# Bio Vectra

# CERTIFICATE OF ANALYSIS cGMP DITHIOTHREITOL

Pioneering Answers H S O H

	<b>SPECIFICATION</b>	<u>ACTUAL</u>
Catalogue Number	1370	
CAS Registry Number	3483-12-3	
Lot Number		46122
Batch Number		46048
Molecular Formula	$C_4H_{10}O_2S_2$	
Molecular Weight	154.25 g.mol <sup>-1</sup>	
Melting Point	42 ± 2°C (Corr.)	41-42°C
I.R.	Consistent with assigned structure	Conforms
Titration ex -SH (iodometric)	≥99.0%	100.1%
T.L.C.	One Spot	Conforms
UV Assays (1) 1% Solution	•	
A <sub>280</sub>	< 0.067	0.018
A <sub>305</sub> (2) 0.02 M Solution	< 0.050	0.010
A <sub>283</sub>	< 0.040	0.019
(3) 1 M Neutral Solution A <sub>400</sub>	< 0.062	0.006
A405	< 0.062	0.006
OD 700-500 nm	$\leq 0.035$	0.004
Loss on Drying	< 0.50%	0.10%
Appearance	White crystals	Conforms
10% Solution in Water	Clear and colorless	Conforms
% Oxidized DTT	< 0.50%	0.33%
Residual Solvents Toluene Hexane Methanol THF	< 890 ppm < 290 ppm < 3000 ppm < 720 ppm	141 ppm 72 ppm < 60 ppm < 72 ppm
Water Insolubles Material Content		• •
Relative Residue (ppm)	Report only	124 ppm Off-white residue
Appearance of Residue Storage	Report only 2-8°C under Nitrogen	On-waite residue
Manufacturer	BioVectra Inc.	
Manufacturing Location	17 Hillstrom Ave., Charlottetown, PE, C	`anada
Date of Manufacture	February 23, 2016	Zanaua
Retest/Expiration Date	February 2018	
QC Method & Version followed	QC2071-8	
Analyst Certification		Mar 13/16
QA Review and Approval	Date	h / 1 0 1 1 1 1 1 1
COA1370-9 August 27, 2014	Date	1110010



**Pioneering** Answers

## **CERTIFICATE OF COMPLIANCE**

#### cGMP DTT

Catalogue Number: 1370

Batch Number: 46048

Lot Number: 46122

Date of Manufacture: Feb 23, 2016

Date of Packaging: Feb 23, 2016

**Bulk Quantity Released: 204.1kg** 

Retest Date of Finished Product: Feb/2018

The above batch has been manufactured in accordance with current Good Manufacturing Practices (cGMPs) and approved Master Batch Production Records, Test Instructions, and Specifications.

All manufacturing, packaging and testing documents for the above batch have been reviewed and approved by the Quality Assurance Department of BioVectra Inc., Charlottetown, Prince Edward Island.

Certified by:

Rehan Babar, QA Associate

Print Name & Title

Signature

Mar16, 2016

Date

COC1370-1 March 12, 2010



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### **BSE/TSE DECLARATION**

**cGMP DITHIOTHREITOL (DTT)** 

**CATALOGUE NUMBER: 1370** 

**BATCH NUMBER: 46048** 

**LOT NUMBER: 46122** 

DATE MANUFACTURED: Feb 23, 2016

COUNTRY OF MANUFACTURE: Canada

This certifies that the production of cGMP Dithiothreitol (DTT) is made using a synthetic process where all the raw materials and reagents used in synthesis are not of animal origin or derived from genetically modified organisms (GMOs).

**Quality Assurance (Signature)** 

Date Mar 16, 2016

COO1370-1 August 14, 2014