



Certificate of Analysis

Product Name:	Crystel Platinum CRY109	
Reference:	CRY/PLA/019	
Batch Number:	P724900	
Date of Manufacture:	2017.06.27	
Expiry Date:	2019.06.30	
This is to certify that Crystel Platinum solution above was tested on 2017.06.28 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	0.986
pH (neat)	9.0 – 10.0	9.8
STERILITY	No growth	Conforms

Completed By:

Quality Department: E Andrews

Date: 2017-10-09

Reviewed By:

[Signature]

Date: 2017-10-09

DRF1399 CRY/PLA/007/Issue3/June 2012

Page 1 of 1



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	Lab Book Reference: ST03-101
Lot No: P724900	Date Received: 08 Sep 2017
ICN: 0917006D	Date Completed: 02 Oct 2017
Subcontractor's Report Number: 2017169564	No. of samples: 10

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: C.Thornton


Date: 02 OCT 2017

Reviewed by:


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

Date: 02 OCT 2017

QA Approved by:


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

Date: 02 Oct 2017

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C.Thornton	02 Oct 2017

CONFIDENTIAL
ST03-101

ICN: 0917006D

Page 1 of 1
TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 02 Oct 2017

UK
Deacon Park
Moungate Road
Knowsley
Liverpool L33 7RN
Tel: +44 (0)151 547 7444
Fax: +44 (0)151 547 7400

USA
124 Bernard E. Saint Jean Drive
East Falmouth
MA 02536-4415
USA
Tel: 001 508 540 3444
Fax: 001 508 540 8680

Germany
PYROQUANT DIAGNOSTIK GmbH
Opelstrasse 14
D-64546 Mosfelden-Walldorf
Germany
Tel: 0049 6105 96 10 0
Fax: 0049 6105 96 10 15



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date issued: 29-Sep-2016

UK33S11715571-2-1

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:	703200
Product Description:	BOTTLE 100ML DV4224 25-45kGy
Validation Reference:	4224
Quantity Received:	12
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	Bottle 018, 1 plt

Irradiation Data

Date and Time of Irradiation:	29-Sep-2016 01:41
Reference Dose Range kGy:	32.1 - 32.1
Calculated Minimum Dose kGy:	30.6
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: 07-Sep-2016

UK33S11700177-1-1

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:	1075628
Customer Reference Number:	703059
Product Description:	BOTTLE 100ML DV4224 25-45kGy
Validation Reference:	4224
Quantity Received:	28
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BOTTLE 100ML, 2PLTS

Irradiation Data

Date and Time of Irradiation:	06-Sep-2016 19:43
Reference Dose Range kGy:	33.9 - 34.5
Calculated Minimum Dose kGy:	32.3
Calculated Maximum Dose kGy:	37.6

Irradiation Release Authorised By Synergy Health plc

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

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: 06-Mar-2017

UK33S11824859-3-1

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:	1075625
Customer Reference Number:	704309
Product Description:	CAP 001-G DV1.4225 25-45kGy
Validation Reference:	1.4225
Quantity Received:	2
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	22022017, 1 plt

Irradiation Data

Date and Time of Irradiation:	06-Mar-2017 00:44
Reference Dose Range kGy:	35.2 - 35.2
Calculated Minimum Dose kGy:	30.6
Calculated Maximum Dose kGy:	39.5

Irradiation Release Authorised By Synergy Health plc

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

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-Apr-2017

UK33S11854017-4-1

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:	1109474
Customer Reference Number:	704631
Product Description:	BAG004 DV4850 25-45kGy
Validation Reference:	4850
Quantity Received:	3
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	10042017

Irradiation Data

Date and Time of Irradiation:	15-Apr-2017 04:10
Reference Dose Range kGy:	34.4 - 34.4
Calculated Minimum Dose kGy:	27.4
Calculated Maximum Dose kGy:	39.7

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