Crystel

Certificate of Analysis

Product Name:	Crystel GOLD CRY 102
Reference:	CRY/GOL/019
Batch Number:	P623700
Date of Manufacture:	22-AUG-16
Expiry Date:	AUG-2018

This is to certify that Crystel Gold solution above was tested on 22-AUG-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%	110%

Completed By:

Quality Department: C Andrews

Date: 7 October 2016

Reviewed By:

.....

Date: 07-OCT-2016

Tristel Solutions Limited. Lynx Business Park, Fordham Road, Snailwell, Cambs CB8 7NY. Registered No: 3518312
Tel: +44 (0)1638 721500 Fax: +44 (0)1638 721911 Email: mail@tristel.com Web: www.tristel.com

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: CRY102 Gold
Lot No:P623700
ICN: 0916012D
Subcontractor's Report Number: 2016220533

Lab Book Reference: ST03-30
Date Received: 14 Sep 2016
Date Completed: 03 Oct 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:

.....
Laboratory Technician: Charlotte Ray

Date: 03 OCT 2016

Reviewed by:

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

Date: 04 OCT 2016

QA Approved by:

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

Date: 04 OCT 2016

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C RAY	03 Oct 2016

UK
Deacon Park
Moorgate Road
Knowsley
Liverpool L33 7RX
Tel: +44 (0)151 547 7444
Fax: +44 (0)151 547 7400

USA
124 Bernard E. Saint Jean Drive
East Falmouth
MA 02536-4445
USA
Tel: 001 508 540 3441
Fax: 001 508 540 8680

Germany
PYROQUANT DIAGNOSTIK GmbH
Opel-trasse 14
D-64546 Mörfelden-Walldorf
Germany
Tel: 0049 6105 96 10 0
Fax: 0049 6105 96 10 15

Web: www.acciuk.co.uk

ASSOCIATES OF CAPE COD INTERNATIONAL

Specialists in Endotoxin and Glucan Detection

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

Sample ID: CRY102 GOLD
Lot No: P623700
ICN No: 0916012D

Lab Book Reference: EL188-22
Date Received: 14 SEP 2016
Date Completed: 21 SEP 2016

Reagents

Pyrotell®-T: Lot Number 516-04-780-T. Pyrotell®-T was reconstituted with Pyrosol® Buffer and used to Assay all dilutions.

Pyrosol® Buffer: Lot Number 226-389.

LAL Reagent Water (LRW): Lot Number AAH207245. 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.

UK
Deacon Park
Moorgate Road
Knowsley
Liverpool L33 7RX
Tel: +44 (0)151 547 7444
Fax: +44 (0)151 547 7400

USA
124 Bernard E. Saint Jean Drive
East Falmouth
MA 02536-4445
USA
Tel: 001 508 540 3444
Fax: 001 508 540 8680

Germany
PYROQUANT DIAGNOSTIK GmbH
Opel-trasse 14
D-64546 Mörfelden-Walldorf
Germany
Tel: 0049 6105 96 10 0
Fax: 0049 6105 96 10 15

Web: www.acciuk.co.uk

Sample Results:

Sample Identification	% Spike Recovery	EU/ml
CRY102 GOLD P623700	110	<0.1

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

Approval:

Technician:..... **Date:** 21 SEP 2016
Laboratory Technician: *Charlotte Ray*

Reviewed By:..... **Date:** 21 SEP 2016

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

QA Approval:..... **Date:** 26 SEP 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	21 SEP 2016

synergyhealth
our work protects your world

http://www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 04-Sep-2016 **UK33S11693825-1-1**

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:	1058415
Customer Reference Number:	703023
Product Description:	ALCOHOL CRY102 15-40kGy
Validation Reference:	4093
Quantity Received:	95
Customer Minimum Specification kGy:	15.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	P623700, 2 PLTS

Irradiation Data

Date and Time of Irradiation:	04-Sep-2016 20:09
Reference Dose Range kGy:	29.5 - 30.9
Calculated Minimum Dose kGy:	24.0
Calculated Maximum Dose kGy:	34.7

Irradiation Release Authorised By Synergy Health plc