

3.2.P.3.1. MANUFACTURER(S) – PRE-FILLED SYRINGE

Table 3.2.P.3.1-1 lists the sites that have responsibilities for the production and testing of BNT162b2 drug product in pre-filled syringe (PFS) presentation and their specified functions.

Table 3.2.P.3.1-1. Sites and Responsibilities for PFS Drug Product Manufacture and Testing

Site	Responsibility
Pfizer Manufacturing Belgium NV Rijksweg 12 Puurs-Sint-Amands, 2870 Belgium	<p>Manufacture 4.2 1st ind. [REDACTED]</p> <p>DP Release and stability testing 4.2 1st ind. [REDACTED]</p> <p>DPI testing 4.2 1st ind. [REDACTED]</p> <p>Batch release by Qualified Person in EEA [European Economic Area]^a</p>
BioNTech Manufacturing Marburg GmbH Emil-von-Behring- Straße 76 35041 Marburg Germany	<p>Manufacture 4.2 1st ind. [REDACTED]</p> <p>DPI testing 4.2 1st ind. [REDACTED]</p>
BioNTech IMFS GmbH Vollmiersbachstrasse 52 55743 Idar-Oberstein Germany	<p>DPI testing 4.2 1st ind. [REDACTED]</p>
BioNTech Manufacturing GmbH An der Goldgrube 12 55131 Mainz Germany	<p>DPI testing 4.2 1st ind. [REDACTED]</p>

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Site	Responsibility
mibe GmbH Arzneimittel Münchener Straße 15 06796 Brehna Germany	DPI testing 4.2 1st ind. [REDACTED]
BioNTech Manufacturing GmbH Kupferbergterrasse 17 – 19 55116 Mainz Germany	Batch release by Qualified Person in EEA [European Economic Area]
Pfizer Ireland Pharmaceuticals Grange Castle Business Park, Clondalkin, Dublin 22 Ireland	DP Release and stability testing 4.2 1st ind. [REDACTED] DPI testing 4.2 1st ind. [REDACTED]
Wyeth BioPharma ^b Division of Wyeth Pharmaceuticals LLC 1 Burt Road Andover MA 01810 United States	Stability testing 4.2 1st ind. [REDACTED]

a. Batch release of commercial lots utilizing drug substance from Wyeth (Pfizer) site in Andover, MA, US or Pfizer, Grange Castle, Ireland.

b. The legal entity name change from Wyeth BioPharma Division of Wyeth Pharmaceuticals was changed at the acquisition by Pfizer in 2009, since then the Wyeth Pharmaceuticals manufacturing site in Andover, Massachusetts belongs to Pfizer's production sites and is embedded in Pfizer's GMP system. Pfizer will be utilized throughout the CTD.

Abbreviations: DPI = Drug Product Intermediate; DP = Drug Product; MDV= Multi Dose Vial; SDV=Single Dose Vial