



Certificate of Analysis

Product Name:	Crystel Platinum CRY109	
Reference:	CRY/PLA/019	
Batch Number:	P624400	
Date of Manufacture:	02-AUG-16	
Expiry Date:	AUG-2018	
This is to certify that Crystel Platinum solution above was tested on 04-AUG-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	0.900 – 1.100	0.990
pH (neat)	9.0 – 10.0	9.8
STERILITY	No growth	Conforms

Completed By:

Reviewed By:

Quality Department: *E Andrews*

[Signature]

Date: *28 Sept 2016*

Date: *28 Sep 16*

DRF1399 CRY/PLA/007/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: CRY109 Platinum Lot No: P624400 ICN: 0916001D Subcontractor's Report Number: 2016213032	Lab Book Reference: ST03-29 Date Received: 05 Sep 2016 Date Completed: 23 Sep 2016 No. of samples: 10
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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: 23 Sep 2016

Reviewed by:

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

Date: 23 Sep 2016

QA Approved by:

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

Date: 26 Sep 2016

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	S. Hughes	23 Sep 2016

CONFIDENTIAL

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ST03-29
REVISION NO: 1

ICN: 0916001D
DATE: 23 Sep 2016

TSCTS044-1 Rev 2

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Registered in England and Wales. Company Registration Number: BR002906



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date issued: 09-Sep-2015

UK33S11455485-2-1

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:	1075628
Customer Reference Number:	700363
Product Description:	BOTTLE 100ML DV4224 25-45kGy
Validation Reference:	4224
Quantity Received:	6
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:	09-Sep-2015 03:37
Reference Dose Range kGy:	32.3 - 32.3
Calculated Minimum Dose kGy:	30.8
Calculated Maximum Dose kGy:	35.2

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: 11-Aug-2016

UK33S11678232-2-1

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:	1075625
Customer Reference Number:	702828
Product Description:	CAP 001-G DV1.4225 25-45kGy
Validation Reference:	1.4225
Quantity Received:	3
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	1 plt

Irradiation Data

Date and Time of Irradiation:	11-Aug-2016 02:38
Reference Dose Range kGy:	33.4 - 33.4
Calculated Minimum Dose kGy:	29.0
Calculated Maximum Dose kGy:	37.5

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: 03-Nov-2015

UK33S11373223-1-1

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:	1094470
Customer Reference Number:	0000015258
Product Description:	BAG003-G VALIDATION
Quantity Received:	5
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	1plt, VALIDATION
Other Process Details:	This validation batch has received an underdose

Irradiation Data

Date and Time of Irradiation:	03-Nov-2015 13:12
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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

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