Crystel

Certificate of Analysis

Product Name:	Crystel GOLD CRY 101
Reference:	CRY/GOL/019
Batch Number:	P616002
Date of Manufacture:	25-MAY-16
Expiry Date:	MAY-2018

This is to certify that Crystel Gold solution above was tested on 25-MAY-16 and found to comply with all requirements as set out in the specifications and method of analysis.

PROPERTIES	SPECIFICATION	RESULTS
APPEARANCE	Clear and free from suspended matter	Conforms
ODOUR	Alcohol like	Conforms
SPECIFIC GRAVITY	0.870 – 0.890	0.872
STERILITY	No growth	Conforms
IRRADIATION	Achieves minimum dose	Conforms
ENDOTOXIN	<0.25EU/ml	<0.1
	Recovery 50-200%	92%

Completed By:

Quality Department: E Andrews

Date: 4 August 16

Reviewed By:

.....

Date: 4. Aug. 16

DRF1574 CRY/GOL/006/Issue4/Sept2012

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ASSOCIATES OF CAPE COD INTERNATIONAL

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: CRY101 Gold
Lot No: P616002
ICN: 0716008D
Subcontractor's Report Number: 2016176804

Lab Book Reference: ST03-17
Date Received: 11 Jul 2016
Date Completed: 03 Aug 2016
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:

..... Date: 03 AUG 2016

Laboratory Technician: Sophie Hughes

Reviewed by:

..... Date: 04 AUG 2016

☐ Quality Assurance Manager
☑ UK General Manager
☐ Technical Manager
☐ CTS Supervisor

QA Approved by:

..... Date: 04 AUG 2016

☑ Quality Assurance Manager
☐ UK General Manager
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Registered in England and Wales. Company Registration Number: BR002906

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	S. Hughes	03 AUG 2016

ASSOCIATES OF CAPE COD INTERNATIONAL

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LIMULUS AMEBOCYTE LYSATE (LAL) ANALYTICAL REPORT
Release Test - Kinetic Turbidimetric Method (SOPCTS012)

Sample ID: CRY101 GOLD
Lot No: P616002
ICN No: 0716008D

Lab Book Reference: EL186-41 (C)
Date Received: 11 JUL 2016
Date Completed: 15 JUL 2016

Reagents

Pyrotell®-T: Lot Number 516-01-766-T. Pyrotell®-T was reconstituted with Pyrosol® Buffer and used to Assay all dilutions.

Pyrosol® Buffer: Lot Number 226-388.

LAL Reagent Water (LRW): Lot Number AAH207242. LRW was used to reconstitute endotoxin, prepare dilutions of endotoxin and sample(s), and serve as the negative control.

Instrumentation: Pyros® Kinetix Incubating Kinetic Tube Reader; S/N; 3G-1166.

Reference Standard Endotoxin (RSE): Lot number 10/178, the reconstituted concentration of the RSE is 2,000 EU/ml.

The sensitivity of the assay is the lowest concentration of RSE used to construct the calibration curve. A series of 10-fold dilutions between 0.001 and 1.0 EU/mL was tested in duplicate and the results were used to construct the standard curve.

Preparation and Testing of Sample: The samples were diluted with LRW and analysed at a 1:100 dilution, in accordance with validation EL168-03. Positive product controls were tested, in parallel, on sample dilutions spiked with an Endotoxin concentration of 0.1 EU/ml. The sample to lysate ratio was 4:1.

Results: The Release Test is performed according to a validated method and is used to release finished products. The test can also be performed for release of raw/in-process materials. The absolute value for the correlation coefficient for the regression of log onset time versus log endotoxin concentration was greater than or equal to 0.980. The negative control (LRW) was tested in duplicate and contained less than 0.001 EU/mL. Inhibition or enhancement of the bacterial Endotoxin test by the sample is absent if the concentration of the Endotoxin assayed in the Positive Product Controls are within 50% to 200% of the nominal concentration.

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Sample Results:

Sample Identification	% Spike Recovery	EU/ml
CRY101 GOLD P616002	92	<0.1

All Samples analysed passed the specification of < 0.25 EU/ml.

Approval:

Technician:..... **Date:** 15 JUL 2016
Laboratory Technician: Charlotte Ray

Reviewed By:..... **Date:** 19/JUL/2016

- ☐ Quality Assurance Manager
- ☐ UK General Manager
- ☐ Technical Manager
- ☑ Laboratory Manager

QA Approval: DSolanki **Date:** 19 JUL 2016

- ☑ Quality Assurance Manager
- ☐ UK General Manager
- ☐ Technical Manager

References:

Associates of Cape Cod SOPCTS012, *General Kinetic LAL Turbidimetric Assay*

United States Pharmacopoeia <85> *Bacterial Endotoxins Test*

European Pharmacopoeia, *Section 2.6.14.*

Revision History:

DCCF No:	Revision:	Description:	Originator	Effective Date:
N/A	1	Revision 1: No Changes	C RAY	15 JUL 2016

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Certificate of Irradiation

Date Issued: 04-Jul-2016 **UK32S11649879-1-1**

This is to certify that Bradford 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
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UNITED KINGDOM

Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1003509
Customer Reference Number:	702510
Product Description:	GOLD IPA 1LTR 25-45 kGy
Validation Reference:	4.1019
Quantity Received:	156
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	B/N P616002 MON 13 JUN 2016 3 PLTS

Irradiation Data

Date and Time of Irradiation:	02-Jul-2016 07:51
Reference Dose Range kGy:	35.3 - 36.2
Calculated Minimum Dose kGy:	27.2
Calculated Maximum Dose kGy:	36.4

Irradiation Release Authorised By Synergy Health plc