Number: SOP-0937 Version: 2.0 Effective Date: 01 May 2020 mRNA-1273: Determination of Protein Expression from mRNA using Cell-Free In-Vitro Translation System



1.0 PURPOSE

The purpose of this procedure is to confirm protein expression from mRNA

2.0 SCOPE

This method will be applied to mRNA-1273.

3.0 REFERENCED DOCUMENTS

Document #	Title
FRM-0679	In-Vitro Translation Assay Worksheet – mRNA-1273, SOP-0937
SOP-0017	Maintaining a RNase Free Work Environment
SOP-0254	Operation and Maintenance of
SOP-0295	Operation and Maintenance of the
SOP-0403	Lab Operations Procedure
SOP-0820	Reconstitution of Lyophilized Drug Product

4.0 RESPONSIBILITIES

Department/ Functional Area	Responsibility	
Quality Control Laboratory Personnel	 Following all procedures outlined in this document, as applicable. Maintaining a RNase free work environment per SOP-0017. Following proper safety measures in the cGMP laboratory. Documenting all materials, reagents, equipment, sample information, preparation and results in per SOP-0403, the appropriate laboratory notebook or QC controlled document. 	
Quality Control Manager	 Ensuring that laboratory personnel are trained in this procedure. Ensuring that all procedures in this document are followed when applicable. Ensure that this procedure is revised as necessary. Data Review 	

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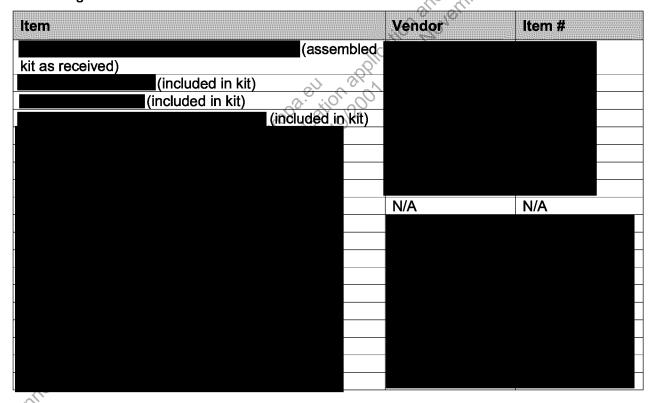
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5.0 DEFINITIONS

Term	Definition
DB	Drug Product
DP	Drug Product
GMP	Good Manufacturing Practices
MPI	mRNA Product Intermediate
PPE	Personal Protective Equipment
QC	Quality Control
UV	Ultraviolet
Vis	Visible

6.0 EQUIPMENT AND MATERIALS

6.1. Reagents



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6.2. Consumables

NOTE: Equivalent consumables may be used.

Item	Vendor	Item #
pipette tips		
Tips, standard, round		
Microcentrifuge tubes		
Microcentrifuge tubes		
	Various	Various

6.3. Equipment

NOTE: Equivalent equipment may be used unless otherwise indicated.

Item	Vendor	Model #
pipette	11/04	
pipette	2: "	
pipette	Sills SILE	
pipette	000	
Calibrated Timer		
_		
	Do Not	
Substitute)		
	Various	Various

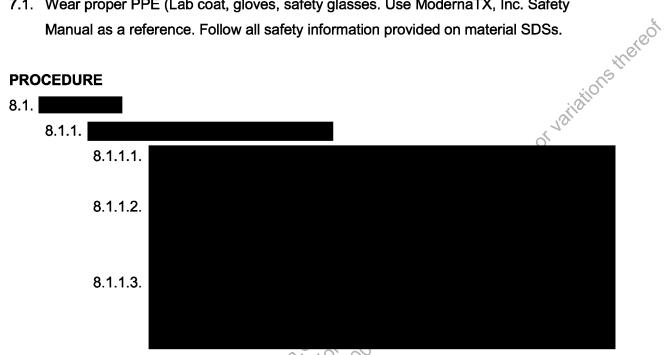
, c	6.4. Controls	
CIII	Control Type	Material
90	Negative Control	
Klis	Positive Controls	

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7.0 SAFETY

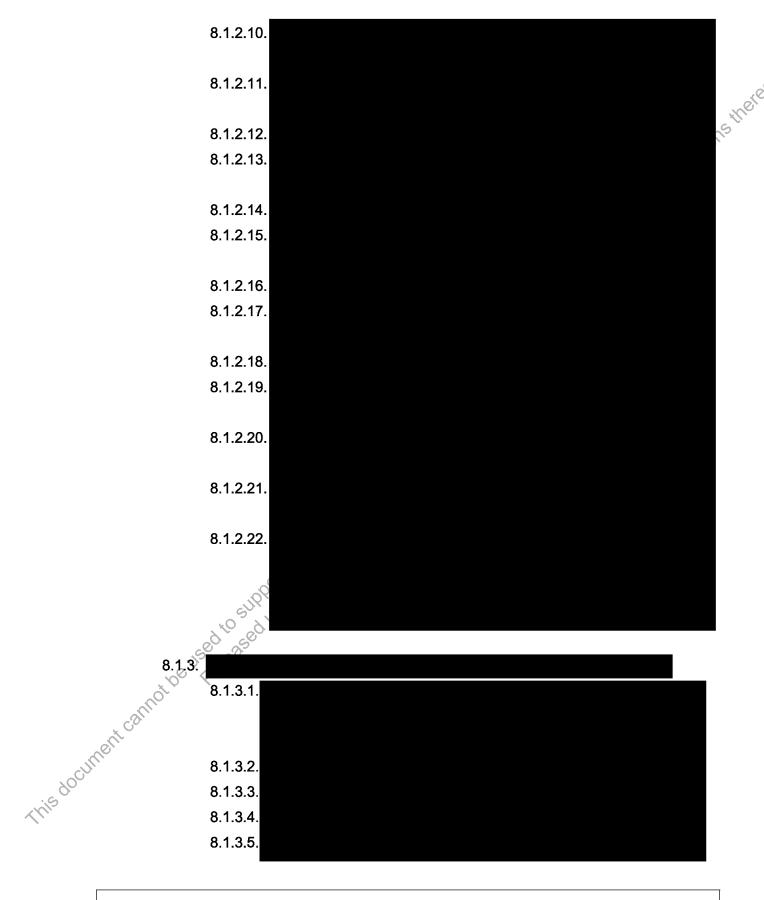
7.1. Wear proper PPE (Lab coat, gloves, safety glasses. Use ModernaTX, Inc. Safety Manual as a reference. Follow all safety information provided on material SDSs.

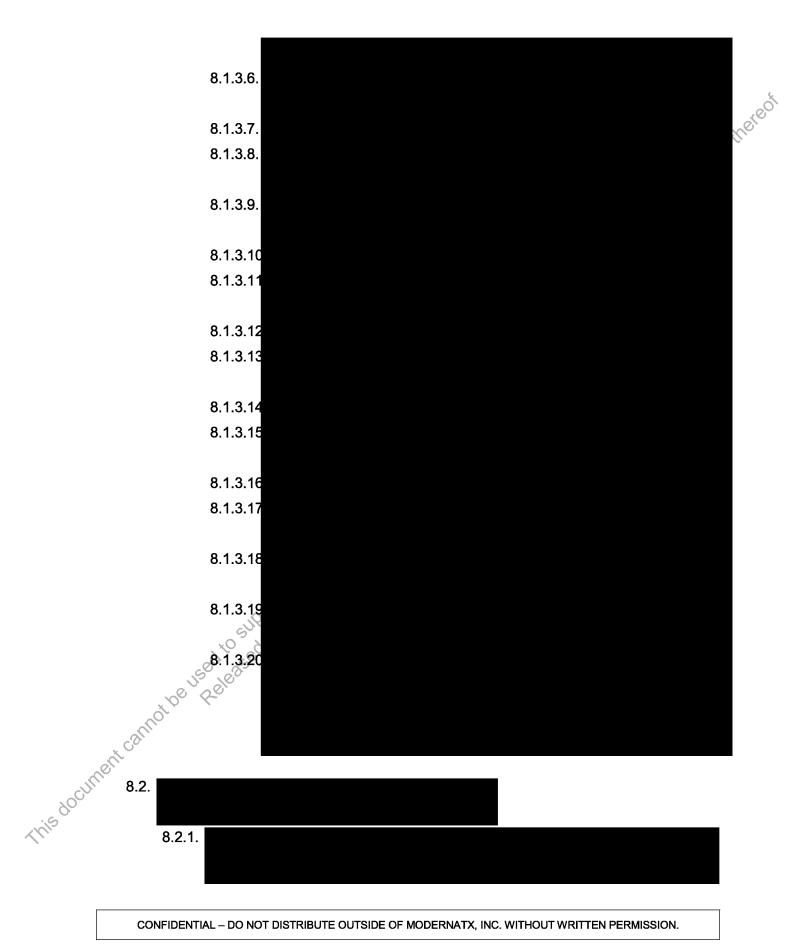
8.0 PROCEDURE

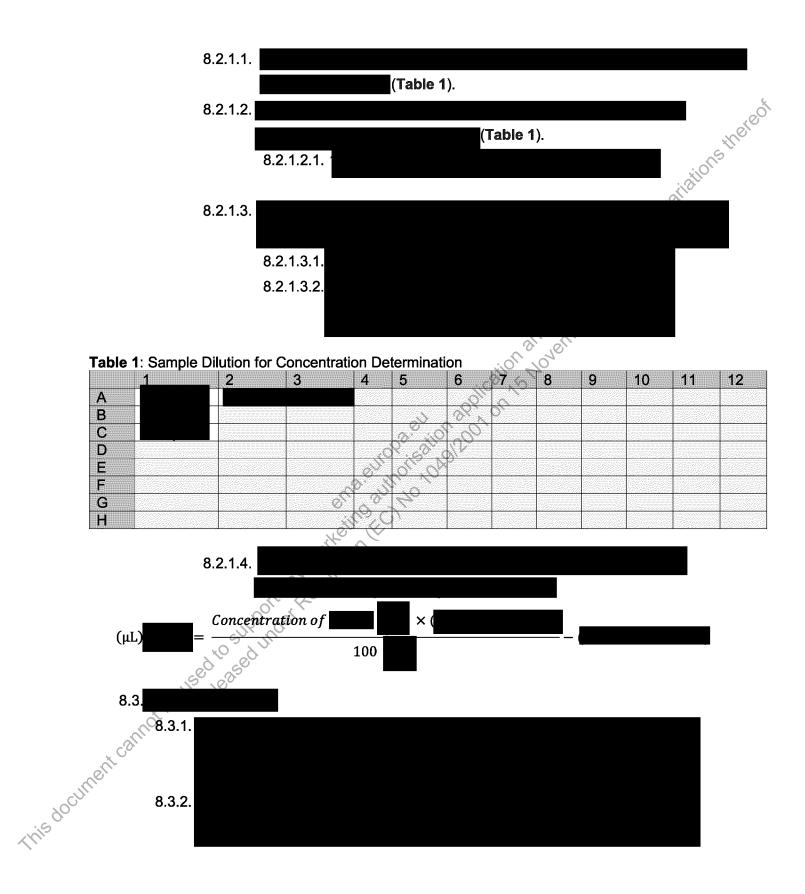


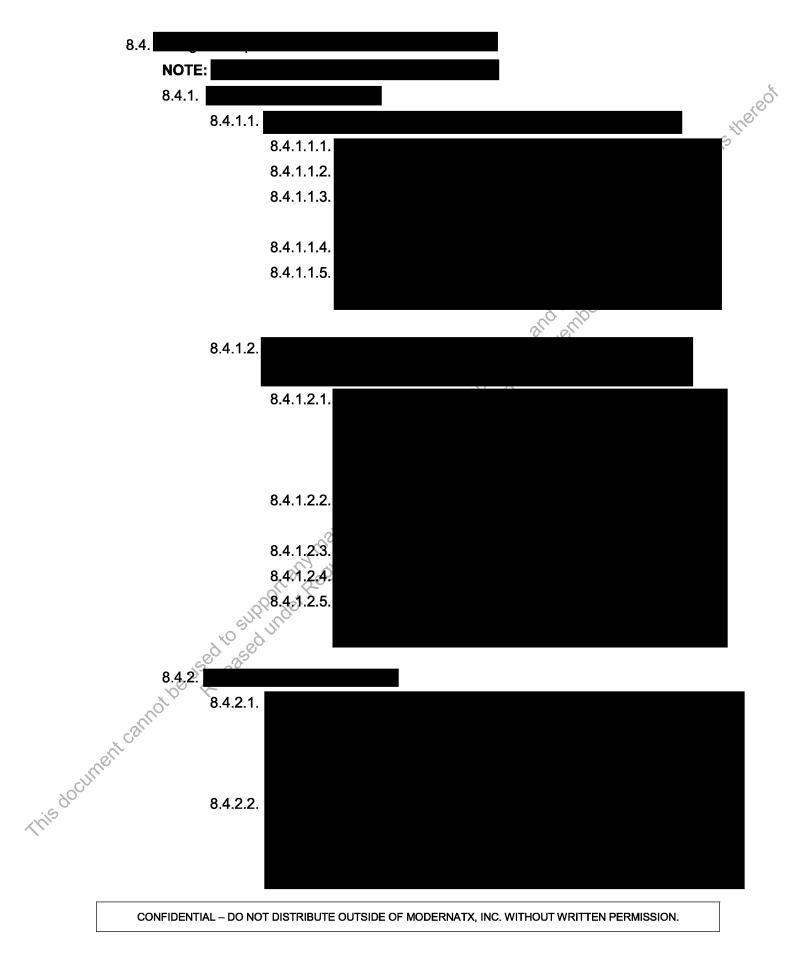


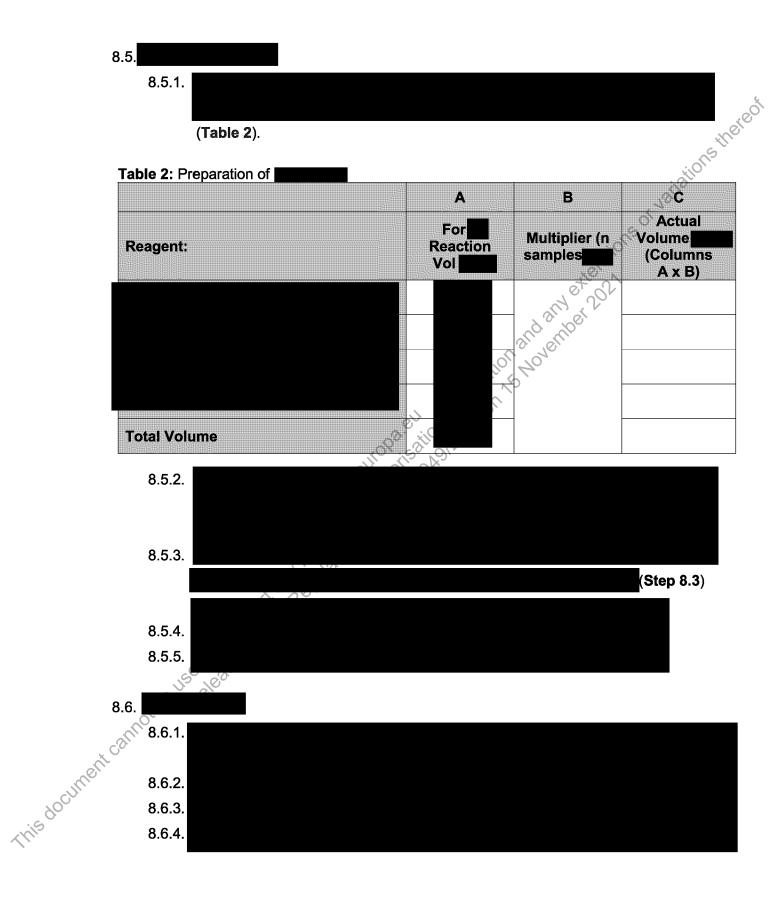
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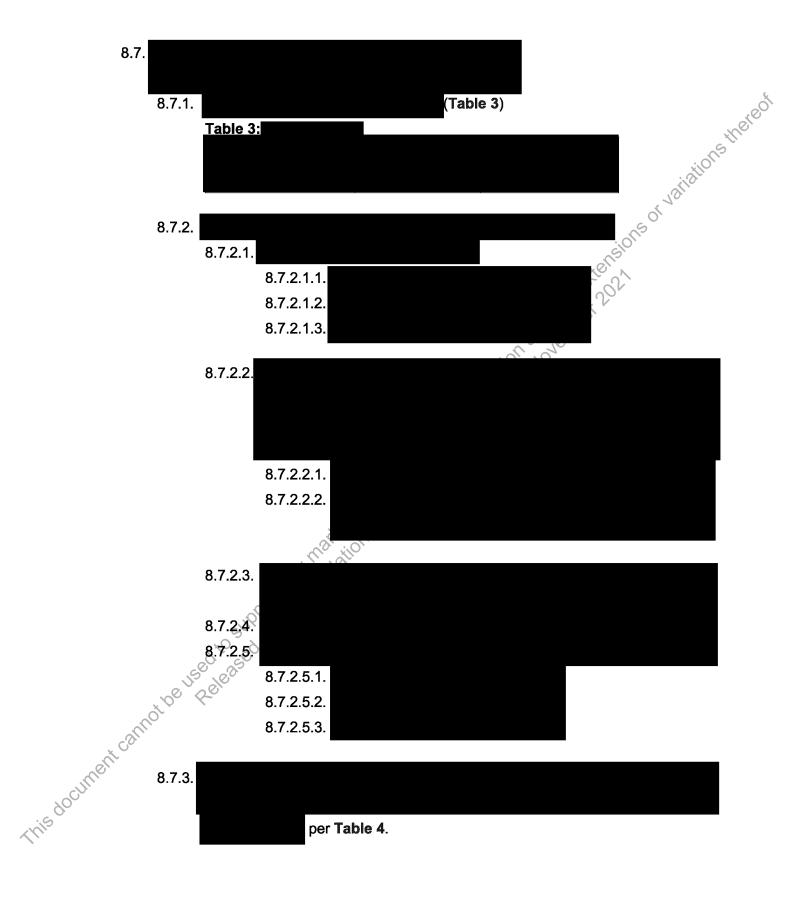


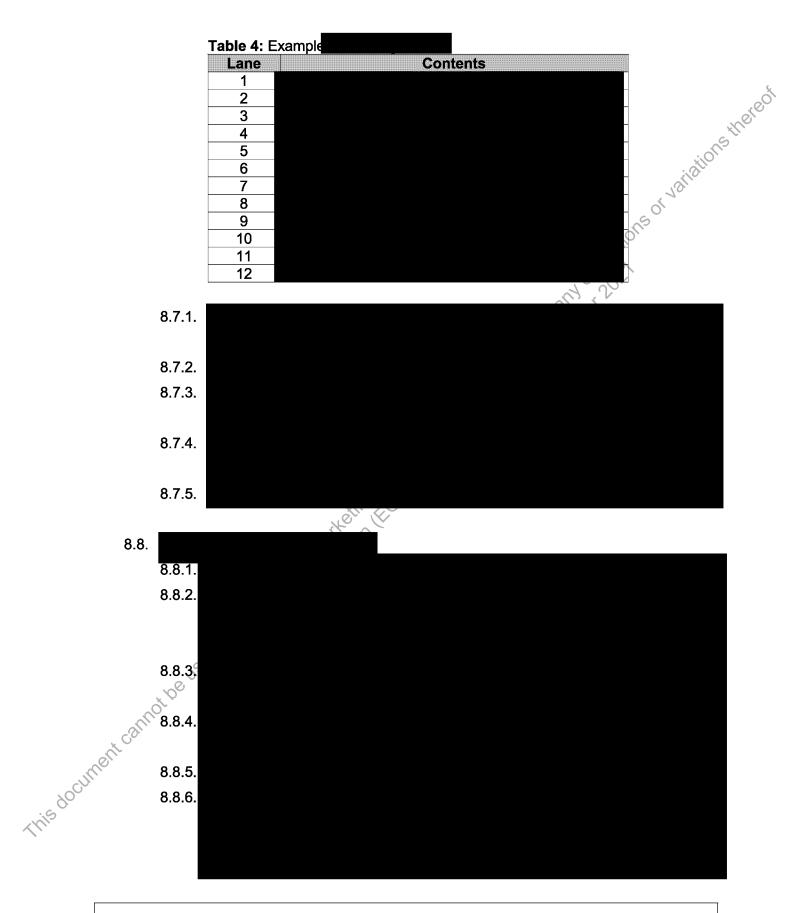


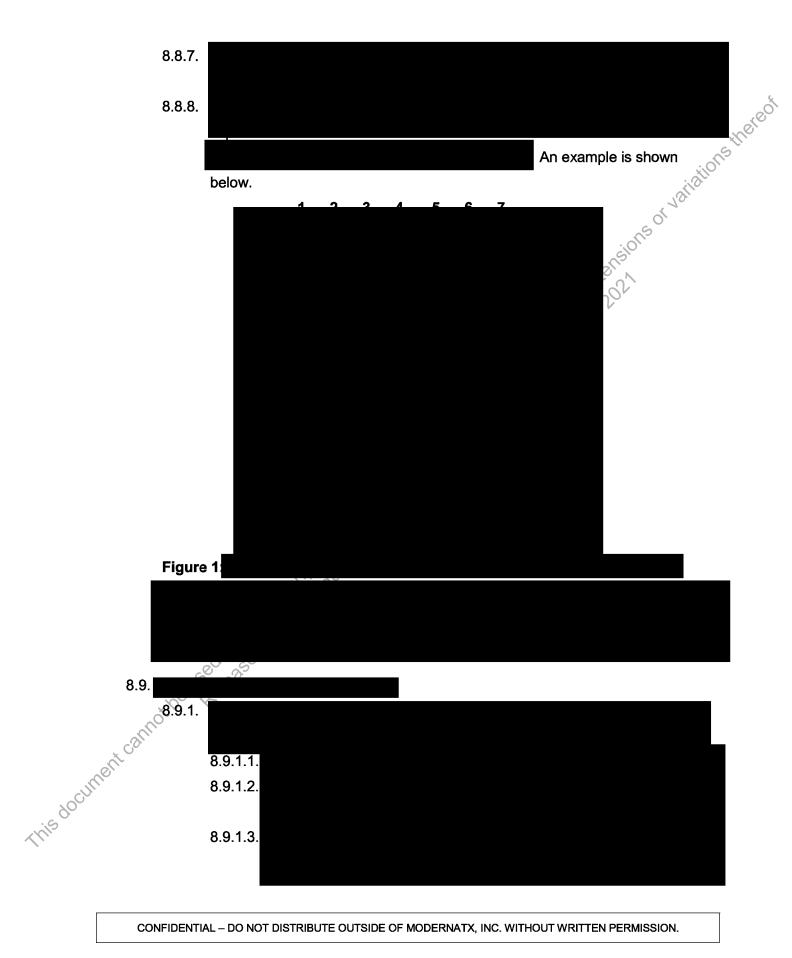


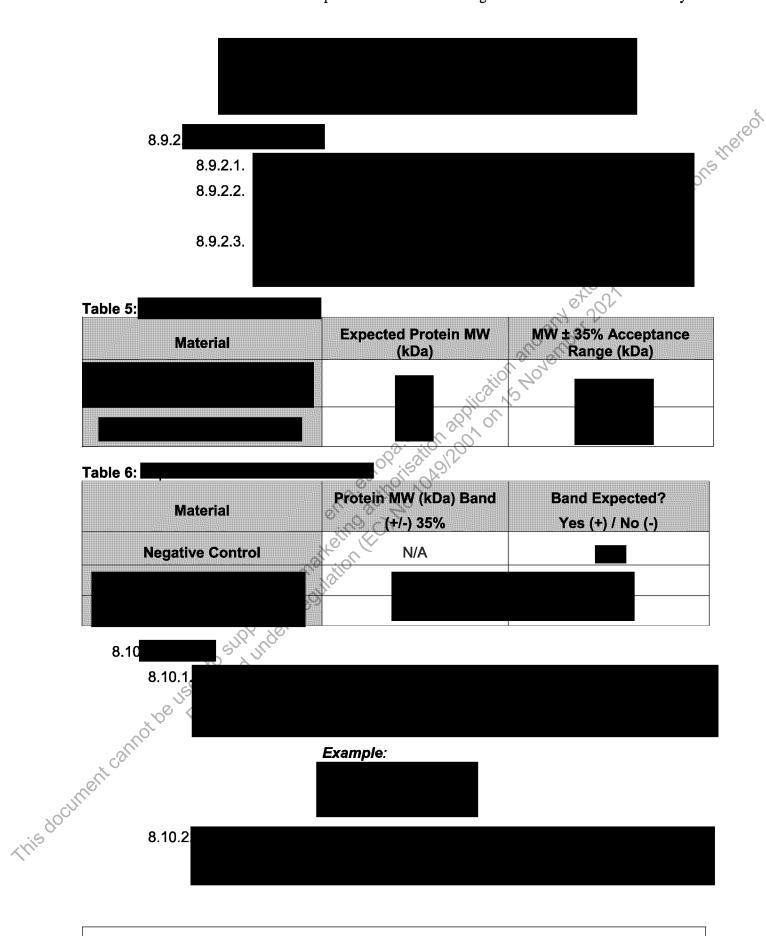












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9.0 ATTACHMENTS

9.1. N/A

10.0 REVISION HISTORY

2.0
1.0
1.0

