



## Certificate of Analysis

Product Name:	<b>Crystel Platinum CRY109</b>	
Reference:	CRY/PLA/019	
Batch Number:	P810100	
Date of Manufacture:	2018-01-15	
Expiry Date:	2020-01-15	
This is to certify that Crystel Platinum solution above was tested on 2018-01-16 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	0.988
pH (neat)	9.0 – 10.0	9.9
STERILITY	No growth	Conforms

Completed By:

Reviewed By:

Quality Department: Gandevos

[Signature]

Date: 2018-05-17

Date: 2018-05-17

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:** P810100  
**ICN:** 0418015D  
**Subcontractor's Report Number:** 2018070292

**Lab Book Reference:** ST03-160  
**Date Received:** 13 Apr 2018  
**Date Completed:** 15 May 2018  
**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: Daniel Jennings

Date: 15 May 2018

#### Reviewed by:

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

Date: 16 MAY 2018

#### QA Approved by:

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

Date: 16 MAY 2018

#### Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	D. Jennings	15 May 2018

CONFIDENTIAL  
ST03-160

ICN: 0418015D

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TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 15 May 2018

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

## Certificate of Irradiation

Date Issued: 11-Mar-2018

UK33S12069394-2-1

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

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### Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1121497
Customer Reference Number:	706678
Product Description:	BOTTLE 100ML DV5155 25-45kGy
Validation Reference:	5155
Quantity Received:	26
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	22022018, 2 plts

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### Irradiation Data

Date and Time of Irradiation:	10-Mar-2018 23:02
Reference Dose Range kGy:	33.2 - 33.8
Calculated Minimum Dose kGy:	31.2
Calculated Maximum Dose kGy:	36.7

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

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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



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## 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

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### 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

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### 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

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

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## 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

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### 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

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### 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

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

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