

Table 1	BNT162b2 Manufacturing Equipment and Scale		
Process Step	Facilities Equipment		
Drug Substance	Andover	BioNTech/Rentschler	Comments/Justification for Differences
<b>Transcription, DNase Digestion, Proteinase K Digestion</b>	Pall LevMixer 50L Jacketed Single Use Mixer (SUM) <ul style="list-style-type: none"> <li>50 L Single Use Bag (ULDPE)</li> <li>37.6L starting volume</li> <li>50L final volume</li> </ul>	<b>Unit Operations Below Performed at BioNTech</b> Biostat STR 50L (Reactor) <ul style="list-style-type: none"> <li>50 L Single Use Bag (PE)</li> <li>37.6L starting volume</li> <li>50L final volume</li> <li>Dispensed into 10L Bags (PE)</li> </ul>	<ul style="list-style-type: none"> <li>Equipment is equivalent. Both are single-use product contact with built-in impeller mixers.</li> <li>BioNTech transfers to 10L bags to transfer to Rentschler for further processing.</li> </ul>
<b>Dilution of IVT solution</b>	Pall LevMixer 200L Jacketed Single Use Mixer (SUM) <ul style="list-style-type: none"> <li>100/200L Single Use Bag (ULDPE)</li> <li>Volume: 200L</li> </ul>	<b>Unit Operations Below Performed at Rentschler</b> Mobius® MIX 200L Jacketed Single Use Mixer (SUM) <ul style="list-style-type: none"> <li>100/200L Single Use Bag (ULDPE)</li> <li>Volume: 200L</li> </ul>	<ul style="list-style-type: none"> <li>Equipment is equivalent. Both are single-use product contact SUM's with built-in impeller mixers.</li> <li>100/200 L bags are of the equivalent material.</li> </ul>
<b>UFDF Purification</b>	Millipore Cogent ultrafiltration system <ul style="list-style-type: none"> <li>2x3. 5m<sup>2</sup> (7m<sup>2</sup>) 300kD membrane</li> <li>Sartocube ECO membrane (stabilized cellulose)</li> <li>Millipore cassette holder (SS)</li> <li>200L SS retentate tank</li> </ul> <b>Filtration Step: Between Purification and Concentration.</b> <ul style="list-style-type: none"> <li>0.45/0.2um filtration. (Sartobran P Filter, Cellulose Acetate)</li> <li>200L SUM bag (ULDPE)</li> </ul>	Sartorius Sartoflow SF20 Ultrafiltration system <ul style="list-style-type: none"> <li>2x3.5m<sup>2</sup> (7m<sup>2</sup>) 300kD membrane</li> <li>Sartocube ECO membrane (stabilized cellulose)</li> <li>Sartorius Sartoflow SF20 holder (SS)</li> <li>200 L SS retentate tank</li> </ul>	<ul style="list-style-type: none"> <li>UF Systems are equivalent. Both are utilized for holding filters and UF/DF of material. UF Skids are different manufactures.</li> <li>Vessels are equivalent holding tanks and MOC.</li> <li>Both use 7 m<sup>2</sup> 300kD Sartorius filters with stabilized cellulose based membranes.</li> <li><b>ACMF has an additional 0.2 um filtration step.</b> In ACMF there is an extra hold for the UF Pool as material is recovered off the UF skid prior to diluting to DS target. At BNT, dilution to the target DS concentration is performed ON the skid. Final Filtrations are equivalent. There is no "UF Pool" step in the BNT/Rentschler process.</li> </ul>
<b>RNA concentration adjustment before 0.2um filtration</b>	Pall LevMixer 200L Jacketed Single Use Mixer (SUM) <ul style="list-style-type: none"> <li>200L Single Use Bag (ULDPE)</li> </ul>	Mobius® MIX 200L Jacketed Single Use Mixer (SUM) <ul style="list-style-type: none"> <li>200L Single Use Bag (ULDPE)</li> </ul>	<ul style="list-style-type: none"> <li>Both are single-use product contact SUMs with built-in impeller mixers.</li> <li>Bags are the same film MOC.</li> </ul>
<b>0.2um filtration</b>	0.45/0.2um filtration. <ul style="list-style-type: none"> <li>Sartobran P Filter, Cellulose Acetate</li> <li>200L SUM bag (ULDPE)</li> </ul>	0.45/0.2um filtration <ul style="list-style-type: none"> <li>Sartobran P Filter, Cellulose Acetate</li> <li>200L SUM bag (PE)</li> </ul>	<ul style="list-style-type: none"> <li>Filters are equivalent based on size and MOC.</li> <li>Bags are the same film MOC</li> </ul>
<b>DS Container</b>	EVA (Ethyl Vinyl Acetate) Bag CFT (controlled Freeze Thaw) <ul style="list-style-type: none"> <li>Bag Volume: 16.6 L</li> </ul>	EVA (Ethyl Vinyl Acetate) Bag FFT (Flexible Freeze Thaw) <ul style="list-style-type: none"> <li>Bag Volume: 12 L</li> </ul>	DS Container is equivalent. Product contact layer is identical for both EVA containers.

<b>Table 1</b>	<b>BNT162b2 Manufacturing Equipment and Scale</b>				
<b>Process Step</b>	<b>Facilities Equipment</b>				
<b>Freezer, Storage</b>	Sartorius FT100 Controlled Rate Freezer, non-product contact • -20C final temp.		Uncontrolled freeze in -20°C cooling chamber • -20C final temp.		Equipment is equivalent. Final temp is the same.
<b>LNP Fabrication/ Drug Product</b>	<b>Kalamazoo</b>	<b>Puurs</b>	<b>Polymun</b>	<b>Mibe (DermaPharm)</b>	<b>Comments/Justification for Differences</b>
<b>Drug Substance Thaw</b>	DS container: EVA CFT (controlled Freeze Thaw) Equipment: controlled thaw equipment FT66 • Scale: up to 70 g RNA	DS container: EVA CFT or FFT (Flexible Freeze Thaw) • EVA CFT Equipment: controlled thaw equipment FT100 • EVA FFT No Equipment (controlled environment) • Scale: up to 70 g RNA	DS container: EVA FFT No Equipment (controlled environment) • Scale: up to 40g RNA	DS container: EVA FFT No Equipment (controlled environment) • Scale: up to 40g RNA	<ul style="list-style-type: none"> <li>• DS Container contact layer is identical for both EVA CFT and FFT containers.</li> <li>• Equipment for controlled thaw is for process efficiency only and thaw rates have been demonstrated to have no impact to product quality.</li> <li>• Scale is matched to capacity of LNP formation equipment.</li> </ul>
<b>Dilution of DS</b>	Mixing/dilution in a 100 L single use mixer tank (SUM). • 100L Single Use Bag • ULDPE	Mixing/dilution in 300 L stainless steel vessel	Mixing/dilution in 20 L glass bottle	Mixing/dilution in 50 L stainless steel vessel	Mixing vessel sizes appropriate to volume. Kalamazoo uses single use bag. Single use bag has acceptable MOC.
	Mixing (10-500 RPM), > 15 min	Mixing (10-400 RPM) > 30 min	Mixing(100 – 200 RPM) ≥ 5 min	Mixing 50-400 RPM for > 15 min	Agitation rates/times are aligned with scale/equipment set. Current batch manufacture & PPQ to support mixing.
	DS Concentration Target: 2.0 mg/mL	DS Concentration Target: 2.0 mg/mL	DS Concentration Target: 2.0 mg/mL	DS Concentration Target: 2.0 mg/mL	Must meet target concentration.
<b>Mixing of diluted DS with citrate buffer</b>	Inline mixing	Inline mixing	Batch mixing in a SS vessel	Inline mixing	<ul style="list-style-type: none"> <li>• The inline mixing eliminates the hold time of the RNA solution at pH 4.0 as the process is scaled.</li> <li>• At Polymun, this step is a batch process where the target concentration is determined/monitored while cooling is performed (helps maintain mRNA stability) until inline heating is to process temperature during the transfer of the aqueous phase to the T-mixer.</li> </ul>

<b>Table 1</b>	<b>BNT162b2 Manufacturing Equipment and Scale</b>				
<b>Process Step</b>	<b>Facilities Equipment</b>				
<b>Preparation of Organic Phase</b>	<b>Kalamazoo</b> Mixing of ethanol and lipids in stainless steel vessel <ul style="list-style-type: none"> <li>• 225L (60gal) SS vessel</li> <li>• Volume: 66L</li> </ul>	<b>Puurs</b> Mixing of ethanol and lipids in stainless steel vessel <ul style="list-style-type: none"> <li>• 300L SS vessel</li> <li>• Volume: 66 L</li> </ul>	<b>Polymun</b> Mixing of ethanol and lipids in glass bottles, then transfer to stainless steel vessel <ul style="list-style-type: none"> <li>• 50 L SS vessel</li> <li>• Volume: 33L</li> </ul>	<b>Mibe (DermaPharm)</b> Mixing of ethanol and lipids in stainless steel vessel <ul style="list-style-type: none"> <li>• 100L SS Vessel</li> <li>• Volume: 70L</li> </ul>	<ul style="list-style-type: none"> <li>• Mixing vessel sizes appropriate to volume.</li> <li>• The Polymun process is a legacy process that was performed at a smaller scale (CTM) and evolved into the current design, while the Pfizer and Dermapharm processes were designed to introduce improvements to the legacy design, without a significant impact on the DP quality. Therefore, there is no impact of mixing in bottles and transfer to mixing in the SS vessel</li> <li>• Volume at Dermapharm is more than Polymun based on a single lipid batch feeds 2 DP productions @ Dermapharm. Therefore, there is no impact of mixing a larger volume.</li> </ul>
	Mixing: Warm ethanol and lipids to 35°C and Mix <ul style="list-style-type: none"> <li>• (10-500 RPM),</li> <li>• &gt; 1 hr 30 min</li> <li>• 0.2um (PES) filter organic phase</li> </ul>	Mixing: Warm ethanol and lipids to 35°C and Mix <ul style="list-style-type: none"> <li>• (10-400 RPM)</li> <li>• &gt; 30 min</li> <li>• 0.2 um (PES) filter organic phase</li> </ul>	Mixing: Warm ethanol <ul style="list-style-type: none"> <li>• (50-150 RPM)</li> <li>• NLT 1 hour</li> <li>• 0.2 um (PES) filter organic phase</li> </ul>	Mixing: Warm ethanol and lipids to 35°C and Mix <ul style="list-style-type: none"> <li>•(50 – 300 rpm)</li> <li>•NLT 1 hour</li> <li>•0.2 um (PES) filter organic phase</li> </ul>	Equivalent process and equipment at this step. Current batch manufacture &PPQ to support mixing.
<b>Preparation of Citrate Buffer</b>	Mixing <ul style="list-style-type: none"> <li>• 170 gallon/640L SS vessel</li> <li>• Volume: 450L</li> <li>• Prefiltered Inline/0.2um PES</li> </ul> Mixing (10-500 RPM), > 20 min	Mixing <ul style="list-style-type: none"> <li>• 1600 L SS vessel</li> <li>• Volume: 1150 L</li> <li>• Prefiltered Inline/0.2um PES</li> </ul> Mixing (10-400 RPM) > 30 min	Mixing <ul style="list-style-type: none"> <li>• 750 L SS vessel</li> <li>• Volume: 650 – 700 L</li> <li>• Prefiltered 0.2um filter</li> <li>• Type: PES</li> </ul> Mixing (200-400 RPM) ≥ 10 min	Mixing <ul style="list-style-type: none"> <li>• 1000 L SS vessel</li> <li>• Volume: 700 L</li> <li>• Prefiltered Inline/0.2 um PES</li> </ul> Mixing (Vortex/no air) > 30 min	Mixing vessel sizes appropriate to volumes made. Additional volumes made for efficiency.  Agitation rates/times are aligned with scale/equipment set. Batch Manuf.&PPQ support mixing.
<b>LNP Formation &amp; Stabilization</b>	0.5 mm T-mixer w/ 20 cm x 0.04" Stabilization Flowpath	0.5 mm T-mixer w/ 20 cm x 0.04" Stabilization Flowpath	0.5 mm T-mixer w/ 20 cm x 0.04" Stabilization Flowpath	0.5 mm T-mixer w/ 20 cm x 0.04" Stabilization Flowpath	Equipment is Equivalent. T-mixer designs achieve same mixing ratios of lipids to RNA and same flow rates at all sites. Greater equipment capacity is achieved by using multiple T-mixers (scale out rather than scale up) maintaining all ratios.
<b>LNP Formation Skid</b>	8 parallel T-mixers, each supported by 2 Knauer HPLC pumps	8 parallel T-mixers, each supported by 2 Knauer HPLC pumps	2 parallel T mixers, each supported by 2 Knauer HPLC pumps	2 parallel T-mixer, each supported by 2 Knauer HPLC pumps	
<b>DS Concentration Post LNP Formation</b>	0.2 mg/mL	0.2 mg/mL	0.2 mg/mL	0.2 mg/mL	Must meet target concentration.

<b>Table 1</b>	<b>BNT162b2 Manufacturing Equipment and Scale</b>				
<b>Process Step</b>	<b>Facilities Equipment</b>				
<b>LNP Pool</b>	<b>Kalamazoo</b>  Pool / Mixing <ul style="list-style-type: none"> <li>• 800 L SS vessel</li> <li>• Volume: 347 L</li> <li>• 10-400 RPM</li> <li>• &gt; 15 min</li> </ul>	<b>Puurs</b>  Pool / Mixing <ul style="list-style-type: none"> <li>• 800 L SS vessel</li> <li>• Volume: 347 L</li> <li>• 10-400 RPM</li> <li>• &gt;15 min</li> </ul>	<b>Polymun</b>  Pool <ul style="list-style-type: none"> <li>• 250 L SS Vessel</li> <li>• Volume: 200 L</li> </ul>	<b>Mibe (DermaPharm)</b>  Pool / Mixing <ul style="list-style-type: none"> <li>• 200 L SS Vessel</li> <li>• Volume: 200 L</li> <li>• 50 RPM</li> <li>• &gt;15 min</li> </ul>	<ul style="list-style-type: none"> <li>• Agitation rates/times are aligned with scale/equipment set. Batch Manuf.&amp;PPQ support mixing.</li> <li>• Polymun process is a legacy process that was performed at a smaller scale (CTM) and evolved into the current design. The pump provides mixing/agitation that allows for the fresh buffer to mix with the retentate. Agitation rates/times are aligned with scale. Batch Manuf.&amp;PPQ support mixing.</li> </ul>
<b>Concentration, Buffer Exchange, Filtration.</b>	TFF/ Hollow Fiber Filter. <ul style="list-style-type: none"> <li>• Membrane loading: NLT 3.2 cm<sup>2</sup>/mg RNA</li> </ul>	TFF/ Hollow Fiber Filter <ul style="list-style-type: none"> <li>• Membrane loading: NLT 3.2 cm<sup>2</sup>/mg RNA</li> </ul>	TFF/ Hollow Fiber Filter <ul style="list-style-type: none"> <li>• Membrane loading: NLT 3.2<sup>2</sup>/mg RNA</li> </ul>	TFF/ Hollow Fiber Filter <ul style="list-style-type: none"> <li>• Membrane loading: NLT 3.2 cm<sup>2</sup>/ mg RNA,</li> </ul>	Filter loading is equivalent. Maximum filter area per mg RNA not to fall below 3.2cm <sup>2</sup> /mg RNA. Total TFF membrane area is scaled appropriate to loading (batch quantity).
<b>Buffer Exchange / TFF Filter Membrane</b>	TFF/Hollow Fiber Filter <ul style="list-style-type: none"> <li>• mPES,</li> <li>• Repligen Corp.</li> <li>• 100 kDa</li> <li>• 68 cm Eff. Length</li> <li>• 0.5 mm Fiber ID</li> <li>• 2 x 12000 Fibers</li> <li>• 25.6 m<sup>2</sup> (Total Area)</li> <li>• 70 g batch.</li> </ul>	TFF/Hollow Fiber Filter <ul style="list-style-type: none"> <li>• mPES,</li> <li>• Repligen Corp.</li> <li>• 100 kDa</li> <li>• 68 cm Eff. Length</li> <li>• 0.5 mm Fiber ID</li> <li>• 2 x 12000 Fibers</li> <li>• 25.6 m<sup>2</sup> (Total Area)</li> <li>• 70 g batch.</li> </ul>	TFF/Hollow Fiber Filter <ul style="list-style-type: none"> <li>• mPES</li> <li>• Repligen Corp.</li> <li>• 100 kDa</li> <li>• 68 cm Eff. Length</li> <li>• 0.5 mm Fiber ID</li> <li>• 4 x 4000 Fibers</li> <li>• 16.4 (Total Area)</li> <li>• 40 g batch.</li> </ul>	TFF/Hollow Fiber Filter <ul style="list-style-type: none"> <li>• mPES</li> <li>• Repligen Corp.</li> <li>• 100 kDa</li> <li>• 68 cm Eff. Length</li> <li>• 0.5 mm Fiber ID</li> <li>• 12000 Fibers Single filter of 12.8 sqm used for</li> <li>• 40 g batch</li> </ul>	
<b>Preparation of Citrate Buffer (TFF)</b>	Mixing <ul style="list-style-type: none"> <li>• 170 gallon/640 L SS vessel</li> <li>• Volume 620 L</li> </ul>	Mixing <ul style="list-style-type: none"> <li>• 1600 L SS vessel</li> <li>• Volume 660 L</li> </ul>	Mixing <ul style="list-style-type: none"> <li>• 750 L SS vessel</li> <li>• 650 – 700 L</li> </ul>	Mixing <ul style="list-style-type: none"> <li>• 1000 L SS vessel</li> <li>• Volume: 700 L</li> </ul>	Agitation rates/times are aligned with scale/equipment set. Batch Manuf.&PPQ support mixing.
	Mixing (10-500 RPM), > 20 min	Mixing (10-400 RPM) > 30 min	Mixing (200-400 RPM) ≥ 10 min	Mixing (Vortex/no air) > 30 min	
<b>Preparation of PBS Buffer (TFF)</b>	Mixing <ul style="list-style-type: none"> <li>• 315 gallon/1200 L SS vessel</li> <li>• Volume 800 L</li> <li>• Mixing (10-500 RPM), &gt; 20 min MT</li> </ul>	Mixing <ul style="list-style-type: none"> <li>• 1600 L SS vessel</li> <li>• 620 L</li> <li>• Mixing (10-400 RPM) &gt; 30 min MT</li> </ul>	Mixing <ul style="list-style-type: none"> <li>• 750 L SS vessel</li> <li>• 700 – 720 L</li> <li>• Mixing (200-400 RPM) ≥ 10 min MT</li> </ul>	Mixing <ul style="list-style-type: none"> <li>• 1000 L SS vessel</li> <li>• Volume: 733 L</li> <li>• Mixing (50-400 RPM) &gt; 10 min MT</li> </ul>	Agitation rates/times are aligned with scale/equipment set. Batch Manuf.&PPQ support mixing.

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<b>Process Step</b>	<b>Facilities Equipment</b>				
<b>TFF Vessel</b>	<p><b>Kalamazoo</b></p> <p>Pool / Mixing</p> <ul style="list-style-type: none"> <li>• 800 L SS vessel</li> <li>• Volume 350L (max)</li> </ul> <p>Mixing (10-500 RPM) Time: throughout the buffer exchange and concentration process.</p>	<p><b>Puurs</b></p> <p>Pool / Mixing</p> <ul style="list-style-type: none"> <li>• 1200 L SS vessel</li> <li>• Volume: 350 L (max)</li> </ul> <p>Mixing (10-400 RPM), Time: throughout the buffer exchange and concentration process.</p>	<p><b>Polymun</b></p> <p>Pool / Mix</p> <ul style="list-style-type: none"> <li>• 250 L SS vessel</li> <li>• Volume: 200L (max)</li> </ul> <p>Vessel not mixed. Pump will mix/circulate material throughout the buffer exchange and concentration process.</p>	<p><b>Mibe (DermaPharm)</b></p> <p>Pool / Mixing</p> <ul style="list-style-type: none"> <li>• 200 L SS Vessel</li> <li>• Volume: 200 L (max)</li> </ul> <p>Mixing with 50-100 RPM Time: throughout the buffer exchange and concentration process.</p>	<p>Agitation rates/times are aligned with scale/equipment set. Polymun: pump provides mixing/agitation. Agitation rates/times are aligned with scale/equipment set. Batch Manuf.&amp;PPQ support mixing.</p>
<b>Bioburden reduction filtration</b>	<p>Hydrophilic Pre-filter: 1.2/0.2 µm mPES Primary Filter:</p> <ul style="list-style-type: none"> <li>• 0.2 µm mPES</li> <li>• 300L SS vessel</li> <li>• Volume 139L</li> </ul>	<p>Hydrophilic Pre-filter: 1.2/0.2 µm mPES Primary Filter:</p> <ul style="list-style-type: none"> <li>• 0.2 µm mPES</li> <li>• 300L SS Vessel</li> <li>• Volume 139L</li> </ul>	<p>Hydrophilic Filter 0.2 µm mPES Filter</p> <ul style="list-style-type: none"> <li>• 250L SS Vessel</li> <li>• 40L volume</li> </ul>	<p>Hydrophilic Pre-filter: 1.2/0.2 µm mPES Primary Filter:</p> <ul style="list-style-type: none"> <li>• 0.2 µm mPES</li> <li>• 100 L SS Vessel</li> <li>• Volume 40L (min)</li> </ul>	<p>The Polymun process is a legacy process that was performed at a smaller scale (CTM) and evolved into the current design, while the Pfizer and Dermapharm processes were designed to introduce improvements to the legacy design. The primary filter that Polymun uses is well oversized for the small process volume and therefore no impact to not having a Pre-filter. Batches Manufactured support the process.</p>
<b>Concentration Adjustment &amp; Addition of Cryoprotectant</b>	<p>Mixing in stainless steel vessel.</p> <ul style="list-style-type: none"> <li>• 300L vessel</li> <li>• Volume 139 L</li> <li>• 10-500 RPM</li> <li>• &gt; 15 min</li> </ul>	<p>Mixing in stainless steel vessel.</p> <ul style="list-style-type: none"> <li>• 300L vessel</li> <li>• Volume: 139 L</li> <li>• 10-400 RPM</li> <li>• &gt; 10min</li> </ul>	<p>Mixing in Stainless steel vessel.</p> <ul style="list-style-type: none"> <li>• 250 L vessel</li> <li>• Volume 80 L</li> <li>• ≤ 200 RPM</li> <li>• ≥ 15 min</li> </ul>	<p>Mixing in Stainless steel vessel.</p> <ul style="list-style-type: none"> <li>• 100 L Vessel</li> <li>• Volume 80 L</li> <li>• 50-150 RPM</li> <li>• 10-30 min</li> </ul>	<p>Agitation rates/times are aligned with scale/equipment set. Batch Manuf.&amp;PPQ support mixing.</p>
<b>(Optional) Hold and Transport to Fill Finish Site</b>	<p>Hold in stainless steel vessel.</p> <ul style="list-style-type: none"> <li>• 400L or 750L</li> <li>• Volume: 139L</li> </ul> <p>No transport</p>	<p>Hold in stainless steel vessel.</p> <ul style="list-style-type: none"> <li>• 300l vessel</li> <li>• Volume: 139L</li> </ul> <p>No transport</p>	<p>Flexible container, transport to fill finish site. EVA (Ethyl Vinyl Acetate) Bag FFT (Flexible Freeze Thaw) 3 x 50 L bags</p>	<p>Flexible container, transport to fill finish site. EVA (Ethyl Vinyl Acetate) Bag FFT (Flexible Freeze Thaw) 8 x 10 L bags</p>	<p>Inclusion of transport step has been demonstrated to not impact product quality and has been included for production of clinical supplies.</p>

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<b>Process Step</b>	<b>Facilities Equipment</b>					
<b>DP Fill/Finish</b>	<b>Puurs- WSL 5</b>	<b>Puurs -FC2</b>	<b>Puurs - VC2</b>	<b>KZO-Line 8</b>	<b>KZO-Line 18</b>	<b>Comments/Justification for Differences</b>
<b>Sterile Filtration</b>	2 sterilizing grade filters in series (0,2 µm mPES)	2 sterilizing grade filters in series (0,2 µm mPES)	2 sterilizing grade filters in series (0,2 µm mPES)	2 sterilizing grade filters in series (0,2 µm mPES)	2 sterilizing grade filters in series (0,2 (0,2 µm mPES)	All Equivalent
	Pressure Transfer, 15 psi-g (~1 Bar-g)	Pressure Transfer, 15 psi-g (~1 Bar-g)	Pressure Transfer, 15 psi-g (~1 Bar-g)	Pressure Transfer, 15 psi-g (~1 Bar-g)	Pressure Transfer, 15 psi-g (~1 Bar-g)	
<b>Container Closure Components</b>	2ml vial, 13 mm stopper	2ml vial, 13 mm stopper	2ml vial, 13 mm stopper	2ml vial, 13 mm stopper	2ml vial, 13 mm stopper	All Equivalent
<b>Aseptic Filling</b>	RABS or conventional hard barrier grade B background - Vial washer - Depyrogenation tunnel - 300L Holding Tank SS - Vial Filler/Pluggger - Vial Capper	Isolator filling line grade C background - Vial washer - Depyrogenation tunnel - 300 L Holding Tank SS - Vial Filler/Pluggger - Vial Capper	Isolator filling line grade C background - Vial washer - Depyrogenation tunnel - 300L Holding Tank SS - Vial Filler/Pluggger - Vial Capper	Conventional rigid barrier filling line grade B background - Vial washer - Depyrogenation tunnel - 400L or 750L Holding Tank - Vial Filler/Pluggger - Vial Capper	RABS filling line grade B background - Vial washer - Depyrogenation tunnel - 400L or 750L Holding Tank - Vial Filler/Pluggger - Vial Capper	All Equivalent
<b>Labeling and inspection</b>	- Vial and box labeler (including vision system) - Automated visual inspection machine - Leak tester	- Vial and box labeler (including vision system) -Automated visual inspection machine -Leak tester	- Vial and box labeler (including vision system) - Automated visual inspection machine - Leak tester	•Vial and box labeler (including vision system) • Automated visual inspection machine •Leak tester	•Vial and box labeler (including vision system) • Automated visual inspection machine •Leak Tester	All Equivalent
<b>Freezing Storage</b>	Ultra low temperature freezer -80°C	Ultra low temperature freezer -80°C	Ultra low temperature freezer -80°C	Ultra low temperature freezer -80°C	Ultra low temperature freezer -80°C	All Equivalent
<b>Storage, Packaging and Shipment</b>	Hold in corrugated tray boxes" @ -60 to -90°C Shipment in cooled containers with temptale(-80°C)	Hold in corrugated tray boxes" @ -60 to -90°C Shipment in cooled containers with temptale. (-80°C)	Hold in corrugated tray boxes" @ -60 to -90°C Shipment in cooled containers with temptale. (-80°C)	Hold in corrugated tray boxes @ -60 to -90°C Shipment in cooled containers with temptale. (-80°C)	Hold in corrugated tray boxes @ -60 to -90°C Shipment in cooled containers with temptale. (-80°C)	All Equivalent
<b>Number of vials/batch? (Target)</b>	Up to 309,000 vials	Up to 309,000 vials	309,000 vials	309,000 vials	309,000 vials	All Equivalent