



Certificate of Analysis

Product Name:	Crystel Platinum RTU Solution CRY111	
Reference:	CRY/PLA/032	
Batch Number:	P807300	
Date of Manufacture:	2018-03-08	
Expiry Date:	2020-03-08	
This is to certify that Crystel Platinum RTU solution above was tested on 2018-03-08 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	9.29
STERILITY	No growth	Conforms

Completed By:

Reviewed By:

Quality Department: Eandreas

Sklienska

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: CRY111 Platinum
Lot No: P807300
ICN: 0318020D
Subcontractor's Report Number: 2018050549

Lab Book Reference: ST03-150
Date Received: 19 Mar 2018
Date Completed: 17 Apr 2018
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:


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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
ST03-150

ICN: 0318020D

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TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 17 Apr 2018

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Registered in England and Wales. Company Registration Number: BR002906



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 18-Oct-2017

UK33S11984764-1-1

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:	705753
Product Description:	BOTTLE 5LT DV4232 25-45kGy
Validation Reference:	4232
Quantity Received:	10
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BOTTLE 046, B/N: 09.10.2017, 1 plt

Irradiation Data

Date and Time of Irradiation:	18-Oct-2017 00:11
Reference Dose Range kGy:	32.3 - 32.8
Calculated Minimum Dose kGy:	30.7
Calculated Maximum Dose kGy:	35.1

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: 15-Mar-2017

UK33S11829406-2-1

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:	704369
Product Description:	BAG002 DV4268 25-70kGy
Validation Reference:	4268
Quantity Received:	6
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	70.0
Customer Unit Lot/Batch Number:	21022017, 1 PLT

Irradiation Data

Date and Time of Irradiation:	14-Mar-2017 18:57
Reference Dose Range kGy:	54.6 - 54.6
Calculated Minimum Dose kGy:	37.0
Calculated Maximum Dose kGy:	59.0

Irradiation Release Authorised By Synergy Health plc

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

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