Crystel

Certificate of Analysis

Product Name:	**Crystel GOLD CRY 101**
Reference:	CRY/GOL/019
Batch Number:	P727700
Date of Manufacture:	2017-09-26
Expiry Date:	2019-09

This is to certify that Crystel Gold solution above was tested on 2017-09-26 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	0.874
STERILITY	No growth	Conforms
IRRADIATION	Achieves minimum dose	Conforms
ENDOTOXIN	<0.25EU/ml	<0.1
	Recovery 50-200%	131%

Completed By:

Quality Department: C Andrews

Date: 2017-11-24

Reviewed By:

.....

Date: 2017-11-24

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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: P727700
ICN: 1017021D
Subcontractor's Report Number: 2017199657

Lab Book Reference: ST03-109
Date Received: 23 Oct 2017
Date Completed: 13 Nov 2017
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: C.Thornton

Date: 16 NOV 2017

Reviewed by:

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

Date: 17 Nov 2017

QA Approved by:

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

Date: 17 NOV 2017

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C.Thornton	13 Nov 2017

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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: P727700
ICN No: 1017024D

Lab Book Reference:EL193-66 (B)
Date Received: 24 Oct 2017
Date Completed: 13 Nov 2017

Reagents

Pyrotell®-T: Lot Number 517-04-820-T. Pyrotell®-T was reconstituted with Pyrosol® Buffer and used to Assay all dilutions.

Pyrosol® Buffer: Lot Number 226-403.

LAL Reagent Water (LRW): Lot Number AC10244555. 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.

Control Standard Endotoxin (CSE): Lot number 154, *Escherichia coli* O113:H10. The potency of the CSE is 11 EU/ng when measured against Reference Standard Endotoxin (RSE), lot number H0K354 (Food and Drug Administration, CBER) with Pyrotell®-T lot number 517-04-820-T.

The sensitivity of the assay is the lowest concentration of CSE 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 P727700	131	<0.1

All samples analysed passed the specification of <0.25 EU/mL.

Approval:

Techncian:..... **Date:** 15 NOV 2017

Laboratory Technician: Daniel Jennings

Reviewed By:..... **Date:** 23 NOV 2017

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

QA Approval:..... **Date:** 23Nov 2017

- ☑ 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	Revison 1, no changes.	Daniel Jennings	13 Nov 2017

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Certificate of Irradiation

Date Issued: 15-Oct-2017

UK33S11984764-2-2

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
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Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1108717
Customer Reference Number:	705753
Product Description:	ALCOHOL 1 LTR TRIGGER SPRAY DV4778 20-45kGy
Validation Reference:	4778
Quantity Received:	149
Customer Minimum Specification kGy:	20.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	CRY101, B/N: P727700, 3 plts

Irradiation Data

Date and Time of Irradiation:	15-Oct-2017 12:25
Reference Dose Range kGy:	31.4 - 33.0
Calculated Minimum Dose kGy:	25.4
Calculated Maximum Dose kGy:	38.0

Irradiation Release Authorised By Synergy Health plc