Number: SOP-1000 Version: 1.0 Effective Date: 01 Sep 2020

SOP-1000: % Encapsulation Efficiency



1.0 PURPOSE

This procedure describes the method for determining free mRNA and the % Encapsulation Efficiency (% EE) in mRNA Lipid Nanoparticles (LNP) and Drug Product (7-2) the 05 OT Val the



2.0 SCOPE

SCOPE

This method applies to testing of formulated mRNA LNP and DP in the Quality Control (QC) laboratory.

REFERENCED DOCUMENTS

Document #	PTINE		
FRM-0120	General Quality Control Sample Submission Form		
FRM-0180	Quality Control Solution Preparation Form		
FRM-0735	Assay Performance Worksheet SOP-1000:		
FRM-0745	Working Solution Preparation SOP-1000:		
SOP-0017	Maintaining a RNase Free Work Environment		
SOP-0033	Out of Specification (OOS)		
SOP-0081	Preparation of Solutions and Samples in the GMP-Quality Control Laboratory		
SOP-0082	Data Review and Reporting in the GMP Quality Control Laboratory		
SOP-0144	Operation of the Analytical Balance		
SOP-0227	Operation and Maintenance		

Number: SOP-1000 Version: 1.0 <u>Effective Date: 01 Sep 2020</u>

SOP-1000: % Encapsulation Efficiency

Document #	Title		
SOP-0254	Operation and Maintenance of Reader		
SOP-0403	QC Procedure		
SOP-0409	Quality Control Invalid Assay Procedure		
SOP-0820	Reconstitution of Lyophilized Drug Product		

4.0 RESPONSIBILITIES

Department/ Functional Area	Responsibility		
Department manager or designee	 Ensuring that laboratory personnel are properly trained in this procedure. Ensuring that all procedures outlined in this document are followed when applicable. Ensuring that this procedure is revised as necessary. 		
Laboratory personnel	 Following all procedures as outlined in this document. Maintaining an RNase free work environment following SOP-0017. Following proper safety standards in the laboratory. 		

5.0 **DEFINITIONS**

Term	Definition			
%EE	% Encapsulation Efficiency			
Abs	Absorbance			
AU	Absorbance Units			
СоА	Certificate of Analysis			
DP 000	Drug Product			
GMP 5	Good Manufacturing Practices			
LNP	Lipid nanoparticle			
mRNA	Messenger ribonucleic acid			
RF	Response Factor			
RNase	Ribonuclease			

Number: SOP-1000 Version: 1.0 Effective Date: 01 Sep 2020

SOP-1000 Version: 1.0 SOP-1000: % Encapsulation Efficiency

6.0 EQUIPMENT AND MATERIALS

Equivalent equipment, materials, reagents and consumables may be used unless otherwise indicated.

Equipment and Materials

Equipment/ Materials	Manufacturer	Part Number/ Model
-		_

Reagents

Reagents	Manufacturer	Part Number	Storage
	39	N/A	N/A

Materials/ Consumables

Materials/ Consumables	Manufacturer	Part Number
(

Number: SOP-1000 Version: 1.0 Effective Date: 01 Sep 2020

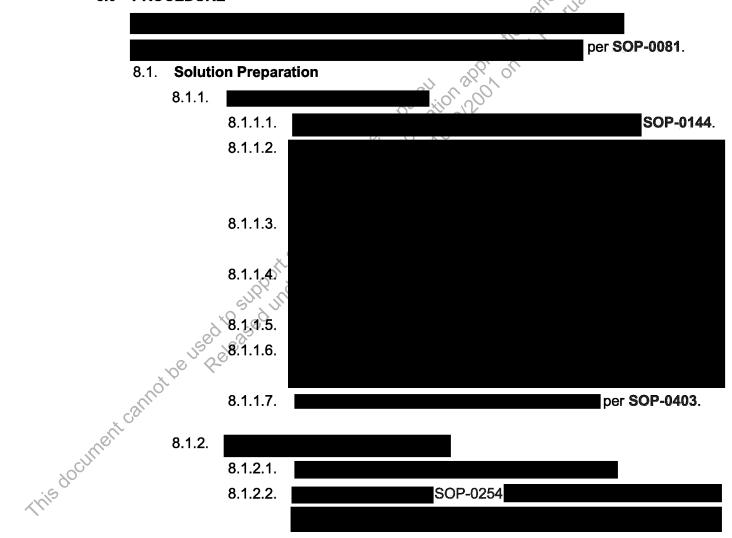
SOP-1000: % Encapsulation Efficiency

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7.1.	. Wear the appropriate personal protective	equipment when	working in the QC	
	laboratory.		Sol	
7.2.	. Adhere to EPA, OSHA, and any other ap	plicable health an	d safety procedures	
	including Safety Data Sheets (SDS) whe	n working with ha	zardous materials.	
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7.0 SAFETY

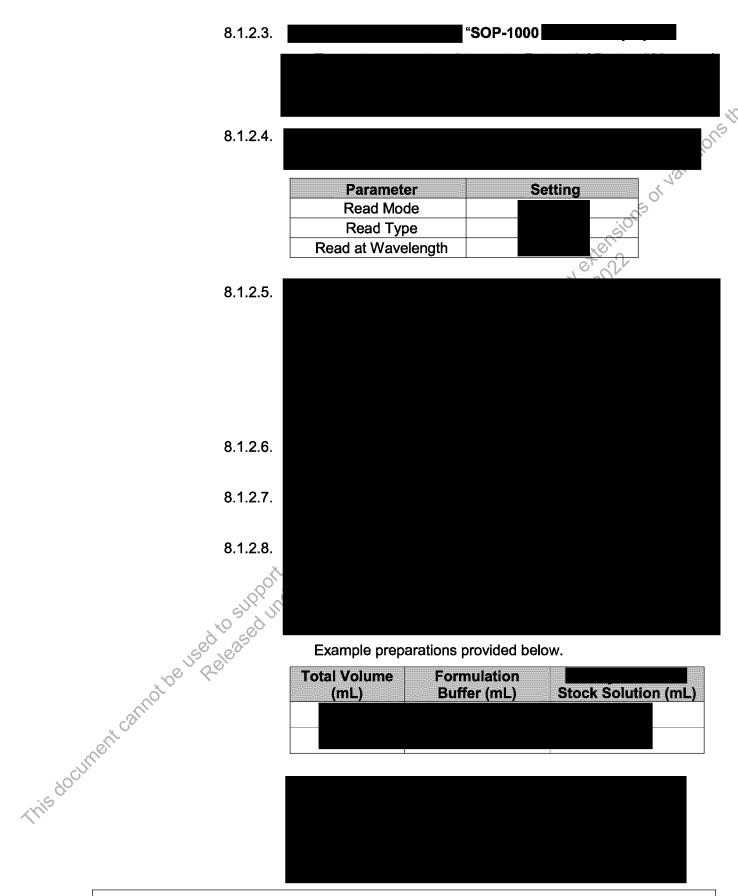
- 7.1.
- 7.2. Adhere to EPA, OSHA, and any other applicable health and safety procedures

8.0 PROCEDURE

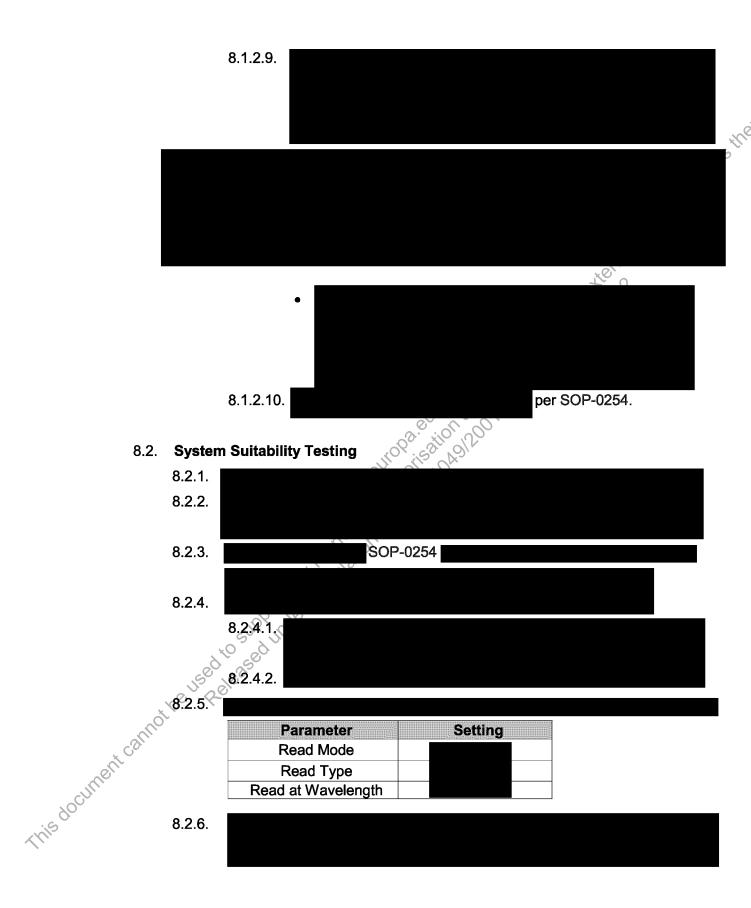


Number: SOP-1000 Version: 1.0 Effective Date: 01 Sep 2020

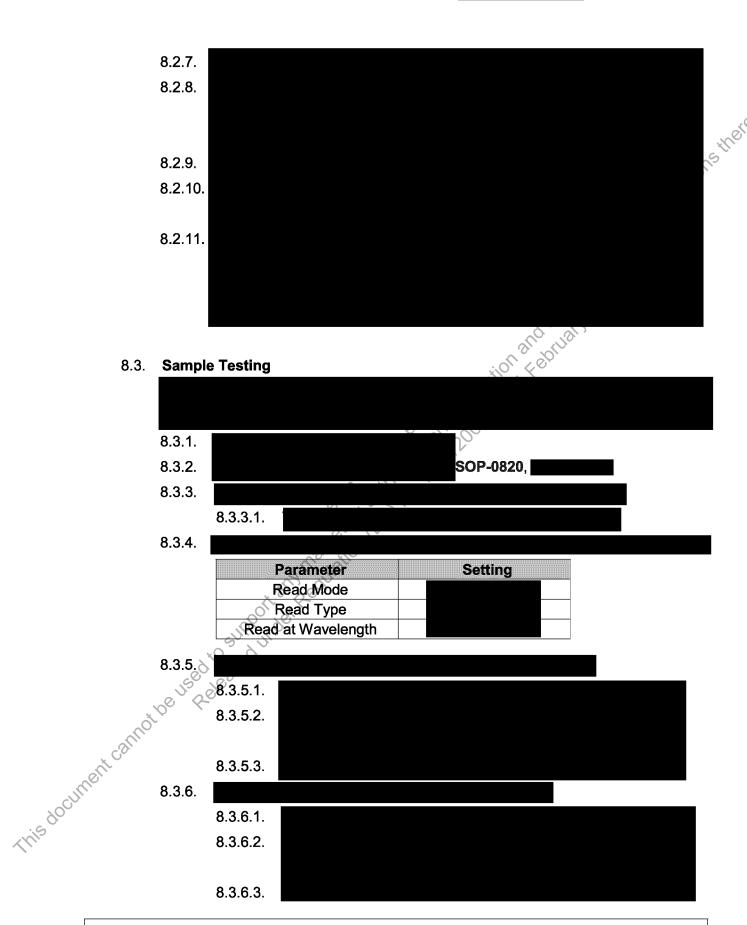
SOP-1000: % Encapsulation Efficiency



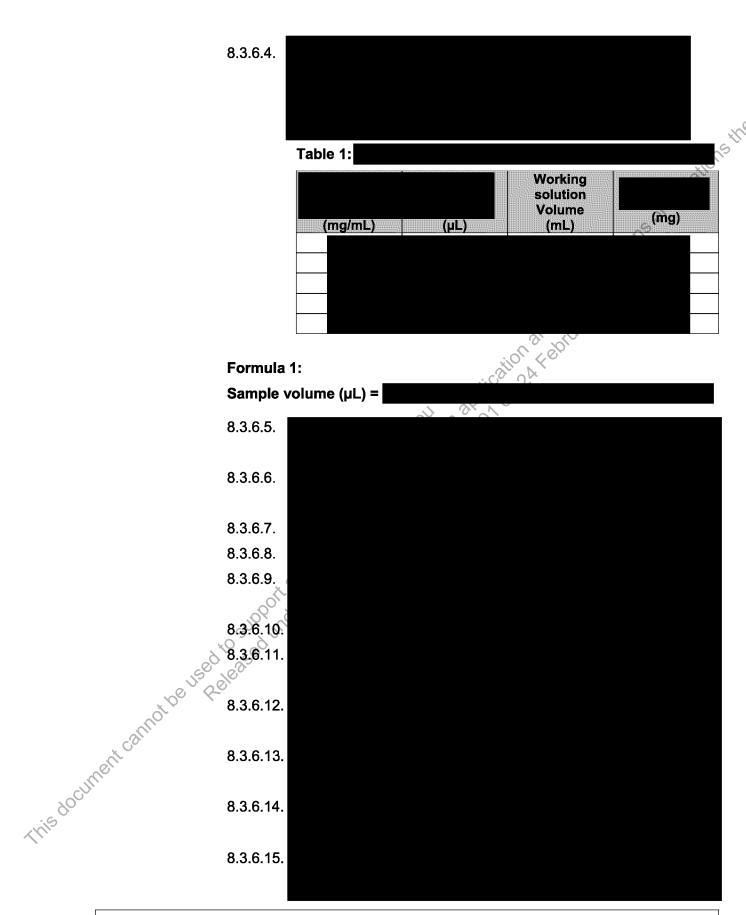
Number: SOP-1000 Version: 1.0 Effective Date: 01 Sep 2020 SOP-1000: % Encapsulation Efficiency



Number: SOP-1000 Version: 1.0 Effective Date: 01 Sep 2020 SOP-1000: % Encapsulation Efficiency

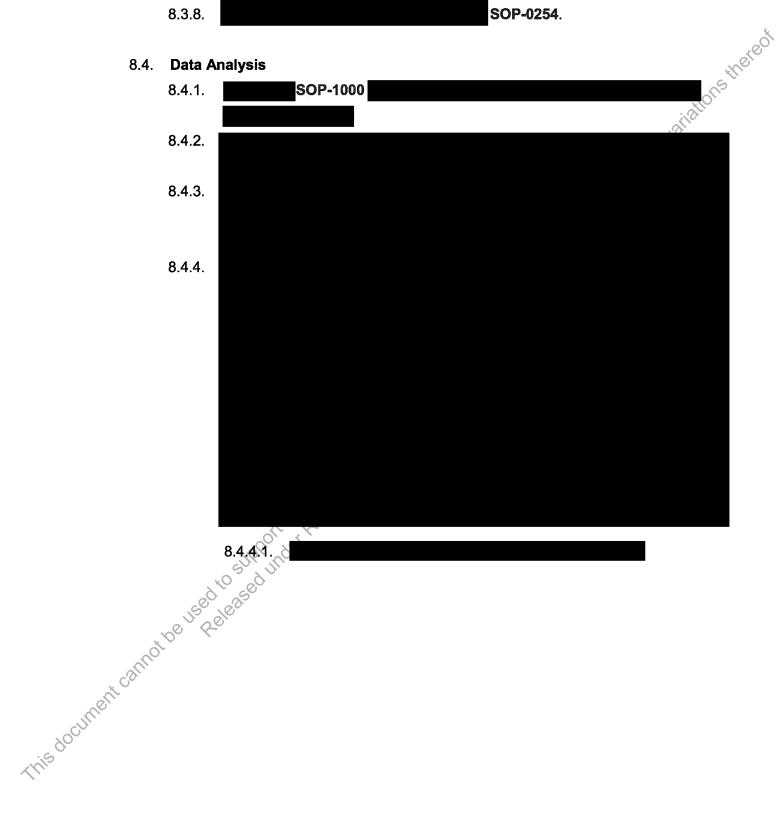


Number: SOP-1000 Version: 1.0 Effective Date: 01 Sep 2020 SOP-1000: % Encapsulation Efficiency



8.3.7. 8.3.8. SOP-0254.

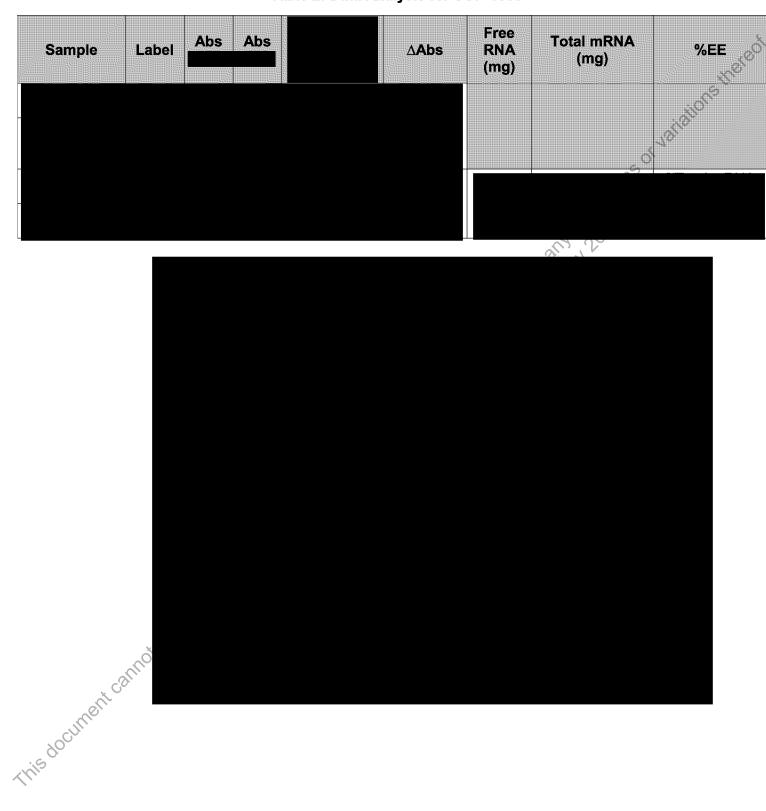
Data Analysis 8.4.



Number: SOP-1000 Version: 1.0 <u>Effective Date: 01</u> Sep 2020

SOP-1000: % Encapsulation Efficiency

Table 2: Data Analysis for SOP-1000



Number: SOP-1000 Effective Date: 01 Sep 2020

Version: 1.0 SOP-1000: % Encapsulation Efficiency

Acceptance Criteria 8.5. 8.5.1. a diations thereof 8.5.1.1. Table 3: **Parameter** 8.5.2. 8.5.2.1. Table 4: Parameter >> 8.6. Reporting 8.6.1. SOP-0082 8.6.2. 8.6.3. This document cannot be used as 8.6.4. 8.6,3.1. 8.6.3.2. 8.6.3.3. SOP-0227. 8.6.4.1.

Version: 1.0 Number: SOP-1000 Effective Date: 01 Sep 2020 SOP-1000: % Encapsulation Efficiency

8.6.4.2. 8.6.5. SOP-0033 8.6.6. SOP-0409 8.6.7.

9.0 ATTACHMENTS

ATTACHMENTS

Attachment I – SOP-1000 Data Analysis spreadsheet (Veeva)

10.0 REVISION HISTORY

	Revision #	Effective Date	Change Details	Author
	1.0	Refer to Veeva Header for Effective Date	New Document	
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Effective Date: 01 Sep 2020 Number: SOP-1000 Version: 1.0

SOP-1000: % Encapsulation Efficiency

Document Approvals Approved Date: 01 Sep 2020

Approval Verdict: Approved	Quality Control Approval 26-Aug-2020 19:08:19 GMT+0000 Quality Assurance Approval 01-Sep-2020 13:34:30 GMT+0000
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