



### Certificate of Analysis

Product Name:	Crystel Platinum CRY109
Reference:	CRY/PLA/019
Batch Number:	P626501
Date of Manufacture:	02-AUG-16
Expiry Date:	AUG-2018

This is to certify that Crystel Platinum solution above was tested on 04-AUG-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	9.8
STERILITY	No growth	Conforms

Completed By:

Reviewed By:

Quality Department: E. Andrews

[Signature]

Date: 25 Oct 2016

Date: 25 Oct 2018

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.

<b>Sample ID:</b> CRY109 Platinum <b>Lot No:</b> P626501 <b>ICN:</b> 1016003D <b>Subcontractor's Report Number:</b> 2016232075	<b>Lab Book Reference:</b> ST03-33 <b>Date Received:</b> 03 Oct 2016 <b>Date Completed:</b> 21 Oct 2016 <b>No. of samples:</b> 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:

.....  
 Laboratory Technician: Charlotte Ray

Date: 21 Oct 2016

### Reviewed by:

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

Date: 21 Oct 2016

### QA Approved by:

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

Date: 21 Oct 2016

### Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C. Ray	21 Oct 2016

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**ST03-33**  
**REVISION NO: 1**

**ICN: 1016003D**  
**DATE: 21 Oct 2016**

**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

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## 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

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## 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

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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: 11-Aug-2016

UK33S11678232-2-1

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

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## Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1075625
Customer Reference Number:	702828
Product Description:	CAP 001-G DV1.4225 25-45kGy
Validation Reference:	1.4225
Quantity Received:	3
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	1 plt

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## Irradiation Data

Date and Time of Irradiation:	11-Aug-2016 02:38
Reference Dose Range kGy:	33.4 - 33.4
Calculated Minimum Dose kGy:	29.0
Calculated Maximum Dose kGy:	37.5

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Irradiation Release Authorised By Synergy Health plc

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 Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069



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# Certificate of Irradiation

Date Issued: 25-Oct-2015

UK33S11487821-2-1

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

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## Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1096575
Customer Reference Number:	700781
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:	1 plt

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## Irradiation Data

Date and Time of Irradiation:	25-Oct-2015 12:49
Reference Dose Range kGy:	34.3 - 34.3
Calculated Minimum Dose kGy:	26.8
Calculated Maximum Dose kGy:	38.6

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Irradiation Release Authorised By Synergy Health plc

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