



Certificate of Analysis

Product Name:	Crystel GOLD	CRY 101
Reference:	CRY/GOL/019	
Batch Number:	P808500	
Date of Manufacture:	2018-03-22	
Expiry Date:	2020-03-22	
<p>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.</p>		
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%	131%

Completed By:

Reviewed By:

Quality Department: E. Andrews

[Signature]

Date: 2018-05-15

Date: 2018-05-15

DRF1574 CRY/GOL/006/Issue4/Sept2012





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: P808500
ICN: 0418024D
Subcontractor's Report Number: 2018072774

Lab Book Reference: ST03-158
Date Received: 18 APR 2018
Date Completed: 08 MAY 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: L. Ellis

Date: 09 MAY 2018

Reviewed by:


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

Date: 09 MAY 2018

QA Approved by:


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

Date: 09 MAY 2018

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
NA	1	Revision 1, no changes	L Ellis	08 MAY 2018

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ST03-158

ICN: 0418024D

Page 1 of 1
TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 08 MAY 2018

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Registered in England and Wales. Company Registration Number: BR002906

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

Sample ID:CRY101 Gold
Lot No:P808500
ICN No:0418024D

Lab Book Reference:EL195-26
Date Received:18-Apr-2018
Date Completed:20-Apr-2018

Reagents

Pyrotell®-T: Lot Number 517-08-838-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 AC11160291. 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, The potency of the CSE is 11EU/ng when measured against Reference Standard Endotoxin (RSE), lot number HOK354 (Food and Drug Administration, CBER) with Pyrotell®-T lot number 517-08-838-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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Page 1 of 2

EL195-26
REVISION NO:1

ICN: 0418024D
DATE:20-Apr-2018

TSCTS015-3.1 Rev 18

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Sample Results:


Sample Identification	% Spike Recovery	EU/ml
P808500	131	<0.1

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

Approval:

Technician: 
Laboratory Technician: L Ellis

Date: 20 APR 2018

Reviewed By: 
 Review Board
 Laboratory Manager

Date: 25 APR 2018

QA Approval: 
 Review Board

Date: 27 APR 2018

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	20Apr2018



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

Certificate of Irradiation

Date Issued: 30-Mar-2018

UK33S12084453-1-1

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:	706897
Product Description:	ALCOHOL 1 LTR TRIGGER SPRAY DV4778 20-45kGy
Validation Reference:	4778
Quantity Received:	89
Customer Minimum Specification kGy:	20.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	P808500, 2 plts

Irradiation Data

Date and Time of Irradiation:	30-Mar-2018 04:44
Reference Dose Range kGy:	34.8 - 35.3
Calculated Minimum Dose kGy:	28.2
Calculated Maximum Dose kGy:	40.7

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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