



Certificate of Analysis

Product Name:	Crystel Platinum CRY109	
Reference:	CRY/PLA/019	
Batch Number:	P807100	
Date of Manufacture:	2018-03-05	
Expiry Date:	2020-03-05	
This is to certify that Crystel Platinum solution above was tested on 2018-03-07 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	10.0
STERILITY	No growth	Conforms

Completed By:

Reviewed By:

Quality Department: E Andrews

Skielinska

Date: 2018-04-09

Date: 2018-04-09

DRF1399 CRY/PLA/007/Issue3/June 2012

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Specialists in Endotoxin and Glucan Detection

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: P807100

ICN: 0318014D

Subcontractor's Report Number: 2018049915

Lab Book Reference: ST03-146

Date Received: 14MAR2018

Date Completed: 04APR2018

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: L ELLIS

Date: 04 APR 2018

Reviewed by:

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

Date: 05 APR 2018

QA Approved by:

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

Date: 06 APR 2018

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
NA	1	Revision 1, no changes	L ELLIS	04APR2018

CONFIDENTIAL
ST03-146

ICN: 0318014D

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TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 04APR2018

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Web: www.acciuk.co.uk

Registered in England and Wales. Company Registration Number: BR002906



<http://www.steris-ast.com>

Certificate of Irradiation

Date Issued: 10-Feb-2018

UK33S12057071-2-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 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:	1121497
Customer Reference Number:	706514
Product Description:	BOTTLE 100ML DV5155 25-45kGy
Validation Reference:	5155
Quantity Received:	13
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	Bottle 018, B/N: 30012018, 1 plt

Irradiation Data

Date and Time of Irradiation:	10-Feb-2018 10:49
Reference Dose Range kGy:	32.6 - 32.6
Calculated Minimum Dose kGy:	30.6
Calculated Maximum Dose kGy:	35.4

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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.steris-ast.com>

Certificate of Irradiation

Date Issued: 25-Feb-2018

UK33S12061299-2-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 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:	1121930
Customer Reference Number:	706585
Product Description:	100ML BOTTLE CAP DV5165 25-45kGy
Validation Reference:	5165
Quantity Received:	6
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	07022018, 1 PLT

Irradiation Data

Date and Time of Irradiation:	24-Feb-2018 19:32
Reference Dose Range kGy:	33.5 - 33.5
Calculated Minimum Dose kGy:	30.7
Calculated Maximum Dose kGy:	37.3

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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.steris-ast.com>

Certificate of Irradiation

Date Issued: 22-Feb-2018

UK33S12057071-3-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 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:	1121936
Customer Reference Number:	706514
Product Description:	BAG 004-G DV5175 25-45kGy
Validation Reference:	5175
Quantity Received:	6
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	Bag 004-G, B/N: 20180131, EXP: 31.01.20, 1 plt

Irradiation Data

Date and Time of Irradiation:	22-Feb-2018 13:44
Reference Dose Range kGy:	34.7 - 34.7
Calculated Minimum Dose kGy:	26.6
Calculated Maximum Dose kGy:	37.2

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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

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