



Certificate of Analysis

Product Name:	Crystel Platinum CRY109
Reference:	CRY/PLA/019
Batch Number:	P803900
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	No Growth

Completed By:

Reviewed By:

Quality Department: *E Andrews*

J Kelinto

Date: *2018-03-09*

Date: *2018-03-09*

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: P803900
ICN: 0218005D
Subcontractor's Report Number: 2018029033

Lab Book Reference: ST03-132
Date Received: 07 Feb 2018
Date Completed: 07 Mar 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: 07 MAR 2018

Reviewed by:


 Quality Assurance Manager
 UK General Manager
 Technical Manager
 Laboratory Manager

Date: 07 MAR 2018

QA Approved by:


 Quality Assurance
 UK General Manager
 Technical Manager

Date: 07 MAR 2018

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	D. Jennings	07 Mar 2018

CONFIDENTIAL
ST03-132

ICN: 0218005D

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REVISION NO: 1

DATE: 07 Mar 2018

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Registered in England and Wales. Company Registration Number BR002906



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

Certificate of Irradiation

Date Issued: 11-Jan-2018

UK33S12034059-1-2

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:	706219
Product Description:	BOTTLE 100ML DV5155 25-45kGy
Validation Reference:	5155
Quantity Received:	16
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	14122017, 1 plt

Irradiation Data

Date and Time of Irradiation:	10-Jan-2018 21:39
Reference Dose Range kGy:	32.7 - 33.1
Calculated Minimum Dose kGy:	30.7
Calculated Maximum Dose kGy:	35.9

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: 08-Jan-2018

UK33S12037706-1-1

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:	706256
Product Description:	100ML BOTTLE CAP DV5165 25-45kGy
Validation Reference:	5165
Quantity Received:	2
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	CAP001-G, BN: 20122017, EXP: 20191230, 1 plit

Irradiation Data

Date and Time of Irradiation:	08-Jan-2018 11:20
Reference Dose Range kGy:	34.4 - 34.4
Calculated Minimum Dose kGy:	31.6
Calculated Maximum Dose kGy:	38.3

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

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

Certificate of Irradiation

Date Issued: 15-Jan-2018

UK33S12041486-1-1

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:	706279
Product Description:	BAG 004-G DV5175 25-45kGy
Validation Reference:	5175
Quantity Received:	4
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	06112017, 1 PLT

Irradiation Data

Date and Time of Irradiation:	15-Jan-2018 21:52
Reference Dose Range kGy:	33.7 - 33.7
Calculated Minimum Dose kGy:	25.9
Calculated Maximum Dose kGy:	36.1

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