



Certificate of Analysis

Product Name:	Crystel GOLD CRY 101
Reference:	CRY/GOL/019
Batch Number:	P813700
Date of Manufacture:	2018-03-22
Expiry Date:	2020-03-22

This is to certify that Crystel Gold solution above was tested on 2018-03-22 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	0.876
STERILITY	No growth	Conforms
IRRADIATION	Achieves minimum dose	Conforms
ENDOTOXIN	<0.25EU/ml	<0.1
	Recovery 50-200%	121%

Completed By:

Reviewed By:

Quality Department: E Andrews

Lielska

Date: 2018-07-02

Date: 2018-07-02

DRF1574 CRY/GOL/006/Issue4/Sept2012



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: P813700
ICN: 0618004D
Subcontractor's Report Number: 2018101996

Lab Book Reference: ST03-175
Date Received: 05 Jun 2018
Date Completed: 25 Jun 2018
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: 25 Jun 2018

Reviewed by:

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

Date: 28 Jun 2018

QA Approved by:

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

Date: 28 JUN 2018

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
N/A	1	Revision 1, no changes	C.Thornton	25 Jun 2018

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ST03-175

ICN: 0618004D

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TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 25 Jun 2018

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

Sample ID:CRY101 Gold
Lot No:P813700
ICN No:0618004D

Lab Book Reference:EL195-57
Date Received:05 JUN 2018
Date Completed:14 JUN 2018

Reagents

Pyrotell®-T: Lot Number 517-10-848-T. Pyrotell®-T was reconstituted with Pyrosol® Buffer and used to Assay all dilutions.

Pyrosol® Buffer: Lot Number 226-414.

LAL Reagent Water (LRW): Lot Number AC10244546. 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 159, The potency of the CSE is 14 EU/ng when measured against Reference Standard Endotoxin (RSE), lot number H0K354 (Food and Drug Administration, CBER) with Pyrotell®-T lot number 517-10-848-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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EL195-57
REVISION NO:1

ICN: 0618004D
DATE:14 JUN 2018

TSCTS015-3.1 Rev 18

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Sample Results:

Sample Identification	% Spike Recovery	EU/ml
P813700	121	<0.1

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

Approval:

Technician:..... *L. Ellis* **Date:**..... *14 JUN 2018*

Laboratory Technician: L Ellis

Reviewed By:..... *J. Hoenert* **Date:**..... *14 Jun 2018*

Review Board
 Laboratory Manager

QA Approval:..... *[Signature]* **Date:**..... *15 Jun 2018*

Review Board

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:
NA	1	Revision 1 No Changes	L Ellis	14JUN2018



<http://www.steris-ast.com>

Certificate of Irradiation

Date Issued: 28-May-2018

UK33S12111134-2-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 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:	1108717
Customer Reference Number:	707232
Product Description:	ALCOHOL 1 LTR TRIGGER SPRAY DV4778 20-45kGy
Validation Reference:	4778
Quantity Received:	65
Customer Minimum Specification kGy:	20.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	P813700, 1 plt

Irradiation Data

Date and Time of Irradiation:	28-May-2018 03:48
Reference Dose Range kGy:	33.4 - 33.8
Calculated Minimum Dose kGy:	27.0
Calculated Maximum Dose kGy:	39.0

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

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