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3.2.P.3.3. LIPID NANOPARTICLE (LNP) PRODUCTION AND BULK DRUG PRODUCT FORMULATION – TRIS/SUCROSE DRUG PRODUCT [PUURS]

3.2.P.3.3.1. Flow Diagram

The process flow diagram for the BNT162b2 LNP production and Tris/Sucrose bulk drug product formulation manufacturing process is presented in [Figure 3.2.P.3.3-1](#).

Figure 3.2.P.3.3-1. Flow Diagram of the BNT162b2 Tris/Sucrose Drug Product Manufacturing Process and Process Controls

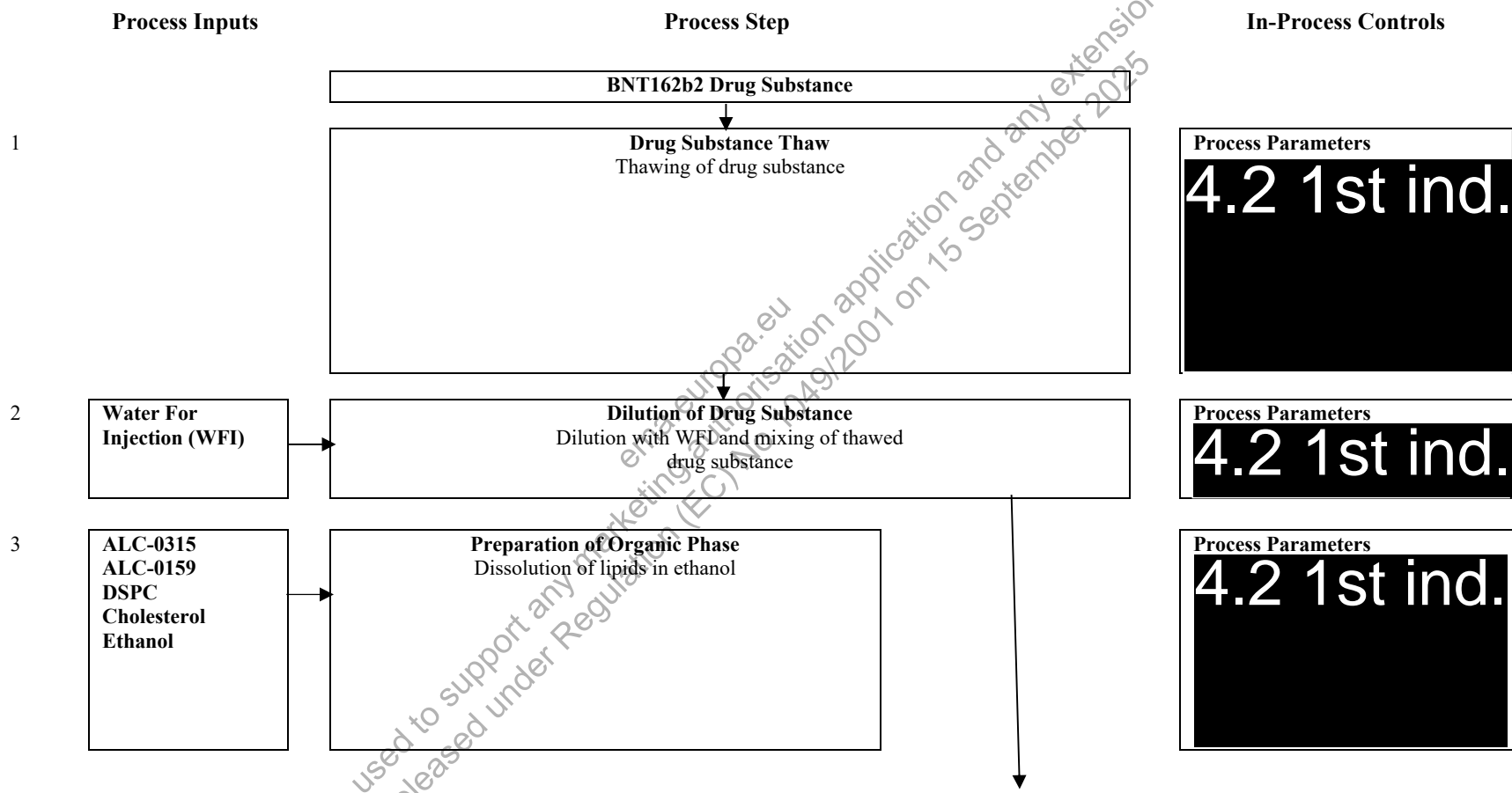
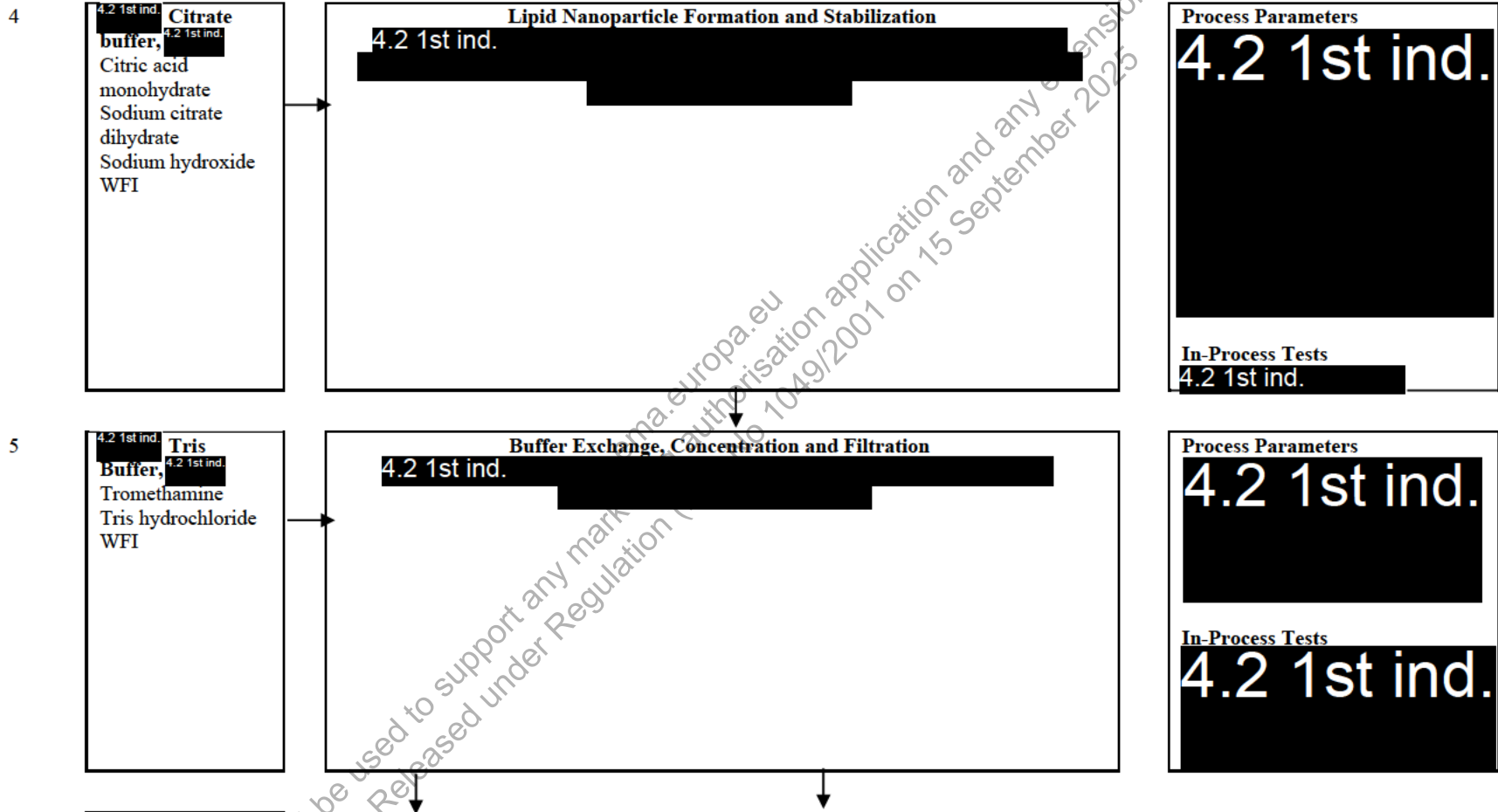


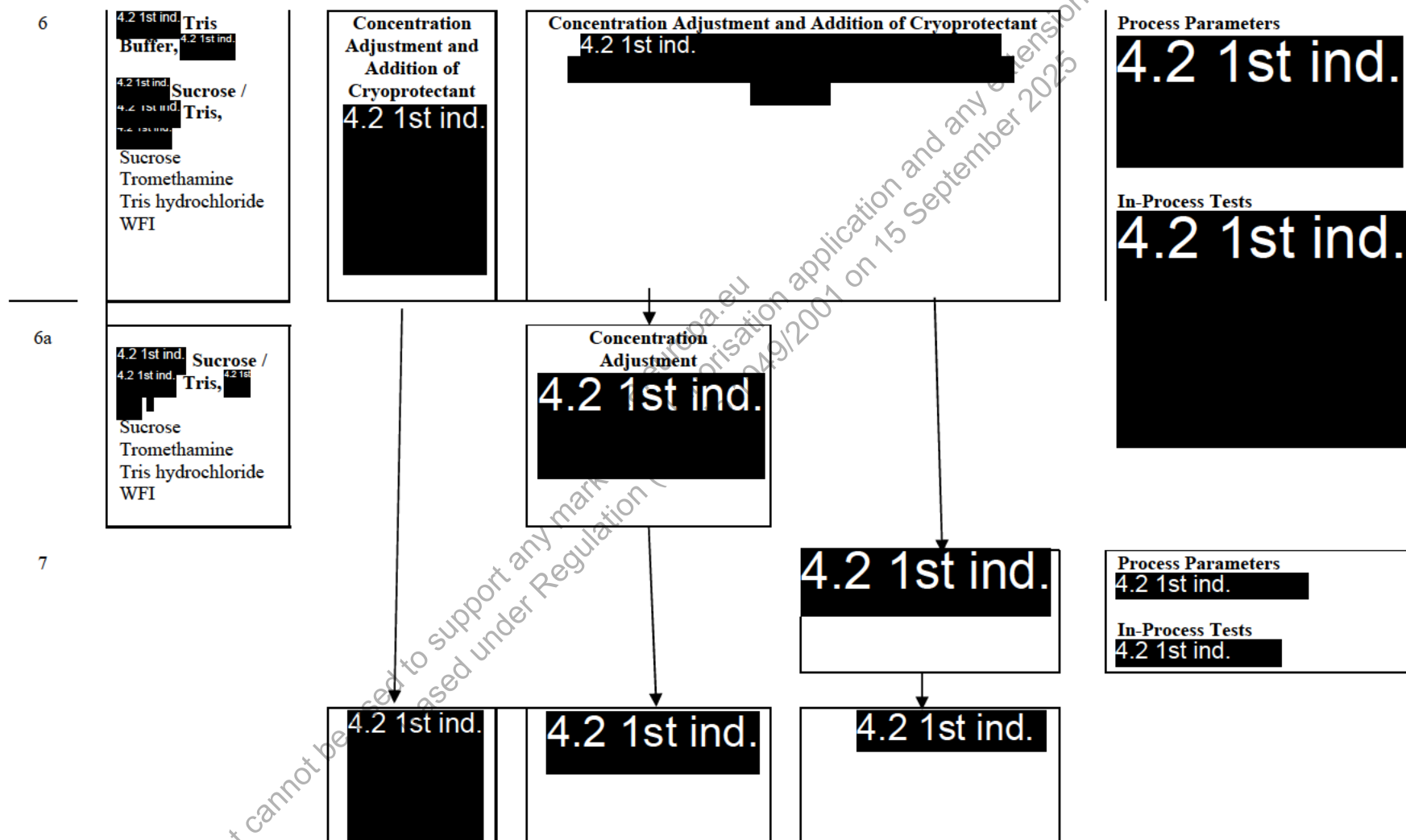
Figure 3.2.P.3.3-1. Flow Diagram of the BNT162b2 Tris/Sucrose Drug Product Manufacturing Process and Process Controls



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3.2.P.3.3. Description of Manufacturing Process and Process Controls

LNP Production and Bulk Drug Product Formulation – Tris-Sucrose [Puurs]

Figure 3.2.P.3.3-1. Flow Diagram of the BNT162b2 Tris/Sucrose Drug Product Manufacturing Process and Process Controls

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3.2.P.3.3. Description of Manufacturing Process and Process Controls

LNP Production and Bulk Drug Product Formulation – Tris-Sucrose [Puurs]

Figure 3.2.P.3.3-1. Flow Diagram of the BNT162b2 Tris/Sucrose Drug Product Manufacturing Process and Process Controls

4.2 1st ind.

Abbreviations: IPT-C = In-process test for control; IPT-M = In-process test for monitoring; ALC-0315 = ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate); ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide; DSPC = 1,2-distearoyl-sn-glycero-3-phosphocholine, [REDACTED]

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3.2.P.3.3.2. LNP Production and Bulk Drug Product Formulation Process Descriptions

Drug substance is stored according to the conditions supported in Section 3.2.S.7.1 Stability Summary and Conclusions.

3.2.P.3.3.2.1. Drug Substance Thaw

Frozen drug substance in ethylene vinyl acetate (EVA) bags may be thawed using controlled thaw equipment which consists of an automated freeze/thaw unit, agitation platform, and a validated thaw recipe. The EVA bags are placed between heat-transfer plates of the freeze/thaw unit. Once thawing is complete, the program ramps the heat transfer fluid (HTF) supply temperature down to a setpoint of 5 °C, at which time the thawed drug substance hold time begins. The controlled thaw equipment remains at a 5 °C setpoint until the EVA bags are removed. The process parameters for controlled thaw of drug substance are summarized in Table 3.2.P.3.3-1.

Table 3.2.P.3.3-1. Process Parameters for Controlled Drug Substance Thaw

Process Parameter	Acceptable Range
4.2 1st ind.	4.2 1st ind.
4.2 1st ind.	4.2 1st ind.

a. Target set-point

Abbreviations: 4.2 1st ind.

Frozen drug substance EVA bags may also be thawed at controlled room temperature between 15-25 °C. The bags are placed in a controlled temperature room and allowed to thaw. The process parameters for controlled room temperature thaw of drug substance are summarized in Table 3.2.P.3.3-2.

Table 3.2.P.3.3-2. Process Parameters for Controlled Room Temperature Drug Substance Thaw

Process Parameter	Acceptable Range
4.2 1st ind.	4.2 1st ind.
4.2 1st ind.	4.2 1st ind.

3.2.P.3.3.2.2. Dilution of Drug Substance

Thawed drug substance is transferred from EVA bags to a manufacturing vessel. 4.2 1st ind. drug substance containers from 4.2 1st ind. drug substance batches from 4.2 1st ind. drug substance supplier may be pooled to achieve the target drug product batch size. 4.2 1st ind.

Based on RNA content and weight of drug substance added to the vessel, the Water for Injection (WFI) amount required for dilution to a target concentration **4.2 1st ind.** is calculated. The drug substance is diluted with WFI, then mixed until homogenous. The process parameters for dilution of drug substance are summarized in Table 3.2.P.3.3-3.

Table 3.2.P.3.3-3. Process Parameters for Dilution of Drug Substance

Process Parameter	Controlled Setpoint
4.2 1st ind.	

Abbreviation: **4.2 1st ind.**

3.2.P.3.3.2.3. Preparation of Buffers, Organic Phase and Sucrose Solution

3.2.P.3.3.2.3.1. Preparation of **4.2 1st ind.** Citrate Buffer, **4.2 1st ind.**

The **4.2 1st ind.** citrate buffer, **4.2 1st ind.** compounded according to the batch formula shown in Table 3.2.P.3.3-4.

Table 3.2.P.3.3-4. Batch Formula for **4.2 1st ind. Citrate Buffer, **4.2 1st ind.****

Component	Grade	Unit Formula per 1 kg (g)
Citric acid monohydrate	USP-NF, Ph. Eur.	4.2 1st ind.
Sodium citrate dihydrate	USP-NF, Ph. Eur.	
Water for Injection	USP, Ph. Eur.	
Sodium hydroxide	USP-NF, Ph. Eur.	
4.2 1st ind.		

The citrate buffer is mixed until homogeneous. The pH of the buffer is measured and adjusted to **4.2 1st ind.** with sodium hydroxide, as necessary. The in-process test for control (IPT-C) for preparation of citrate buffer is summarized in Table 3.2.P.3.3-5. The citrate buffer is filtered **4.2 1st ind.** prior to use.

Table 3.2.P.3.3-5. IPT-C Test for **4.2 1st ind. Citrate Buffer, **4.2 1st ind.****

In-process Test	Acceptance Criteria
4.2 1st ind.	

3.2.P.3.3.2.3.2. Preparation of **4.2 1st ind.** Tris Buffer, **4.2 1st ind.**

4.2 1st ind. Tris buffer, **4.2 1st ind.** are compounded according to the batch formulas shown in Table 3.2.P.3.3-6.

Table 3.2.P.3.3-6. Batch Formulas for 4.2 1st ind. Tris Buffer, 4.2 1st ind.

Component	Grade	Unit Formula (g/kg) for 4.2 1st ind. Tris Buffer	Unit Formula (g/kg) for 4.2 1st ind. Tris Buffer
Tromethamine	USP, Ph. Eur.	4.2 1st ind.	
Tris Hydrochloride	In-house specification		
Water for Injection	USP, Ph. Eur.		

The 4.2 1st ind. Tris buffer, 4.2 1st ind. are mixed until homogeneous and measured for pH. The IPT-C test for preparation of the Tris buffer is summarized in Table 3.2.P.3.3-7.

Table 3.2.P.3.3-7. IPT-C Test for 4.2 1st ind. and 4.2 1st ind. Tris Buffer, 4.2 1st ind.

In-process Test	Acceptance Criteria
4.2 1st ind.	4.2 1st ind.

The 4.2 1st ind. Tris buffer may also be received from external suppliers, as detailed in [Section 3.2.P.3.4 In-Process Monitoring and Control - LNP Production and Drug Product Formulation - Tris-Sucrose \[Puurs\]](#).

3.2.P.3.3.2.3.2.1. Preparation of 4.2 1st ind. Tris Buffer, 4.2 1st ind. by Dilution of 4.2 1st ind. Tris Buffer, 4.2 1st ind.

The 4.2 1st ind. Tris buffer, 4.2 1st ind. may be compounded internally as detailed above in [Section 3.2.P.3.3.2.3.2](#) or prepared by in-line dilution of 4.2 1st ind. Tris buffer, 4.2 1st ind.

For in-line dilution, the 4.2 1st ind. Tris buffer, 4.2 1st ind. is diluted with Water for Injection (WFI) using an In-Line Dilution (ILD) skid. The 4.2 1st ind. Tris buffer and WFI are connected to the ILD skid and dilution proceeds with the ratio of WFI to 4.2 1st ind. Tris buffer controlled by the pumps on the ILD skid to result in a 4.2 1st ind. dilution. The WFI and 4.2 1st ind. Tris buffer paths converge and form one continuous flow followed by static mixing. The diluted 4.2 1st ind. Tris buffer is sampled 4.2 1st ind., as detailed in Table 3.2.P.3.3-7, and is filtered 4.2 1st ind. prior to use.

The 4.2 1st ind. Tris buffer, 4.2 1st ind. is used to flush filters during Buffer Exchange and Concentration ([Section 3.2.P.3.3.2.5.1](#)), and for Concentration Adjustment and Addition of Cryoprotectant ([Section 3.2.P.3.3.2.6](#)) of the bulk drug product.

3.2.P.3.3.2.3.3. Preparation of the Lipid Organic Phase

The lipid organic phase is compounded according to the batch formula shown in [Table 3.2.P.3.3-8](#).

Table 3.2.P.3.3-8. Batch Formula for Lipid Organic Phase

Component	Grade	Unit Formula per 1 kg (g)
Ethanol	USP-NF, Ph. Eur.	4.2 1st ind.
ALC-0315	In-house specification	
ALC-0159	In-house specification	
DSPC	In-house specification	
Cholesterol	Ph. Eur.	

Abbreviations: ALC-0315 = ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate); ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide; DSPC = 1,2-distearoyl-sn-glycero-3-phosphocholine

The lipids are thawed to 4.2 1st ind., if applicable. Ethanol is added to the organic phase vessel and heated to improve dissolution of the lipids. The lipids are added to the organic phase vessel 4.2 1st ind.

The process parameters for preparation of the organic phase are summarized in Table 3.2.P.3.3-9.

Table 3.2.P.3.3-9. Process Parameters for Preparation of Lipid Organic Phase

Process Parameter	Acceptable Range
4.2 1st ind.	4.2 1st ind.

a. Target set-point.

b. Target range.

Abbreviations: ALC-0315 = ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate); ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide; DSPC = 1,2-distearoyl-sn-glycero-3-phosphocholine

3.2.P.3.3.2.3.4. Preparation of Sucrose, Tris Solution

Concentration adjustment of the filtered bulk can be performed 4.2 1st ind.

3.2.P.3.3.2.3.4.1. Preparation of 4.2 1st ind. Sucrose, 4.2 1st ind. Tris Solution

The 4.2 1st ind. sucrose, 4.2 1st ind. Tris (Sucrose/Tris) solution is compounded according to the batch formula shown in Table 3.2.P.3.3-10.

Table 3.2.P.3.3-10. Batch Formula for 4.2 1st ind. Sucrose, 4.2 1st ind. Tris Solution

Component	Grade	Unit Formula per 1 kg (g)
Sucrose	USP-NF, Ph. Eur.	4.2 1st ind.
Tromethamine	USP, Ph. Eur.	
Tris Hydrochloride	In-house specification	
Water for Injection	USP, Ph. Eur.	

The Sucrose/Tris solution is mixed until homogeneous and measured for pH. The Sucrose/Tris solution is filtered 4.2 1st ind. prior to use. The IPT-C test for preparation of the Sucrose/Tris solution is summarized in Table 3.2.P.3.3-11.

Table 3.2.P.3.3-11. IPT-C Tests for 4.2 1st ind. Sucrose, 4.2 1st ind. Tris Solution

In-process Test	Acceptance Criteria
4.2 1st ind.	

3.2.P.3.3.2.3.4.2. Preparation of 4.2 1st ind. Sucrose, 4.2 1st ind. Tris Solution

The 4.2 1st ind. sucrose, 4.2 1st ind. Tris (Sucrose/Tris) solution is compounded according to the batch formula shown in Table 3.2.P.3.3-12.

Table 3.2.P.3.3-12. Batch Formula for 4.2 1st ind. Sucrose, 4.2 1st ind. Tris Solution

Component	Grade	Unit Formula per 1 kg (g)
Sucrose	USP-NF, Ph. Eur.	4.2 1st ind.
Tromethamine	USP, Ph. Eur.	
Tris Hydrochloride	In-house specification	
Water for Injection	USP, Ph. Eur.	

The Sucrose/Tris solution is mixed until homogeneous and measured for pH. The Sucrose/Tris solution is filtered 4.2 1st ind. prior to use. The IPT-C test for preparation of the Sucrose/Tris solution is summarized in Table 3.2.P.3.3-13.

Table 3.2.P.3.3-13. IPT-C Tests for 4.2 1st ind. Sucrose, 4.2 1st ind. Tris Solution

In-process Test	Acceptance Criteria
4.2 1st ind.	

3.2.P.3.3.2.4. Lipid Nanoparticle (LNP) Formation and Stabilization

4.2 1st ind.

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4.2 1st ind.

The process parameters for formation and stabilization of lipid nanoparticles is summarized in Table 3.2.P.3.3-14.

Table 3.2.P.3.3-14. Process Parameters for Formation and Stabilization of LNPs

Process Parameter	Acceptable Range
4.2 1st ind.	

a. Target set-point during LNP formation. Ratios may be calculated from input flow rates.
Abbreviation: LNP = lipid nanoparticle

3.2.P.3.3.2.5. Buffer Exchange, Concentration and Filtration

3.2.P.3.3.2.5.1. Buffer Exchange and Concentration

For batches containing 4.2 1st ind. RNA and 4.2 1st ind. RNA, 4.2 1st ind. tangential flow filtration (TFF) filters 4.2 1st ind. are used in a parallel product flow path. For batches containing 4.2 1st ind. RNA, 4.2 1st ind. TFF filters are used, 4.2 1st ind. in series for 4.2 1st ind. product flow paths 4.2 1st ind.

To prepare for the Buffer Exchange and Concentration operation, the TFF membranes are flushed with 4.2 1st ind. Tris buffer, 4.2 1st ind. for equilibration. When membranes are re-used between lots, the membrane and fluid path are sanitized 4.2 1st ind. prior to equilibration with 4.2 1st ind. Tris buffer, 4.2 1st ind.

4.2 1st ind.

Membranes that will be reused are cleaned 4.2 1st ind.

The filter information for buffer exchange and concentration is summarized in Table 3.2.P.3.3-15.

Table 3.2.P.3.3-15. Filter Properties for Buffer Exchange and Concentration

4.2 1st ind.			
4.2 1st ind.			

The process parameters for tangential flow filtration are summarized in Table 3.2.P.3.3-16.

Table 3.2.P.3.3-16. Process Parameters for Buffer Exchange and Concentration

Process Parameter	Acceptable Range
4.2 1st ind.	

3.2.P.3.3.2.5.2. Filtration

Samples are taken for 4.2 1st ind. testing prior to 4.2 1st ind. filtration.

The formulated drug product suspension is filtered through a bioburden reduction filter into a holding vessel 4.2 1st ind.

3.2.P.3.3.2.6. Concentration Adjustment and Addition of Cryoprotectant

4.2 1st ind.

4.2 1st ind. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Table 3.2.P.3.3-17. Process Parameters for Concentration Adjustment to 0.1 mg/ml and Addition of Cryoprotectant

Process Parameter	Acceptable Range
4.2 1st ind. [REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

3.2.P.3.3.2.7. Concentration Adjustment and Addition of Cryoprotectant for a target batch size range 4.2 1st ind. [REDACTED]

4.2 1st ind. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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4.2 1st ind.

Table 3.2.P.3.3-18. Process Parameters for Concentration Adjustment and Addition of Cryoprotectant

Process Parameter	Acceptable Range
-------------------	------------------

4.2 1st ind.

4.2 1st ind.

3.2.P.3.3.2.7.2. Second dilution step

4.2 1st ind.

Table 3.2.P.3.3-19. Process Parameters for 4.2 1st ind. Concentration Adjustment Step
4.2 1st ind.

Process Parameter	Acceptable Range
4.2 1st ind.	

3.2.P.3.3.2.7.2.1. Filling into Flexible Freeze Thaw (FFT) Bags

The bulk solution with RNA concentration of 0.5 mg/mL is filtered through a 4.2 1st ind. filter before dispensing into FFT bags with a fill volume 4.2 1st ind. A sample for determination 4.2 1st ind. taken during dispensing.

The bulk solution with RNA concentration of 0.5 mg/mL filled into FFT bags is defined as the Drug Product Intermediate (DPI). The DPI is stored at -90 to -60 °C (Section 3.2.P.3.4 Controls of Critical Steps and Intermediates – Drug Product Intermediate 0.5 mg/mL – Stability Summary and Conclusion – Tris/Sucrose). The process parameters for the DPI are outlined in Table 3.2.P.3.3-20.

Table 3.2.P.3.3-20. Process Parameters For Drug Product Intermediate

Process Parameters	Acceptable Range
Storage temperature	-90 to -60 °C ^a
a. The drug product intermediate shelf life at -90 to -60 °C is described in 3.2.P.3.4 Controls of Critical Steps and Intermediates – Drug Product Intermediate 0.5 mg/mL – Stability Summary and Conclusion – Tris/Sucrose	

Further processing of the DPI is described in 3.2.P.3.3 Description of Manufacturing Process and Process Controls – Fill and Finish – Tris-Sucrose [Puurs].

3.2.P.3.3.2.8. Hold Times

The hold times of the in-process materials during LNP formation and bulk drug product formulation are provided in Table 3.2.P.3.3-21

Table 3.2.P.3.3-21. LNP Production and Bulk Drug Product Formulation Process Hold Times

Material or In-Process Hold Description ^a	Process Steps	Target Hold Time
Drug substance thaw	Controlled thaw equipment: Time drug substance in ethylene vinyl acetate (EVA) containers is thawed [REDACTED]	4.2 1st ind. [REDACTED]
	Controlled room temperature thaw: Time drug substance in EVA containers is thawed at controlled room temperature.	
Drug substance post thaw	Maximum time that thawed BNT162b2 drug substance can be held 4.2 1st ind. [REDACTED] in the ethylene vinyl acetate (EVA) container including addition of DS to the vessel up to the point of dilution.	
Drug substance post dilution 4.2 1st ind. [REDACTED]	Time from addition of WFI to drug substance until end of LNP formation step	
Organic phase post mix [REDACTED]	Time from end of organic phase mixing until end of LNP formation.	
Citrate buffer 4.2 1st ind. [REDACTED]	Total hold time for citrate buffer post addition of Water for Injection to be used for LNP formulation or concentration/buffer exchange step.	
4.2 1st ind. [REDACTED] Tris buffer at 4.2 1st ind. [REDACTED]	Total hold time for Tris buffer post addition of WFI to be used for buffer exchange/concentration, filtration and concentration adjustment steps.	
	Total hold time for Tris buffer from start of in-line dilution to be used for buffer exchange/concentration, filtration and concentration adjustment steps.	
4.2 1st ind. [REDACTED] sucrose, 4.2 1st ind. [REDACTED] Tris solution 4.2 1st ind. [REDACTED]	Total hold time for Sucrose/Tris solution post addition of WFI to be used for concentration adjustment step.	
4.2 1st ind. [REDACTED] sucrose, 4.2 1st ind. [REDACTED] Tris solution 4.2 1st ind. [REDACTED]	Total hold time for Sucrose/Tris solution post addition of WFI to be used for concentration adjustment step.	
LNP formation	Time from start of mixing aqueous and organic phases at 4.2 1st ind. [REDACTED] until start 4.2 1st ind. [REDACTED] including collection and hold 4.2 1st ind. [REDACTED]	4.2 1st ind. [REDACTED]
Time of 4.2 1st ind. [REDACTED] filtration unit operation 4.2 1st ind. [REDACTED]	Time from start of [REDACTED] operation to end of bioburden reduction filtration while product is at 4.2 1st ind. [REDACTED]	
Post bioburden reduction filtration 4.2 1st ind. [REDACTED]	Time post bioburden reduction filtration until end of sterile filtration or freezing of DPI 4.2 1st ind. [REDACTED] until the start of concentration adjustment and cryoprotectant addition.	

a. Temperature values of 15-25 °C represent room temperature

Abbreviations: RT = Room temperature; WFI = Water for Injection; LNP = lipid nanoparticle; [REDACTED]