



Certificate of Analysis

Product Name:	Crystel GOLD CRY 101
Reference:	CRY/GOL/019
Batch Number:	WO45263-1
Date of Manufacture:	2018-04-25
Expiry Date:	2020-04-25

This is to certify that Crystel Gold solution above was tested on 2018-04-25 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%	118%

Completed By:

Reviewed By:

Quality Department: E. Andrews

Stielinska

Date: 2018-06-15

Date: 2018-06-15

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: W045263-1
ICN: 0518025D
Subcontractor's Report Number: 2018096148

Lab Book Reference: ST03-171
Date Received: 25 MAY 2018
Date Completed: 14 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:

L. Ellis

 Laboratory Technician/Designee: L Ellis

Date: *14 JUN 2018*

Reviewed by:

J. McManus

 Quality Assurance Manager
 UK General Manager
 Technical Manager
 Laboratory Manager

Date: *14 Jun 2018*

QA Approved by:

[Signature]

 Quality Assurance
 UK General Manager
 Technical Manager

Date: *15 Jun 2018*

Revision History:

DCCF No:	Revision:	Description:	Originator:	Effective Date:
NA	1	Revision 1, no changes	L Ellis	14JUN2018

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 ST03-171

ICN: 0518025D

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 TSCTS044-1 Rev 3

REVISION NO: 1

DATE: 14 JUN 2018

UK
 Deacon Park
 Moungate Road
 Knowsley
 Liverpool L33 7RN
 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
 Opelsunne 14
 D-64546 Mörfelden-Walldorf
 Germany
 Tel: 0049 6105 96 10 0
 Fax: 0049 6105 96 10 15

Web: www.acciuk.co.uk

Registered in England and Wales. Company Registration Number: BR002906



Specialists in Endotoxin and Glucan Detection

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

Sample ID:CRY101 Gold
Lot No:W045263-1
ICN No:0518025D

Lab Book Reference:EL195-48-B
Date Received:25 MAY 2018
Date Completed:31 MAY 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 226-390.

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 HOK354 (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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UK
Dewon Park
Moorgate Road
Knowsley
Liverpool L33 7RN
Tel: +44 (0)151 517 7444
Fax: +44 (0)151 517 7100

USA
124 Bernard E. Saint Jean Drive
East Falmouth
MA 02536-1445
USA
Tel: 001 508 540 3444
Fax: 001 508 540 8680

Germany
PYROQUANT DIAGNOSTIK GmbH
Opelstrasse 14
D-64546 Morfelden-Walldorf
Germany
Tel: 0049 6105 96 10 0
Fax: 0049 6105 96 10 15

Web: www.acciuk.co.uk

Registered in England and Wales. Company Registration Number: BR002906



Sample Results:

Sample Identification	% Spike Recovery	EU/ml
W045263-1	118	<0.1

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

Approval:

Technician: *L. Ellis*
Laboratory Technician: L Ellis

Date: *31 MAY 2018*

Reviewed By: *J. Marshall*
 Review Board
 Laboratory Manager

Date: *01 JUN 2018*

QA Approval: *[Signature]*
 Review Board

Date: *05 JUN 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	31MAY2018

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EL195-48-B
REVISION NO:1

ICN: 0518025D
DATE:31 MAY 2018

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

Certificate of Irradiation

Date Issued: 21-May-2018

UK33S12107921-3-2

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:	707186
Product Description:	ALCOHOL 1 LTR TRIGGER SPRAY DV4778 20-45kGy
Validation Reference:	4778
Quantity Received:	157
Customer Minimum Specification kGy:	20.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BN: W045263-1, 3 PLTS

Irradiation Data

Date and Time of Irradiation:	21-May-2018 01:03
Reference Dose Range kGy:	34.3 - 34.4
Calculated Minimum Dose kGy:	27.8
Calculated Maximum Dose kGy:	39.7

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

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM
Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069