



Certificate of Analysis

Product Name:	Crystel Platinum CRY109
Reference:	CRY/PLA/019
Batch Number:	P700401
Date of Manufacture:	06-DEC-16
Expiry Date:	DEC-2018

This is to certify that Crystel Platinum solution above was tested on 07-DEC-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	9.9
STERILITY	No growth	Conforms

Completed By:

Reviewed By:

Quality Department: E Andrews

[Signature]

Date: 7 Feb 2017

Date: 7th FEB 2017

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: P700401 ICN: 0117004D Subcontractor's Report Number: 2017009087	Lab Book Reference: ST03-55 Date Received: 12 JAN 2017 Date Completed: 06 FEB 2017 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:

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 Laboratory Technician: Charlotte Ray

Date: 06 FEB 2017

Reviewed by:

-
 Quality Assurance Manager
 UK General Manager
 Technical Manager
 Laboratory Manager

Date: 06 FEB 2017

QA Approved by:

-
 Quality Assurance Manager
 UK General Manager
 Technical Manager

Date: 06 FEB 2017

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C RAY	06 FEB 2017

CONFIDENTIAL

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ST03-55
REVISION NO: 1

ICN: 0117004D
DATE: 06 FEB 2017

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: 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: 04-Oct-2016

UK33S11715571-4-1

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:	1075625
Customer Reference Number:	703200
Product Description:	CAP 001-G DV1.4225 25-45kGy
Validation Reference:	1.4225
Quantity Received:	4
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	CAP001-G, 1 plt

Irradiation Data

Date and Time of Irradiation:	03-Oct-2016 23:41
Reference Dose Range kGy:	32.2 - 32.2
Calculated Minimum Dose kGy:	28.0
Calculated Maximum Dose kGy:	36.1

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: 31-Aug-2016

UK33S11690237-2-1

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:	1096575
Customer Reference Number:	702993
Product Description:	BAG004 DV4398 25-40kGy
Validation Reference:	4398
Quantity Received:	5
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BAG004-G, 1 pit

Irradiation Data

Date and Time of Irradiation:	31-Aug-2016 03:00
Reference Dose Range kGy:	32.0 - 32.0
Calculated Minimum Dose kGy:	25.0
Calculated Maximum Dose kGy:	36.0

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