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3.2.P.7. CONTAINER CLOSURE SYSTEM [OTHER SITES]

This section contains the container closure information for the fill and finish sites except Pfizer sites. The primary container closure system for the BNT162b2 vaccine consists of the vial components listed in Table 3.2.P.7-1.

The materials of construction for the primary packaging components in the container closure system consist of Type I borosilicate glass and bromobutyl rubber. Safety data for the vials and elastomeric closure rubber formulations are provided in [Section 3.2.P.2.4 Container Closure System](#).

Listed component dimensions are subject to standard industry tolerances. Added drawings of the container closure system components are for information purposes and will be maintained on-site at the manufacturing location.

Table 3.2.P.7-1. List of Components in Container Closure System

Component	Description
Vial	2 mL Type I borosilicate glass vial, 13 mm finish
Vial Stopper	13 mm vial stopper composed of gray 4.2 1ind elastomer (bromobutyl rubber) coated with 4.2 1ind
Vial Seal	13 mm aluminum vial seal with tamper-evident polypropylene flip off cap

- a. 4.2 1ind complies with USP/National Formulary (NF) requirements for 4.2 1ind Ph. Eur. requirements for 4.2 1ind Ph. Eur. requirements for 4.2 1ind 4.2 1ind

3.2.P.7.1. Vial

BNT162b2 drug product container consists of a clear and colorless Type I borosilicate glass vial with a 2 mL nominal fill volume and 13 mm finish (lip/flange) diameter. Vials are manufactured by the companies listed in [Table 3.2.P.7-2](#). Each manufacturer utilizes the same glass cane and convert the glass cane to vial dimensions listed in the representative schematic drawings referenced below. Vials from all manufacturers have materials of construction and main dimensions that are the same and the vials from all suppliers are considered equivalent in terms of processability, container closure integrity and drug product interaction. The vial meets USP <660>, Ph. Eur. 3.2.1 and JP 7.01 requirements for Type I glass containers. The vials are sterilized and depyrogenated by dry heat as described in detail in the manufacturing section for the individual site including the reference to the validation of this step.

For information purposes, a representative schematic drawing of the vial is illustrated in [Figure 3.2.P.7-1](#). The vial manufacturing sites are listed in [Table 3.2.P.7-2](#).

Table 3.2.P.7-2. Vial Manufacturing Sites

Site	Activity
4.2 1ind	Vial manufacture location
	Vial manufacture location

3.2.P.7.1.1. Vial Dimensions

The sites are only using 2R vials according to ISO 8362-1. The main dimensions of the 2R vial are provided in Table 3.2.P.7-3.

Table 3.2.P.7-3. Vial Dimensions 2R Vial

Measurements	Limits
Finish Outside Diameter	4.2 1ind
Finish Inside Diameter	
Finish Lip Height	
Body Outside Diameter	
Overall Height	
Wall Thickness	

3.2.P.7.1.2. Vial Quality Control

The testing performed on the vials is detailed in Table 3.2.P.7-4. The supplier's certificate may be accepted for one or more tests.

Table 3.2.P.7-4. Quality Control Testing of the Vials

Test	Requirements
Visual Inspection	Performed per lot
Physical Inspection	Performed per lot
USP and Ph. Eur. Type I Glass tests	Manufacturer's certification is accepted per lot Annual verification is performed on one lot per year

3.2.P.7.2. Vial Stopper

The elastomeric closure is a vial stopper composed of 4.2 1ind gray bromobutyl rubber that is not manufactured from dry natural rubber (latex). The vial stopper meets the requirements of USP <381>, Ph. Eur. 3.2.9, and JP 7.03. Vial stoppers are sterilized by wet

heat at the drug product manufacturing site as described in detail in the manufacturing section for the individual site including the reference to the validation of this step.

For informational purposes, representative schematic drawings of the vial stopper are illustrated in Figure 3.2.P.7-2 through Figure 3.2.P.7-3. The vial stoppers are manufactured at the locations listed in Table 3.2.P.7-5.

Table 3.2.P.7-5. Vial Stopper Manufacturing Sites

Site	Activity
4.2 1ind	Stopper manufacture location

3.2.P.7.2.1. Vial Stopper Dimensions

The dimensions of the vial stoppers are provided in Table 3.2.P.7-6.

Table 3.2.P.7-6. Vial Stopper Dimensions

Measurements	Limits
Height	4.2 1ind
Plug Outside Diameter	
Flange Thickness	

3.2.P.7.2.2. Vial Stopper Quality Control

The testing performed on the vial stoppers is detailed in Table 3.2.P.7-7. Alternatively, the supplier's certificate may be accepted for one or more tests.

Table 3.2.P.7-7. Quality Control Testing of the Vial Stoppers

Test	Requirements
Visual Inspection	Performed per lot
Dimensional testing	Performed per lot
Identification of Elastomer and Silicone	Performed per lot

3.2.P.7.3. Vial Seal

The vial seal is a 13 mm flip-off design constructed of aluminum with a polypropylene tamper-evident flip-off vial seal that has no embossing.

For informational purposes, representative schematic drawings of the vial seal are illustrated in Figure 3.2.P.7-2 through Figure 3.2.P.7-3. The vial seals are manufactured at the locations listed in Table 3.2.P.7-8.

Table 3.2.P.7-8. Vial Seal Manufacturing Sites

Site	Activity
4.2 1ind	Vial seal manufacture location

Table 3.2.P.7-9. Vial Seal Dimensions

	4.2 1ind
Description	
Flip-Off Cap Diameter	
Seal Inner Diameter	
Overall Height	

The testing performed on the vial seal is detailed in Table 3.2.P.7-10. Alternatively, the supplier's certificate may be accepted for one or more tests.

Table 3.2.P.7-10. Quality Control Testing of the Vial Seal

Test	Requirements
Visual Inspection	Performed per lot
Physical Inspection	Performed per lot

3.2.P.7.4. Secondary Packaging Components

Drug product vials are placed into corrugated boxes with lids.

3.2.P.7.5. Drawings of the Packaging Components

3.2.P.7.5.1. Drawings of the Vials

Examples of the drawings of the 2R vials are presented on the following pages.

4.2 1ind

4.2 1ind 4.1(b) 4.2 1ind

4.2 1ind

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4.2 1ind

4.2 1ind	4.1(b)	4.2 1ind			
4.2 1ind	4.2 1ind	4.2 1ind	4.2 1ind	4.2 1ind	4.2 1ind
4.2 1ind	4.1(b)	4.2 1ind	4.2 1ind	4.2 1ind	4.2 1ind
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4.2 1ind					

4.2 1ind

4.2 1ind

4.2 1ind

4.1(b)

4.2 1ind