:

Quality Department: E Andrews

Date: 24 MAR 2017

Reviewed By:

[Signature]

Date: 24 MAR 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: CRY111 Platinum Lot No: P704700 ICN: 0317001D Subcontractor's Report Number: 2017039893	Lab Book Reference: ST03-63 Date Received: 01 Mar 2017 Date Completed: 22 Mar 2017 No. of samples: 3
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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: Sophie Hughes

Date: 22 MAR 2017

Reviewed by:



 Quality Assurance Manager
 UK General Manager
 Technical Manager
 Laboratory Manager

Date: 23 MAR 2017

QA Approved by:



 Quality Assurance Manager
 UK General Manager
 Technical Manager

Date: 23 MAR 2017

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	S. Hughes	22 Mar 2017

CONFIDENTIAL

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ST03-63
REVISION NO: 1

ICN: 0317001D
DATE: 22 Mar 2017

TSCTS044-1 Rev 2

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<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

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 pit

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

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

UK33S11548367-2-1

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:	1078033
Customer Reference Number:	701365
Product Description:	BAG002 DV4268 25-70kGy
Validation Reference:	4268
Quantity Received:	4
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	70.0
Customer Unit Lot/Batch Number:	1 plt

Irradiation Data

Date and Time of Irradiation:	09-Mar-2016 16:08
Reference Dose Range kGy:	54.9 - 54.9
Calculated Minimum Dose kGy:	37.2
Calculated Maximum Dose kGy:	59.3

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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