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### 3.2.P.5.4. BATCH ANALYSES

BNT162b2 drug product lots used for nonclinical toxicology studies, clinical trials, process performance qualification (PPQ), emergency supply, and stability are summarized in [Table 3.2.P.5.4-1](#). A global approach to development has been undertaken across multiple manufacturing facilities in order to maximize vaccine production and availability. As such, information presented within the 3.2.P.5.4 Batch Analyses section reflects the global development effort and the drug product lots included are not limited to those produced in market-specific registered manufacturing facilities. The lot analyses data for BNT162b2 drug product lots are listed in [Table 3.2.P.5.4-2](#) through [Table 3.2.P.5.4-21](#). A full drug product genealogy can be found in [Section 3.2.P.2.3 Lot Genealogy](#). The analytical testing strategy applied to BNT162b2 drug product has evolved throughout the development history. Information on the drug product method evolution/testing strategy is provided in [Section 3.2.P.2.3 Analytical Method Evolution](#). All results met the acceptance criteria at the time of release. The lots listed have been used in clinical studies and toxicology studies as indicated.

**Table 3.2.P.5.4-1. Summary of BNT162b2 Drug Product Lots**

DP Lot Number	Date of Manufacture	Lipid Nanoparticle Manufacturing Site	Drug Product Fill and Finish Site	Lot Size (Number of Vials)	Drug Substance Batch(es)	Purpose of Material	Data Location
COVVAC/270320	27-MAR-2020	Polymun Scientific	Polymun Scientific	(b) (4)	(b) (4)	Nonclinical toxicology, Stability	<a href="#">Table 3.2.P.5.4-2</a>
BCV40420-A	30-APR-2020	Polymun Scientific	Polymun Scientific			Clinical, Stability	<a href="#">Table 3.2.P.5.4-3</a>
BCV40620-A	24-JUN-2020	Polymun Scientific	Polymun Scientific			Clinical, Stability	<a href="#">Table 3.2.P.5.4-3</a>
BCV40620-B	25-JUN-2020	Polymun Scientific	Polymun Scientific			Clinical	<a href="#">Table 3.2.P.5.4-3</a>
BCV40620-C	26-JUN-2020	Polymun Scientific	Polymun Scientific			Clinical	<a href="#">Table 3.2.P.5.4-3</a>
BCV40620-D	29-JUN-2020	Polymun Scientific	Polymun Scientific			Clinical	<a href="#">Table 3.2.P.5.4-3</a>
BCV40620-E	30-JUN-2020	Polymun Scientific	Polymun Scientific			Nonclinical, Stability	<a href="#">Table 3.2.P.5.4-3</a>
BCV40720-A	23-JUL-2020	Polymun Scientific	Polymun Scientific			Clinical, Stability	<a href="#">Table 3.2.P.5.4-4</a>
BCV40720-B	24-JUL-2020	Polymun Scientific	Polymun Scientific			Clinical	<a href="#">Table 3.2.P.5.4-4</a>
BCV40720-C	25-JUL-2020	Polymun Scientific	Polymun Scientific			Clinical, Stability	<a href="#">Table 3.2.P.5.4-4</a>
ED3938 <sup>a</sup>	16-JUL-2020	Polymun Scientific	Pfizer Puurs			Clinical, Stability	<a href="#">Table 3.2.P.5.4-4</a>
EE3813 <sup>b</sup>	29-JUL-2020	Polymun Scientific	Pfizer Puurs			Clinical, Stability	<a href="#">Table 3.2.P.5.4-4</a>

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**Table 3.2.P.5.4-1. Summary of BNT162b2 Drug Product Lots**

DP Lot Number	Date of Manufacture	Lipid Nanoparticle Manufacturing Site	Drug Product Fill and Finish Site	Lot Size (Number of Vials)	Drug Substance Batch(es)	Purpose of Material	Data Location
EE8492	05-AUG-2020	Polymun Scientific	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply, Stability	<a href="#">Table 3.2.P.5.4-5</a>
EE8493	05-AUG-2020	Polymun Scientific	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply, Clinical, Stability	<a href="#">Table 3.2.P.5.4-5</a>
EJ0553	25-SEP-2020	Polymun Scientific	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply, Clinical, Stability	<a href="#">Table 3.2.P.5.4-5</a>
EJ0724	29-SEP-2020	mibe	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-5</a>
EJ1685	05-OCT-2020	Polymun Scientific	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply, Clinical inventory, Stability	<a href="#">Table 3.2.P.5.4-5</a>
EJ1686	07-OCT-2020	Polymun Scientific	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply, Clinical inventory, Stability	<a href="#">Table 3.2.P.5.4-5</a>
EH9899	08-OCT-2020	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply, Stability	<a href="#">Table 3.2.P.5.4-8</a>
EJ1688	12-OCT-2020	mibe	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply, Stability	<a href="#">Table 3.2.P.5.4-6</a>
EK4175	12-OCT-2020	mibe	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-6</a>
EK1768	16-OCT-2020	Polymun Scientific	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply, Clinical inventory, Stability	<a href="#">Table 3.2.P.5.4-6</a>
EK4176	16-OCT-2020	Polymun Scientific	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-8</a>

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**Table 3.2.P.5.4-1. Summary of BNT162b2 Drug Product Lots**

DP Lot Number	Date of Manufacture	Lipid Nanoparticle Manufacturing Site	Drug Product Fill and Finish Site	Lot Size (Number of Vials)	Drug Substance Batch(es)	Purpose of Material	Data Location
EK5730	23-OCT-2020	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-8</a>
EL0140	29-OCT-2020	mibe	Pfizer Puurs			Emergency supply	<a href="#">Table 3.2.P.5.4-6</a>
EL0141	29-OCT-2020	Polymun Scientific	Pfizer Puurs			Emergency supply	<a href="#">Table 3.2.P.5.4-6</a>
EL0142	29-OCT-2020	mibe	Pfizer Puurs			Emergency supply	<a href="#">Table 3.2.P.5.4-7</a>
EL0725	30-OCT-2020	Pfizer Puurs	Pfizer Puurs			Emergency supply	<a href="#">Table 3.2.P.5.4-8</a>
EL0739	03-NOV-2020	Pfizer Puurs	Pfizer Puurs			Emergency supply	<a href="#">Table 3.2.P.5.4-9</a>
EK9231	04-NOV-2020	Pfizer Kalamazoo	Pfizer Kalamazoo			Emergency supply	<a href="#">Table 3.2.P.5.4-9</a>
EL1484	04-NOV-2020	Pfizer Puurs	Pfizer Puurs			Emergency supply	<a href="#">Table 3.2.P.5.4-9</a>
EK4237	05-NOV-2020	mibe	Pfizer Puurs			Emergency supply	<a href="#">Table 3.2.P.5.4-7</a>
EK4243	05-NOV-2020	mibe	Pfizer Puurs			Emergency supply	<a href="#">Table 3.2.P.5.4-7</a>
EK4244	05-NOV-2020	mibe	Pfizer Puurs			Emergency supply	<a href="#">Table 3.2.P.5.4-7</a>
EL1283	11-NOV-2020	Pfizer Kalamazoo	Pfizer Kalamazoo			Emergency supply	<a href="#">Table 3.2.P.5.4-9</a>

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**Table 3.2.P.5.4-1. Summary of BNT162b2 Drug Product Lots**

DP Lot Number	Date of Manufacture	Lipid Nanoparticle Manufacturing Site	Drug Product Fill and Finish Site	Lot Size (Number of Vials)	Drug Substance Batch(es)	Purpose of Material	Data Location
EJ6795	12-NOV-2020	Pfizer Puurs	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-14</a>
EK4241	12-NOV-2020	Polymun Scientific	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-7</a>
EK4245	12-NOV-2020	mibe	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-14</a>
EJ6796	13-NOV-2020	Pfizer Puurs	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-14</a>
EJ6797	17-NOV-2020	Pfizer Puurs	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-14</a>
EK4238	17-NOV-2020	Polymun Scientific	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-14</a>
EK4240	17-NOV-2020	mibe	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-14</a>
EK4242	17-NOV-2020	mibe	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply, Process performance qualification, Stability	<a href="#">Table 3.2.P.5.4-10</a>
EL1284	17-NOV-2020	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-9</a>
EL7834	17-NOV-2020	Polymun Scientific	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply, Process performance qualification, Stability	<a href="#">Table 3.2.P.5.4-10</a>
EL1491	18-NOV-2020	Pfizer Puurs	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply, Clinical, Process performance qualification, Stability	<a href="#">Table 3.2.P.5.4-10</a>

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**Table 3.2.P.5.4-1. Summary of BNT162b2 Drug Product Lots**

DP Lot Number	Date of Manufacture	Lipid Nanoparticle Manufacturing Site	Drug Product Fill and Finish Site	Lot Size (Number of Vials)	Drug Substance Batch(es)	Purpose of Material	Data Location
EL3246	20-NOV-2020	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-15</a>
EJ3002	24-NOV-2020	Polymun Scientific	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-15</a>
EL0200	24-NOV-2020	mibe	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-15</a>
EL0203	24-NOV-2020	mibe	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-15</a>
EM0477	24-NOV-2020	Pfizer Puurs	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-16</a>
EL3248	25-NOV-2020	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply, Clinical, Process performance qualification, Stability	<a href="#">Table 3.2.P.5.4-10</a>
EJ6134	26-NOV-2020	Pfizer Puurs	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-16</a>
EJ6136	27-NOV-2020	Pfizer Puurs	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-16</a>
EJ6788	30-NOV-2020	Pfizer Puurs	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-16</a>
EL1404	01-DEC-2020	mibe	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-16</a>
EL3249	02-DEC-2020	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply, Clinical, Process performance qualification, Stability	<a href="#">Table 3.2.P.5.4-10</a>

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**Table 3.2.P.5.4-1. Summary of BNT162b2 Drug Product Lots**

DP Lot Number	Date of Manufacture	Lipid Nanoparticle Manufacturing Site	Drug Product Fill and Finish Site	Lot Size (Number of Vials)	Drug Substance Batch(es)	Purpose of Material	Data Location
EK9788	03-DEC-2020	Pfizer Puurs	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-17</a>
EL1406	03-DEC-2020	mibe	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-17</a>
EN3924	03-DEC-2020	mibe	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-17</a>
EL3247	05-DEC-2020	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-17</a>
EJ6789	07-DEC-2020	Pfizer Puurs	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-17</a>
EL3302	07-DEC-2020	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-18</a>
EL8982	09-DEC-2020	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-18</a>
EJ6790	10-DEC-2020	Pfizer Puurs	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-18</a>
EL8723	11-DEC-2020	Pfizer Puurs	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply, Clinical, Process performance qualification, Stability	<a href="#">Table 3.2.P.5.4-11</a>
EM6950	11-DEC-2020	Pfizer Puurs	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply, Process performance qualification, Stability	<a href="#">Table 3.2.P.5.4-11</a>
EL9261	12-DEC-2020	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-18</a>

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**Table 3.2.P.5.4-1. Summary of BNT162b2 Drug Product Lots**

DP Lot Number	Date of Manufacture	Lipid Nanoparticle Manufacturing Site	Drug Product Fill and Finish Site	Lot Size (Number of Vials)	Drug Substance Batch(es)	Purpose of Material	Data Location
EL9262	15-DEC-2020	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-18</a>
EN1185	16-DEC-2020	Polymun Scientific	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-19</a>
EL9263	17-DEC-2020	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-19</a>
EN9581	17-DEC-2020	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-19</a>
EN5318	19-DEC-2020	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-19</a>
EL9266	21-DEC-2020	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply, Process performance qualification, Stability	<a href="#">Table 3.2.P.5.4-13</a>
EL9265	22-DEC-2020	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-19</a>
EL8713	23-DEC-2020	Pfizer Puurs	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply, Process performance qualification, Stability	<a href="#">Table 3.2.P.5.4-11</a>
EP2163	23-DEC-2020	Pfizer Puurs	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply, Process performance qualification	<a href="#">Table 3.2.P.5.4-11</a>
EP2166	23-DEC-2020	Pfizer Puurs	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply, Process performance qualification, Stability	<a href="#">Table 3.2.P.5.4-11</a>

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**Table 3.2.P.5.4-1. Summary of BNT162b2 Drug Product Lots**

DP Lot Number	Date of Manufacture	Lipid Nanoparticle Manufacturing Site	Drug Product Fill and Finish Site	Lot Size (Number of Vials)	Drug Substance Batch(es)	Purpose of Material	Data Location
EL9267	29-DEC-2020	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply, Process performance qualification, Stability	<a href="#">Table 3.2.P.5.4-13</a>
EL9269	30-DEC-2020	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-20</a>
EL9264	31-DEC-2020	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-20</a>
EM9809	01-JAN-2021	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-20</a>
EM9810	04-JAN-2021	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-20</a>
EP6775	04-JAN-2021	Pfizer Puurs	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply, Process performance qualification	<a href="#">Table 3.2.P.5.4-11</a>
EN6200	05-JAN-2021	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply, Process performance qualification	<a href="#">Table 3.2.P.5.4-13</a>
EN6201	07-JAN-2021	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-21</a>
EN1195	08-JAN-2021	mibe	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply, Process performance qualification, Stability	<a href="#">Table 3.2.P.5.4-12</a>
EP6017	11-JAN-2021	Pfizer Puurs	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-21</a>
EP9598	12-JAN-2021	Pfizer Puurs	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-21</a>

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**Table 3.2.P.5.4-1. Summary of BNT162b2 Drug Product Lots**

DP Lot Number	Date of Manufacture	Lipid Nanoparticle Manufacturing Site	Drug Product Fill and Finish Site	Lot Size (Number of Vials)	Drug Substance Batch(es)	Purpose of Material	Data Location
EN6198	13-JAN-2021	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply, Process performance qualification	<a href="#">Table 3.2.P.5.4-13</a>
EP9605	13-JAN-2021	Pfizer Puurs	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-21</a>
EN1196	18-JAN-2021	mibe	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply, Process performance qualification	<a href="#">Table 3.2.P.5.4-12</a>
EN6199	19-JAN-2021	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply, Process performance qualification, Stability	<a href="#">Table 3.2.P.5.4-13</a>
ER1741	13-JAN-2021	Pfizer Puurs	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-21</a>
EM4965	20-JAN-2021	Polymun Scientific	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply, Process performance qualification, Stability	<a href="#">Table 3.2.P.5.4-12</a>
ET0384	28-JAN-2021	Polymun Scientific	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply, Process performance qualification	<a href="#">Table 3.2.P.5.4-12</a>
EP6955	30-JAN-2021	Pfizer Kalamazoo	Pfizer Kalamazoo	(b) (4)	(b) (4)	Emergency supply	<a href="#">Table 3.2.P.5.4-21</a>

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**Table 3.2.P.5.4-1. Summary of BNT162b2 Drug Product Lots**

DP Lot Number	Date of Manufacture	Lipid Nanoparticle Manufacturing Site	Drug Product Fill and Finish Site	Lot Size (Number of Vials)	Drug Substance Batch(es)	Purpose of Material	Data Location
EW6126	19-FEB-2021	Pfizer Puurs	Pfizer Puurs	(b) (4)	(b) (4)	Emergency supply, Process performance qualification	<a href="#">Table 3.2.P.5.4-11</a>

- a. This lot number is equivalent to BCV40720-P.
- b. This lot number is equivalent to BCV40820-P.

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**Table 3.2.P.5.4-2. Batch Analyses for Nonclinical Toxicology BNT162b2 Drug Product Lot**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Lot Number
			COVVAC/270320
			Results
Appearance	Appearance (Visual)	Report result	White to off-white suspension
pH	(b) (4)	Report result	(b) (4)
Osmolality	Osmometry	Report result, mOsmol/kg	
LNP size	Dynamic light scattering (DLS)	Report result, nm	
LNP polydispersity	Dynamic light scattering (DLS)	Report result	
RNA encapsulation	Fluorescence assay	Report result, %	
RNA content	Fluorescence assay	Report result, µg/mL	
ALC-0315 content	HPLC-CAD	Report result, mg/mL	
ALC-0159 content	HPLC-CAD	Report result, mg/mL	
DSPC content	HPLC-CAD	Report result, mg/mL	
Cholesterol content	HPLC-CAD	Report result, mg/mL	
Identity of encoded RNA sequence	Capillary gel electrophoresis	Report result	Retention times conforms to reference
RNA integrity	Capillary gel electrophoresis	Report result, %	(b) (4)
Bacterial endotoxin	Endotoxin (LAL)	Report result, EU/mL	
Bioburden	Bioburden	Report result, CFU	(b) (4)

a. The information provided in this table represents the acceptance criteria used at the time of lot release. Abbreviations: CAD = Charged aerosol detection; CFU = Colony forming unit; EU = Endotoxin unit; HPLC = High performance liquid chromatography; LAL = Limulus amoebocyte lysate; LNP = Lipid nanoparticle; RT-PCR = Reverse transcription polymerase chain reaction

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**Table 3.2.P.5.4-3. Batch Analyses for Nonclinical and Clinical BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Lot Number					
			BCV40420-A	BCV40620-A	BCV40620-B	BCV40620-C	BCV40620-D	BCV40620-E
			Results					
Appearance	Appearance (Visual)	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension
Appearance (visible particulates)	Appearance (Particles)	Free from observable particles	Free from observable particles	Free from observable particles	Free from observable particles	Free from observable particles	Free from observable particles	Free from observable particles
Subvisible particles	Subvisible particulate matter	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
pH	(b) (4)	7.4 ± 0.5	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
Osmolality	Osmometry	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
LNP size	Dynamic light scattering (DLS)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
LNP polydispersity	Dynamic light scattering (DLS)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
RNA encapsulation	Fluorescence assay	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
RNA content	Fluorescence assay	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
ALC-0315 content	HPLC-CAD	Report result, mg/mL	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
ALC-0159 content	HPLC-CAD	Report result, mg/mL	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
DSPC content	HPLC-CAD	Report result, mg/mL	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
Cholesterol content	HPLC-CAD	Report result, mg/mL	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
Lipid identities	HPLC-CAD	Retention times consistent with references	Conforms to reference	Conforms to reference	Conforms to reference	Conforms to reference	Conforms to reference	Conforms to reference

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**Table 3.2.P.5.4-3. Batch Analyses for Nonclinical and Clinical BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Lot Number					
			BCV40420-A	BCV40620-A	BCV40620-B	BCV40620-C	BCV40620-D	BCV40620-E
			Results					
Identity of encoded RNA sequence	Capillary gel electrophoresis	Migration time of the RNA conforms to the migration time of the reference RNA	Conforms to reference	Conforms to reference	Conforms to reference	Conforms to reference	Conforms to reference	Conforms to reference
RNA integrity	Capillary gel electrophoresis	(b) (4)						
Bacterial endotoxin	Endotoxin (LAL)							
Sterility	Sterility							

a. The information provided in this table represents the acceptance criteria used at the time of lot release.  
 Abbreviations: CAD = Charged aerosol detection; EU = Endotoxin unit;; HPLC = High performance liquid chromatography; LAL = Limulus ameocyte lysate; LNP = Lipid nanoparticle;

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**Table 3.2.P.5.4-4. Batch Analyses for Clinical BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Lot Number					
			BCV40720-A	BCV40720-B	BCV40720-C	ED3938	EE3813	
			Results					
Appearance	Appearance (Visual)	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	
Appearance (visible particulates)	Appearance (Particles)	Free from observable particles	Free from observable particles	Free from observable particles	Free from observable particles	Free from observable particles	Free from observable particles	
Subvisible particles	Subvisible particulate matter	(b) (4)	(b) (4)					
pH	(b) (4)	7.4 ± 0.5						(b) (4)
Osmolality	Osmometry	(b) (4)						
LNP size	Dynamic light scattering (DLS)							
LNP polydispersity	Dynamic light scattering (DLS)							
RNA encapsulation	Fluorescence assay							
RNA content	Fluorescence assay							
ALC-0315 content	HPLC-CAD	Report result, mg/mL						
ALC-0159 content	HPLC-CAD	Report result, mg/mL						
DSPC content	HPLC-CAD	Report result, mg/mL						
Cholesterol content	HPLC-CAD	Report result, mg/mL						
Lipid identities	HPLC-CAD	Retention times consistent with references	Conforms to reference	Conforms to reference	Conforms to reference	Conforms to reference	Conforms to reference	

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**Table 3.2.P.5.4-4. Batch Analyses for Clinical BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Lot Number				
			BCV40720-A	BCV40720-B	BCV40720-C	ED3938	EE3813
			Results				
Identity of encoded RNA sequence	Capillary gel electrophoresis	Migration time of the RNA conforms to the migration time of the reference RNA	Conforms to reference	Conforms to reference	Conforms to reference	Conforms to reference	Conforms to reference
RNA integrity	Capillary gel electrophoresis	(b) (4)					
Bacterial endotoxin	Endotoxin (LAL)						
Sterility	Sterility	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile

a. The information provided in this table represents the acceptance criteria used at the time of lot release.

Abbreviations: CAD = Charged aerosol detection; EU = Endotoxin unit; HPLC = High performance liquid chromatography; LAL = Limulus amoebocyte lysate; LNP = Lipid nanoparticle;

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**Table 3.2.P.5.4-5. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Lot Number					
			EE8492	EE8493	EJ0553	EJ0724	EJ1685	EJ1686
Appearance	Appearance (Visual)	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension
Appearance (visible particulates)	Appearance (Particles)	Essentially free from visible particulates	Essentially free from visible particulates	Essentially free from visible particulates	Essentially free from visible particulates	Essentially free from visible particulates	Essentially free from visible particulates	Essentially free from visible particulates
Subvisible particles	Subvisible particulate matter	Meets compendial requirements	Meets compendial requirements (b) (4)	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements
pH	(b) (4)	7.4 ± 0.5	(b) (4)					
Osmolality	Osmometry	(b) (4)						
LNP size	Dynamic light scattering (DLS)							
LNP polydispersity	Dynamic light scattering (DLS)							
RNA encapsulation	Fluorescence assay							
RNA content	Fluorescence assay							
ALC-0315 content	HPLC-CAD							
ALC-0159 content	HPLC-CAD							
DSPC content	HPLC-CAD							
Cholesterol content	HPLC-CAD							

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**Table 3.2.P.5.4-5. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Lot Number					
			EE8492	EE8493	EJ0553	EJ0724	EJ1685	EJ1686
Container content for injections	Volume of injections in containers	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of	Not less than the sum of the nominal values of	Not less than the sum of the nominal values of	Not less than the sum of the nominal values of	Not less than the sum of the nominal values of	Not less than the sum of the nominal values of
Lipid identities	HPLC-CAD	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)
Identity of encoded RNA sequence	RT-PCR	Identity confirmed	Confirmed	Confirmed	Confirmed	Confirmed	Confirmed	Confirmed
<i>In-vitro</i> expression	Cell-based flow cytometry	(b) (4)						
RNA integrity	Capillary gel electrophoresis							
Bacterial endotoxin	Endotoxin (LAL)							
Sterility	Sterility	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected

- a. The information provided in this table represents the acceptance criteria used at the time of lot release.
- b. Acceptance criteria at the time of release were “Report result”. Most current EUA acceptance criteria reflected in this table.
- Abbreviations: CAD = Charged aerosol detection; EU = Endotoxin unit; EUA = Emergency use authorization; RP-HPLC = Reverse phase high performance liquid chromatography; LAL = Limulus amoebocyte lysate; LNP = Lipid nanoparticle; RT-PCR = Reverse transcription PCR

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**Table 3.2.P.5.4-6. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Lot Number				
			EJ1688	EK4175	EK1768	EL0140	EL0141
			Results				
Appearance	Appearance (Visual)	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension
Appearance (visible particulates)	Appearance (Particles)	Essentially free from visible particulates	Essentially free from visible particulates	Essentially free from visible particulates	Essentially free from visible particulates	Essentially free from visible particulates	Essentially free from visible particulates
Subvisible particles	Subvisible particulate matter	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements
pH	(b) (4)	7.4 ± 0.5	(b) (4)				
Osmolality	Osmometry	(b) (4)					
LNP size	Dynamic light scattering (DLS)						
LNP polydispersity	Dynamic light scattering (DLS)						
RNA encapsulation	Fluorescence assay						
RNA content	Fluorescence assay						
ALC-0315 content	HPLC-CAD						
ALC-0159 content	HPLC-CAD						
DSPC content	HPLC-CAD						
Cholesterol content	HPLC-CAD						
Container content for injections	Volume of injections in containers	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)

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**Table 3.2.P.5.4-6. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Lot Number				
			EJ1688	EK4175	EK1768	EL0140	EL0141
			Results				
Lipid identities	HPLC-CAD	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)
Identity of encoded RNA sequence	RT-PCR	Identity confirmed	Confirmed	Confirmed	Confirmed	Confirmed	Confirmed
<i>In-vitro</i> expression	Cell-based flow cytometry	(b) (4)					
RNA integrity	Capillary gel electrophoresis						
Bacterial endotoxin	Endotoxin (LAL)						
Sterility	Sterility	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected

a. The information provided in this table represents the acceptance criteria used at the time of lot release.

b. Acceptance criteria at the time of release were “Report result”. Most current EUA acceptance criteria reflected in this table.

Abbreviations: CAD = Charged aerosol detection; EU = Endotoxin unit; EUA = Emergency use authorization; RP-HPLC = Reverse phase high performance liquid chromatography; LAL = Limulus ameobocyte lysate; LNP = Lipid nanoparticle; RT-PCR = Reverse transcription PCR

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**Table 3.2.P.5.4-7. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Lot Number				
			EL0142	EK4237	EK4243	EK4244	EK4241
			Results				
Appearance	Appearance (Visual)	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension
Appearance (visible particulates)	Appearance (Particles)	Essentially free from visible particulates	Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates
Subvisible particles	Subvisible particulate matter	Meets compendial requirements	Meets compendial requirements (b) (4)	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements
pH	(b) (4)	7.4 ± 0.5	(b) (4)				
Osmolality	Osmometry	(b) (4)					
LNP size	Dynamic light scattering (DLS)						
LNP polydispersity	Dynamic light scattering (DLS)						
RNA encapsulation	Fluorescence assay						
RNA content	Fluorescence assay						
ALC-0315 content	HPLC-CAD						
ALC-0159 content	HPLC-CAD						
DSPC content	HPLC-CAD						
Cholesterol content	HPLC-CAD						
Container content for injections	Volume of injections in containers	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)

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**Table 3.2.P.5.4-7. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Lot Number				
			EL0142	EK4237	EK4243	EK4244	EK4241
Results							
Lipid identities	HPLC-CAD	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)
Identity of encoded RNA sequence	RT-PCR	Identity confirmed	Confirmed	Confirmed	Confirmed	Confirmed	Confirmed
<i>In-vitro</i> expression	Cell-based flow cytometry	(b) (4)					
RNA integrity	Capillary gel electrophoresis						
Bacterial endotoxin	Endotoxin (LAL)						
Sterility	Sterility	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected

- a. The information provided in this table represents the acceptance criteria used at the time of lot release.  
 b. Acceptance criteria at the time of release were “Report result”. Most current acceptance criteria reflected in this table.  
 Abbreviations: CAD = Charged aerosol detection; EU = Endotoxin unit; RP-HPLC = Reverse phase high performance liquid chromatography; LAL = Limulus amoebocyte lysate; LNP = Lipid nanoparticle; RT-PCR = Reverse transcription PCR

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**Table 3.2.P.5.4-8. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Lot Number			
			EH9899	EK4176	EK5730	EL0725
			Results			
Appearance	Appearance (Visual)	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension
Appearance (visible particulates)	Appearance (Particles)	Essentially free from visible particulates	Essentially free from visible particulates	Essentially free from visible particulates	Essentially free from visible particulates	Essentially free from visible particulates
Subvisible particles	Subvisible particulate matter	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements
pH	(b) (4)	7.4 ± 0.5	(b) (4)			
Osmolality	Osmometry	(b) (4)				
LNP size	Dynamic light scattering (DLS)					
LNP polydispersity	Dynamic light scattering (DLS)					
RNA encapsulation	Fluorescence assay					
RNA content	Fluorescence assay					
ALC-0315 content	HPLC-CAD					
ALC-0159 content	HPLC-CAD					
DSPC content	HPLC-CAD					
Cholesterol content	HPLC-CAD					
Container content for injections	Volume of injections in containers	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)
Lipid identities	HPLC-CAD	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)
Identity of encoded RNA sequence	RT-PCR	Identity confirmed	Confirmed	Confirmed	Confirmed	Confirmed
<i>In-vitro</i> expression	Cell-based flow cytometry	(b) (4)	(b) (4)			

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**Table 3.2.P.5.4-8. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Lot Number			
			EH9899	EK4176	EK5730	EL0725
			Results			
RNA integrity	Capillary gel electrophoresis	(b) (4)				
Bacterial endotoxin	Endotoxin (LAL)					
Sterility	Sterility	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected

a. The information provided in this table represents the acceptance criteria used at the time of lot release.

Abbreviations: CAD = Charged aerosol detection; EU = Endotoxin unit; RP-HPLC = Reverse phase high performance liquid chromatography; LAL = Limulus ameocyte lysate; LNP = Lipid nanoparticle; RT-PCR = Reverse transcription PCR

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**Table 3.2.P.5.4-9. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Lot Number				
			EL0739	EK9231	EL1484	EL1283	EL1284
			Results				
Appearance	Appearance (Visual)	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension
Appearance (visible particulates)	Appearance (Particles)	Essentially free from visible particulates	Essentially free from visible particulates	Essentially free from visible particulates	Essentially free from visible particulates	Meets. Essentially free from visible particulates.	Meets. Essentially free from visible particulates
Subvisible particles	Subvisible particulate matter	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements
pH	(b) (4)	7.4 ± 0.5	(b) (4)				
Osmolality	Osmometry	(b) (4)					
LNP size	Dynamic light scattering (DLS)						
LNP polydispersity	Dynamic light scattering (DLS)						
RNA encapsulation	Fluorescence assay						
RNA content	Fluorescence assay						
ALC-0315 content	HPLC-CAD						
ALC-0159 content	HPLC-CAD						
DSPC content	HPLC-CAD						
Cholesterol content	HPLC-CAD						
Container content for injections	Volume of injections in containers	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)

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**Table 3.2.P.5.4-9. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Lot Number				
			EL0739	EK9231	EL1484	EL1283	EL1284
			Results				
Lipid identities	HPLC-CAD	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)
Identity of encoded RNA sequence	RT-PCR	Identity confirmed	Confirmed	Confirmed	Confirmed	Confirmed	Confirmed
<i>In-vitro</i> expression	Cell-based flow cytometry	(b) (4)					
RNA integrity	Capillary gel electrophoresis						
Bacterial endotoxin	Endotoxin (LAL)						
Sterility	Sterility	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected

a. The information provided in this table represents the acceptance criteria used at the time of lot release. Abbreviations: CAD = Charged aerosol detection; EU = Endotoxin unit; RP-HPLC = Reverse phase high performance liquid chromatography; LAL = Limulus amoebocyte lysate; LNP = Lipid nanoparticle; RT-PCR = Reverse transcription PCR

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**Table 3.2.P.5.4-10. Batch Analyses for Network Process Performance Qualification BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number				
				EK4242	EL7834	EL1491	EL3248	EL3249
				Results				
Appearance	Appearance (Visual)	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension
Appearance (visible particulates)	Appearance (Particles)	May contain white to off-white opaque, amorphous particles	May contain white to off-white opaque, amorphous particles	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates
Subvisible particles	Subvisible particulate matter	(b) (4)	(b) (4)	Meets compendial requirements (b) (4)	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements
pH	(b) (4)	6.9 – 7.9	6.9 – 7.9					
Osmolality	Osmometry	(b) (4)						
LNP size	Dynamic light scattering (DLS)							
LNP polydispersity	Dynamic light scattering (DLS)							
RNA encapsulation	Fluorescence assay							
RNA content	Fluorescence assay							
ALC-0315 content	HPLC-CAD							
ALC-0159 content	HPLC-CAD							
DSPC content	HPLC-CAD							
Cholesterol content	HPLC-CAD							

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**Table 3.2.P.5.4-10. Batch Analyses for Network Process Performance Qualification BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number				
				EK4242	EL7834	EL1491	EL3248	EL3249
				Results				
Container content for injections	Volume of injections in containers	Not less than the sum of the nominal values of (b) (4)	Not less than (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)
Lipid identities	HPLC-CAD	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)
Identity of encoded RNA sequence	RT-PCR	Identity confirmed	Identity confirmed	Confirmed	Confirmed	Confirmed	Confirmed	Confirmed
<i>In-vitro</i> expression	Cell-based flow cytometry	(b) (4)						
RNA integrity	Capillary gel electrophoresis	(b) (4)						
Bacterial endotoxin	Endotoxin (LAL)	(b) (4)						
Sterility	Sterility	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected

a. The information provided in this table represents the acceptance criteria used at the time of lot release.

(b) (4)

c. This commercial acceptance criterion refers to the vial content (volume) quality attribute and container content analytical procedure.

Abbreviations: CAD = Charged aerosol detection; EU = Endotoxin unit; RP-HPLC = Reverse phase high performance liquid chromatography; LAL = Limulus ameocyte lysate; LNP = Lipid nanoparticle; RT-PCR = Reverse transcription PCR

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**Table 3.2.P.5.4-11. Batch Analyses for Pfizer Puurs LNP and Pfizer Puurs Fill/Finish Process Performance Qualification BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number						
				EL8723	EM6950	EL8713	EP2163	EP2166	EP6775	EW6126
				Results						
Appearance	Appearance (Visual)	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension
Appearance (visible particulates)	Appearance (Particles)	May contain white to off-white opaque, amorphous particles	May contain white to off-white opaque, amorphous particles	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets test <sup>c</sup>	Meets test <sup>c</sup>	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates
Subvisible particles	Subvisible particulate matter	(b) (4)	(b) (4)	Meets compendial requirements (b) (4)	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements
pH	(b) (4)	6.9 – 7.9	6.9 – 7.9							
Osmolality	Osmometry	(b) (4)								
LNP size	Dynamic light scattering (DLS)									
LNP poly-dispersity	Dynamic light scattering (DLS)									
RNA encapsulation	Fluorescence assay									
RNA content	Fluorescence assay									
ALC-0315 content	HPLC-CAD									

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**Table 3.2.P.5.4-11. Batch Analyses for Pfizer Puurs LNP and Pfizer Puurs Fill/Finish Process Performance Qualification BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number						
				EL8723	EM6950	EL8713	EP2163	EP2166	EP6775	EW6126
				Results						
ALC-0159 content	HPLC-CAD	(b) (4)								
DSPC content	HPLC-CAD	(b) (4)								
Cholesterol content	HPLC-CAD	(b) (4)								
Container content for injections	Volume of injections in containers <sup>d</sup>	Not less than the sum of the nominal values of (b) (4)	N/A	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)
Vial content (volume)	Container content <sup>d</sup>	Not less than (b) mL	Not less than (b) mL	N/A	N/A	N/A	Not less than (b) mL	Not less than (b) mL	Not less than (b) mL	Not less than (b) mL
Lipid identities	HPLC-CAD	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)
Identity of encoded RNA sequence	RT-PCR	Identity confirmed	Identity confirmed	Confirmed	Confirmed	Confirmed	Confirmed	Confirmed	Confirmed	Confirmed
<i>In-vitro</i> expression	Cell-based flow cytometry	(b) (4)								

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**Table 3.2.P.5.4-11. Batch Analyses for Pfizer Puurs LNP and Pfizer Puurs Fill/Finish Process Performance Qualification BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number						
				EL8723	EM6950	EL8713	EP2163	EP2166	EP6775	EW6126
				Results						
RNA integrity	Capillary gel electrophoresis	(b) (4)								
Bacterial endotoxin	Endotoxin (LAL)									
Sterility	Sterility	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected

a. The information provided in this table represents the acceptance criteria used at the time of lot release.

(b) (4)

d. Some lots were released using both volume of injections in containers and container content analytical procedures, while some were released using the volume of injections in containers analytical procedure only.

e. Differences in reporting occurred due to changes in testing location.

Abbreviations: CAD = Charged aerosol detection; EU = Endotoxin unit; RP-HPLC = Reverse phase high performance liquid chromatography; LAL = Limulus ameocyte lysate; LNP = Lipid nanoparticle; N/A = Not applicable; RT-PCR = Reverse transcription PCR

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**Table 3.2.P.5.4-12. Batch Analyses for Polymun Scientific LNP and Pfizer Puurs Fill/Finish Process Performance Qualification BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number			
				EN1195	EN1196	EM4965	ET0384
				Results			
Appearance	Appearance (Visual)	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension
Appearance (visible particulates)	Appearance (Particles)	May contain white to off-white opaque, amorphous particles	May contain white to off-white opaque, amorphous particles	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates
Subvisible particles	Subvisible particulate matter	(b) (4)	(b) (4)	Meets compendial requirements (b) (4)	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements
pH	(b) (4)	6.9 – 7.9	6.9 – 7.9	(b) (4)			
Osmolality	Osmometry	(b) (4)	(b) (4)				
LNP size	Dynamic light scattering (DLS)	(b) (4)	(b) (4)				
LNP polydispersity	Dynamic light scattering (DLS)	(b) (4)	(b) (4)				
RNA encapsulation	Fluorescence assay	(b) (4)	(b) (4)				
RNA content	Fluorescence assay	(b) (4)	(b) (4)				
ALC-0315 content	HPLC-CAD	(b) (4)	(b) (4)				
ALC-0159 content	HPLC-CAD	(b) (4)	(b) (4)				
DSPC content	HPLC-CAD	(b) (4)	(b) (4)				
Cholesterol content	HPLC-CAD	(b) (4)	(b) (4)				

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**Table 3.2.P.5.4-12. Batch Analyses for Polymun Scientific LNP and Pfizer Puurs Fill/Finish Process Performance Qualification BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number			
				EN1195	EN1196	EM4965	ET0384
				Results			
Container content for injections	Volume of injections in containers <sup>c</sup>	Not less than the sum of the nominal values of (b) (4)	N/A	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)
Vial content (volume)	Container content <sup>c</sup>	Not less than (b) (4)	Not less than	Not less than	Not less than	Not less than	Not less than
Lipid identities	HPLC-CAD	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)
Identity of encoded RNA sequence	RT-PCR	Identity confirmed	Identity confirmed	Confirmed	Confirmed	Confirmed	Confirmed
<i>In-vitro</i> expression	Cell-based flow cytometry	(b) (4)					
RNA integrity	Capillary gel electrophoresis	(b) (4)					
Bacterial endotoxin	Endotoxin (LAL)	(b) (4)					
Sterility	Sterility	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected

a. The information provided in this table represents the acceptance criteria used at the time of lot release.

(b) (4)

c. Some lots were released using both volume of injections in containers and container content analytical procedures, while some were released using the volume of injections in containers analytical procedure only.

Abbreviations: CAD = Charged aerosol detection; EU = Endotoxin unit; RP-HPLC = Reverse phase high performance liquid chromatography; LAL = Limulus amoebocyte lysate; LNP = Lipid nanoparticle; N/A = Not applicable; RT-PCR = Reverse transcription PCR

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**Table 3.2.P.5.4-13. Batch Analyses for Pfizer Kalamazoo LNP and Pfizer Kalamazoo Fill/Finish Process Performance Qualification BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number				
				EL9266	EL9267	EN6200	EN6198	EN6199
				Results				
Appearance	Appearance (Visual)	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension
Appearance (visible particulates)	Appearance (Particles)	May contain white to off-white opaque, amorphous particles	May contain white to off-white opaque, amorphous particles	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates
Subvisible particles	Subvisible particulate matter	(b) (4)	(b) (4)	Meets compendial requirements (b) (4)	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements
pH	(b) (4)	6.9 – 7.9	6.9 – 7.9					
Osmolality	Osmometry	(b) (4)						
LNP size	Dynamic light scattering (DLS)							
LNP polydispersity	Dynamic light scattering (DLS)							
RNA encapsulation	Fluorescence assay							
RNA content	Fluorescence assay							
ALC-0315 content	HPLC-CAD							
ALC-0159 content	HPLC-CAD							

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**Table 3.2.P.5.4-13. Batch Analyses for Pfizer Kalamazoo LNP and Pfizer Kalamazoo Fill/Finish Process Performance Qualification BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number				
				EL9266	EL9267	EN6200	EN6198	EN6199
Results								
DSPC content	HPLC-CAD	(b) (4)						
Cholesterol content	HPLC-CAD	(b) (4)						
Container content for injections	Volume of injections in containers <sup>d</sup>	Not less than the sum of the nominal values of (b) (4)	N/A	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)
Vial content (volume)	Container content <sup>d</sup>	Not less than (b) (4)	Not less than (b) (4)	N/A	N/A	N/A	Not less than (b) (4)	Not less than (b) (4)
Lipid identities	HPLC-CAD	Retention times consistent with references (ALC-0315, ALC-0159, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)
Identity of encoded RNA sequence	RT-PCR	Identity confirmed	Identity confirmed	Confirmed	Confirmed	Confirmed	Confirmed	Confirmed
<i>In-vitro</i> expression	Cell-based flow cytometry	(b) (4)						
RNA integrity	Capillary gel electrophoresis	(b) (4)						
Bacterial endotoxin	Endotoxin (LAL)	(b) (4)						
Sterility	Sterility	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected

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**Table 3.2.P.5.4-13. Batch Analyses for Pfizer Kalamazoo LNP and Pfizer Kalamazoo Fill/Finish Process Performance Qualification BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number				
				EL9266	EL9267	EN6200	EN6198	EN6199
Results								

a. The information provided in this table represents the acceptance criteria used at the time of lot release.

(b) (4)



d. Some lots were released using both volume of injections in containers and container content analytical procedures, while some were released using the volume of injections in containers analytical procedure only.

Abbreviations: CAD = Charged aerosol detection; EU = Endotoxin unit; RP-HPLC = Reverse phase high performance liquid chromatography; LAL = Limulus ameobocyte lysate; LNP = Lipid nanoparticle; N/A = Not applicable; RT-PCR = Reverse transcription PCR

**Table 3.2.P.5.4-14. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number					
				EJ6795	EK4245	EJ6796	EJ6797	EK4238	EK4240
Results									
Appearance	Appearance (Visual)	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension
Appearance (visible particulates)	Appearance (Particles)	May contain white to off-white opaque, amorphous particles	May contain white to off-white opaque, amorphous particles	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates
Subvisible particles	Subvisible particulate matter	(b) (4)	(b) (4)	Meets compendial requirements (b) (4)	Meets compendial requirements (b) (4)	Meets compendial requirements (b) (4)	Meets compendial requirements (b) (4)	Meets compendial requirements (b) (4)	Meets compendial requirements (b) (4)
pH	(b) (4)	6.9 – 7.9	6.9 – 7.9	(b) (4)					
Osmolality	Osmometry	(b) (4)	(b) (4)	(b) (4)					
LNP size	Dynamic light scattering (DLS)	(b) (4)	(b) (4)	(b) (4)					
LNP polydispersity	Dynamic light scattering (DLS)	(b) (4)	(b) (4)	(b) (4)					
RNA encapsulation	Fluorescence assay	(b) (4)	(b) (4)	(b) (4)					
RNA content	Fluorescence assay	(b) (4)	(b) (4)	(b) (4)					
ALC-0315 content	HPLC-CAD	(b) (4)	(b) (4)	(b) (4)					
ALC-0159 content	HPLC-CAD	(b) (4)	(b) (4)	(b) (4)					
DSPC content	HPLC-CAD	(b) (4)	(b) (4)	(b) (4)					

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**Table 3.2.P.5.4-14. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number					
				EJ6795	EK4245	EJ6796	EJ6797	EK4238	EK4240
Results									
Cholesterol content	HPLC-CAD	(b) (4)							
Container content for injections	Volume of injections in containers	Not less than the sum of the nominal values of (b) (4)	Not less than (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)
Lipid identities	HPLC-CAD	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)
Identity of encoded RNA sequence	RT-PCR	Identity confirmed	Identity confirmed	Confirmed	Confirmed	Confirmed	Confirmed	Confirmed	Confirmed
<i>In-vitro</i> expression	Cell-based flow cytometry	(b) (4)							
RNA integrity	Capillary gel electrophoresis	(b) (4)							
Bacterial endotoxin	Endotoxin (LAL)	(b) (4)							
Sterility	Sterility	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected

a. The information provided in this table represents the acceptance criteria used at the time of lot release.

(b) (4)

c. This commercial acceptance criterion refers to the vial content (volume) quality attribute and container content analytical procedure. Abbreviations: CAD = Charged aerosol detection; EU = Endotoxin unit; RP-HPLC = Reverse phase high performance liquid chromatography; LAL = Limulus amoebocyte lysate; LNP = Lipid nanoparticle; RT-PCR = Reverse transcription PCR

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**Table 3.2.P.5.4-15. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number			
				EL3246	EJ3002	EL0200	EL0203
				Results			
Appearance	Appearance (Visual)	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension
Appearance (visible particulates)	Appearance (Particles)	May contain white to off-white opaque, amorphous particles	May contain white to off-white opaque, amorphous particles	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates
Subvisible particles	Subvisible particulate matter	(b) (4)	(b) (4)	Meets compendial requirements (b) (4)	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements
pH	(b) (4)	6.9 – 7.9	6.9 – 7.9	(b) (4)			
Osmolality	Osmometry	(b) (4)					
LNP size	Dynamic light scattering (DLS)						
LNP polydispersity	Dynamic light scattering (DLS)						
RNA encapsulation	Fluorescence assay						
RNA content	Fluorescence assay						
ALC-0315 content	HPLC-CAD						
ALC-0159 content	HPLC-CAD						
DSPC content	HPLC-CAD						
Cholesterol content	HPLC-CAD						

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**Table 3.2.P.5.4-15. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number			
				EL3246	EJ3002	EL0200	EL0203
				Results			
Container content for injections	Volume of injections in containers	Not less than the sum of the nominal values of (b) (4)	Not less than (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)
Lipid identities	HPLC-CAD	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)
Identity of encoded RNA sequence	RT-PCR	Identity confirmed	Identity confirmed	Confirmed	Confirmed	Confirmed	Confirmed
<i>In-vitro</i> expression	Cell-based flow cytometry	(b) (4)					
RNA integrity	Capillary gel electrophoresis						
Bacterial endotoxin	Endotoxin (LAL)						
Sterility	Sterility	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected

a. The information provided in this table represents the acceptance criteria used at the time of lot release.  
(b) (4)

Abbreviations: CAD = Charged aerosol detection; EU = Endotoxin unit; RP-HPLC = Reverse phase high performance liquid chromatography; LAL = Limulus ameobocyte lysate; LNP = Lipid nanoparticle; RT-PCR = Reverse transcription PCR

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**Table 3.2.P.5.4-16. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number				
				EM0477	EJ6134	EJ6136	EJ6788	EL1404
				Results				
Appearance	Appearance (Visual)	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension
Appearance (visible particulates)	Appearance (Particles)	May contain white to off-white opaque, amorphous particles	May contain white to off-white opaque, amorphous particles	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates
Subvisible particles	Subvisible particulate matter	(b) (4)	(b) (4)	Meets compendial requirements (b) (4)	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements
pH	(b) (4)	6.9 – 7.9	6.9 – 7.9					
Osmolality	Osmometry	(b) (4)						
LNP size	Dynamic light scattering (DLS)							
LNP polydispersity	Dynamic light scattering (DLS)							
RNA encapsulation	Fluorescence assay							
RNA content	Fluorescence assay							
ALC-0315 content	HPLC-CAD							
ALC-0159 content	HPLC-CAD							
DSPC content	HPLC-CAD							

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**Table 3.2.P.5.4-16. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number				
				EM0477	EJ6134	EJ6136	EJ6788	EL1404
				Results				
Cholesterol content	HPLC-CAD	(b) (4)						
Container content for injections	Volume of injections in containers	Not less than the sum of the nominal values of (b) (4)	Not less than (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)
Lipid identities	HPLC-CAD	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)
Identity of encoded RNA sequence	RT-PCR	Identity confirmed	Identity confirmed	Confirmed	Confirmed	Confirmed	Confirmed	Confirmed
<i>In-vitro</i> expression	Cell-based flow cytometry	(b) (4)						
RNA integrity	Capillary gel electrophoresis	(b) (4)						
Bacterial endotoxin	Endotoxin (LAL)	(b) (4)						
Sterility	Sterility	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected

a. The information provided in this table represents the acceptance criteria used at the time of lot release.

(b) (4)

c. This commercial acceptance criterion refers to the vial content (volume) quality attribute and container content analytical procedure. Abbreviations: CAD = Charged aerosol detection; EU = Endotoxin unit; RP-HPLC = Reverse phase high performance liquid chromatography; LAL = Limulus amoebocyte lysate; LNP = Lipid nanoparticle; RT-PCR = Reverse transcription PCR

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**Table 3.2.P.5.4-17. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number				
				EK9788	EL1406	EN3924	EL3247	EJ6789
				Results				
Appearance	Appearance (Visual)	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension
Appearance (visible particulates)	Appearance (Particles)	May contain white to off-white opaque, amorphous particles	May contain white to off-white opaque, amorphous particles	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates
Subvisible particles	Subvisible particulate matter	(b) (4)	(b) (4)	Meets compendial requirements (b) (4)	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements
pH	(b) (4)	6.9 – 7.9	6.9 – 7.9	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
Osmolality	Osmometry	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
LNP size	Dynamic light scattering (DLS)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
LNP polydispersity	Dynamic light scattering (DLS)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
RNA encapsulation	Fluorescence assay	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
RNA content	Fluorescence assay	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
ALC-0315 content	HPLC-CAD	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
ALC-0159 content	HPLC-CAD	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
DSPC content	HPLC-CAD	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)

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**Table 3.2.P.5.4-17. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number				
				EK9788	EL1406	EN3924	EL3247	EJ6789
				Results				
Cholesterol content	HPLC-CAD	(b) (4)						
Container content for injections	Volume of injections in containers	Not less than the sum of the nominal values of (b) (4)	Not less than (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)
Lipid identities	HPLC-CAD	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)
Identity of encoded RNA sequence	RT-PCR	Identity confirmed	Identity confirmed	Confirmed	Confirmed	Confirmed	Confirmed	Confirmed
<i>In-vitro</i> expression	Cell-based flow cytometry	(b) (4)						
RNA integrity	Capillary gel electrophoresis	(b) (4)						
Bacterial endotoxin	Endotoxin (LAL)	(b) (4)						
Sterility	Sterility	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected

a. The information provided in this table represents the acceptance criteria used at the time of lot release.

(b) (4)

c. This commercial acceptance criterion refers to the vial content (volume) quality attribute and container content analytical procedure.

Abbreviations: CAD = Charged aerosol detection; EU = Endotoxin unit; RP-HPLC = Reverse phase high performance liquid chromatography; LAL = Limulus amoebocyte lysate; LNP = Lipid nanoparticle; RT-PCR = Reverse transcription PCR

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**Table 3.2.P.5.4-18. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number				
				EL3302	EL8982	EJ6790	EL9261	EL9262
				Results				
Appearance	Appearance (Visual)	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension
Appearance (visible particulates)	Appearance (Particles)	May contain white to off-white opaque, amorphous particles	May contain white to off-white opaque, amorphous particles	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates
Subvisible particles	Subvisible particulate matter	(b) (4)	(b) (4)	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements
pH	(b) (4)	6.9 – 7.9	6.9 – 7.9	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
Osmolality	Osmometry	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
LNP size	Dynamic light scattering (DLS)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
LNP polydispersity	Dynamic light scattering (DLS)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
RNA encapsulation	Fluorescence assay	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
RNA content	Fluorescence assay	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
ALC-0315 content	HPLC-CAD	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
ALC-0159 content	HPLC-CAD	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
DSPC content	HPLC-CAD	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)

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**Table 3.2.P.5.4-18. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number				
				EL3302	EL8982	EJ6790	EL9261	EL9262
				Results				
Cholesterol content	HPLC-CAD	(b) (4)						
Container content for injections	Volume of injections in containers	Not less than the sum of the nominal values of (b) (4)	Not less than (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)
Lipid identities	HPLC-CAD	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)
Identity of encoded RNA sequence	RT-PCR	Identity confirmed	Identity confirmed	Confirmed	Confirmed	Confirmed	Confirmed	Confirmed
<i>In-vitro</i> expression	Cell-based flow cytometry	(b) (4)						
RNA integrity	Capillary gel electrophoresis	(b) (4)						
Bacterial endotoxin	Endotoxin (LAL)	(b) (4)						
Sterility	Sterility	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected

a. The information provided in this table represents the acceptance criteria used at the time of lot release.

(b) (4)

c. This commercial acceptance criterion refers to the vial content (volume) quality attribute and container content analytical procedure. Abbreviations: CAD = Charged aerosol detection; EU = Endotoxin unit; RP-HPLC = Reverse phase high performance liquid chromatography; LAL = Limulus amoebocyte lysate; LNP = Lipid nanoparticle; RT-PCR = Reverse transcription PCR

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**Table 3.2.P.5.4-19. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number				
				EN1185	EL9263	EN9581	EN5318	EL9265
				Results				
Appearance	Appearance (Visual)	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension
Appearance (visible particulates)	Appearance (Particles)	May contain white to off-white opaque, amorphous particles	May contain white to off-white opaque, amorphous particles	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates
Subvisible particles	Subvisible particulate matter	(b) (4)	(b) (4)	Meets compendial requirements (b) (4)	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements
pH	(b) (4)	6.9 – 7.9	6.9 – 7.9	(b) (4)				
Osmolality	Osmometry	(b) (4)	(b) (4)					
LNP size	Dynamic light scattering (DLS)	(b) (4)	(b) (4)					
LNP polydispersity	Dynamic light scattering (DLS)	(b) (4)	(b) (4)					
RNA encapsulation	Fluorescence assay	(b) (4)	(b) (4)					
RNA content	Fluorescence assay	(b) (4)	(b) (4)					
ALC-0315 content	HPLC-CAD	(b) (4)	(b) (4)					
ALC-0159 content	HPLC-CAD	(b) (4)	(b) (4)					
DSPC content	HPLC-CAD	(b) (4)	(b) (4)					

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**Table 3.2.P.5.4-19. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number				
				EN1185	EL9263	EN9581	EN5318	EL9265
				Results				
Cholesterol content	HPLC-CAD	(b) (4)						
Container content for injections	Volume of injections in containers	Not less than the sum of the nominal values of (b) (4)	Not less than (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)
Lipid identities	HPLC-CAD	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)
Identity of encoded RNA sequence	RT-PCR	Identity confirmed	Identity confirmed	Confirmed	Confirmed	Confirmed	Confirmed	Confirmed
<i>In-vitro</i> expression	Cell-based flow cytometry	(b) (4)						
RNA integrity	Capillary gel electrophoresis	(b) (4)						
Bacterial endotoxin	Endotoxin (LAL)	(b) (4)						
Sterility	Sterility	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected

a. The information provided in this table represents the acceptance criteria used at the time of lot release.

(b) (4)

c. This commercial acceptance criterion refers to the vial content (volume) quality attribute and container content analytical procedure. Abbreviations: CAD = Charged aerosol detection; EU = Endotoxin unit; RP-HPLC = Reverse phase high performance liquid chromatography; LAL = Limulus ameocyte lysate; LNP = Lipid nanoparticle; RT-PCR = Reverse transcription PCR

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**Table 3.2.P.5.4-20. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number			
				EL9269	EL9264	EM9809	EM9810
				Results			
Appearance	Appearance (Visual)	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension
Appearance (visible particulates)	Appearance (Particles)	May contain white to off-white opaque, amorphous particles	May contain white to off-white opaque, amorphous particles	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates
Subvisible particles	Subvisible particulate matter	(b) (4)	(b) (4)	Meets compendial requirements (b) (4)	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements
pH	(b) (4)	6.9 – 7.9	6.9 – 7.9	(b) (4)			
Osmolality	Osmometry	(b) (4)	(b) (4)				
LNP size	Dynamic light scattering (DLS)	(b) (4)	(b) (4)				
LNP polydispersity	Dynamic light scattering (DLS)	(b) (4)	(b) (4)				
RNA encapsulation	Fluorescence assay	(b) (4)	(b) (4)				
RNA content	Fluorescence assay	(b) (4)	(b) (4)				
ALC-0315 content	HPLC-CAD	(b) (4)	(b) (4)				
ALC-0159 content	HPLC-CAD	(b) (4)	(b) (4)				
DSPC content	HPLC-CAD	(b) (4)	(b) (4)				
Cholesterol content	HPLC-CAD	(b) (4)	(b) (4)				

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**Table 3.2.P.5.4-20. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number			
				EL9269	EL9264	EM9809	EM9810
				Results			
Container content for injections	Volume of injections in containers	Not less than the sum of the nominal values of (b) (4)	Not less than (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)	Not less than the sum of the nominal values of (b) (4)
Lipid identities	HPLC-CAD	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)
Identity of encoded RNA sequence	RT-PCR	Identity confirmed	Identity confirmed	Confirmed	Confirmed	Confirmed	Confirmed
<i>In-vitro</i> expression	Cell-based flow cytometry	(b) (4)					
RNA integrity	Capillary gel electrophoresis						
Bacterial endotoxin	Endotoxin (LAL)						
Sterility	Sterility	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected

a. The information provided in this table represents the acceptance criteria used at the time of lot release.

(b) (4)

c. This commercial acceptance criterion refers to the vial content (volume) quality attribute and container content analytical procedure.

Abbreviations: CAD = Charged aerosol detection; EU = Endotoxin unit; RP-HPLC = Reverse phase high performance liquid chromatography; LAL = Limulus amoebocyte lysate; LNP = Lipid nanoparticle; RT-PCR = Reverse transcription PCR

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**Table 3.2.P.5.4-21. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number					
				EN6201	EP6017	EP9598	EP9605	ER1741	EP6955
				Results					
Appearance	Appearance (Visual)	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension
Appearance (visible particulates)	Appearance (Particles)	May contain white to off-white opaque, amorphous particles	May contain white to off-white opaque, amorphous particles	Meets. Essentially free from visible particulates	Meets. Essentially free from visible particulates	Meets test <sup>b</sup>	Meets test <sup>b</sup>	Meets. Essentially free from visible particulates	Meets test <sup>b</sup>
Subvisible particles	Subvisible particulate matter	(b) (4)		Meets compendial requirements (b) (4)	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements	Meets compendial requirements
pH	(b) (4)	6.9 – 7.9	6.9 – 7.9	(b) (4)					
Osmolality	Osmometry	(b) (4)							
LNP size	Dynamic light scattering (DLS)								
LNP polydispersity	Dynamic light scattering (DLS)								
RNA encapsulation	Fluorescence assay								
RNA content	Fluorescence assay								
ALC-0315 content	HPLC-CAD								
ALC-0159 content	HPLC-CAD								

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**Table 3.2.P.5.4-21. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number						
				EN6201	EP6017	EP9598	EP9605	ER1741	EP6955	
				Results						
DSPC content	HPLC-CAD	(b) (4)								
Cholesterol content	HPLC-CAD	(b) (4)								
Container content for injections	Volume of injections in containers <sup>d</sup>	Not less than the sum of the nominal values of	N/A	Not less than the sum of the nominal values of	Not less than the sum of the nominal values of	N/A	Not less than the sum of the nominal values of	Not less than the sum of the nominal values of	Not less than the sum of the nominal values of (b) (4)	
Vial content (volume)	Container content <sup>d</sup>	Not less than (b) (4)	Not less than	Not less than	Not less than	Not less than	Not less than	Not less than	Not less than	
Lipid identities	HPLC-CAD	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)
Identity of encoded RNA sequence	RT-PCR	Identity confirmed	Identity confirmed	Confirmed	Confirmed	Confirmed	Confirmed	Confirmed	Confirmed	
<i>In-vitro</i> expression	Cell-based flow cytometry	(b) (4)								
RNA integrity	Capillary gel electrophoresis	(b) (4)								
Bacterial endotoxin	Endotoxin (LAL)	(b) (4)								
Sterility	Sterility	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	No growth detected	

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**Table 3.2.P.5.4-21. Batch Analyses for Emergency Supply BNT162b2 Drug Product Lots**

Quality Attribute	Analytical Procedure	Acceptance Criteria <sup>a</sup>	Commercial Acceptance Criteria	Lot Number					
				EN6201	EP6017	EP9598	EP9605	ER1741	EP6955
				Results					

- a. The information provided in this table represents the acceptance criteria used at the time of lot release.
- b. Differences in reporting occurred due to changes in testing location.

(b) (4)

- d. Some lots were released using both volume of injections in containers and container content analytical procedures, while some were released using the volume of injections in containers analytical procedure only.

Abbreviations: CAD = Charged aerosol detection; EU = Endotoxin unit; RP-HPLC = Reverse phase high performance liquid chromatography; LAL = Limulus ameocyte lysate; LNP = Lipid nanoparticle; N/A = Not applicable; RT-PCR = Reverse transcription PCR

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