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3.2.P.7. CONTAINER CLOSURE SYSTEM – TRIS/SUCROSE DRUG PRODUCT [PUURS]

The primary container closure system for the BNT162b2 Tris/Sucrose vaccine consists of the vial components listed in Table 3.2.P.7-1.

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

Component	Description
Vial	2 mL Type I borosilicate glass vial, 4.2 1 ind. wall thickness, 13 mm finish 2 mL Aluminosilicate glass vial, 13 mm finish
Vial Stopper	13 mm vial stopper composed of gray 4.2 1 ind. elastomer (bromobutyl rubber) coated with 4.2 1 ind.
Vial Seal	13 mm aluminum vial seal with tamper-evident polypropylene flip off cap
a.	4.2 1 ind. complies with USP/National Formulary (NF) requirements for 4.2 1 ind. Ph. Eur. requirements for 4.2 1 ind. Ph. Eur. requirements for 4.2 1 ind. 4.2 1 ind.

The materials of construction for the primary packaging components in the container closure system consist of pharmacopeial grade Type 1 borosilicate glass or aluminosilicate glass for the vials and bromobutyl rubber for the stoppers. Safety data for the vials and elastomeric closure rubber formulations are provided in [Section 3.2.P.2.4 Container Closure System – Tris/Sucrose \[Puurs\]](#).

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.

The borosilicate glass vials have 4.2 1 ind. wall thickness, which is specified to distinguish between borosilicate glass vials with 4.2 1 ind. wall thickness used for PBS/Sucrose drug product.

3.2.P.7.1. Vial

BNT162b2 Tris/Sucrose drug product containers consist of a clear and colorless Type I borosilicate glass vial or an aluminosilicate glass vial with a 2 mL nominal fill volume and 13 mm finish (lip/flange) diameter.

3.2.P.7.1.1. Vial Manufacturing Sites

Vials are manufactured by the companies and at the sites listed in [Table 3.2.P.7-2](#). Each manufacturer utilizes glass cane and converts the glass cane to vials.

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

Site	Activity
4.2 1 ind.	Vial manufacture (borosilicate)
	Vial manufacture (borosilicate)
	Vial manufacture (aluminosilicate)
	Vial manufacture (aluminosilicate)
	Vial manufacture (borosilicate)

3.2.P.7.1.2. Vial Dimensions

The major dimensions of the vial are provided in Table 3.2.P.7-3.

Table 3.2.P.7-3. Vial Dimensions

Measurements	Limits
Finish Outside Diameter	4.2 1 ind.
Finish Inside Diameter	
Finish Lip Height	
Body Outside Diameter	
Overall Height	
Glass thickness ^a	

a. Glass thickness is based on the supplier drawings and is not verified upon incoming receipt.

The vials are qualified for processability, container closure integrity and drug product interaction. The vials meet USP <660>, Ph. Eur. 3.2.1 hydrolytic resistance and JP 7.01 soluble alkali test requirements for glass containers. The vials are sterilized and depyrogenated by dry heat as described in [Section 3.2.P.3.3 Fill and Finish – Tris-Sucrose \[Puurs\]](#).

3.2.P.7.1.3. Vial Quality Control

The testing performed on the vials is detailed in [Table 3.2.P.7-4](#). Alternatively, 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. hydrolytic resistance and JP soluble alkali test	Manufacturer's certification is accepted per lot Annual verification is performed on one lot per year
Identity test for aluminosilicate glass	Manufacturer's certification is accepted per lot Annual verification is performed on one lot per year

For information purposes, representative schematic drawings of the vials are illustrated in [Figure 3.2.P.7-1](#) and [Figure 3.2.P.7-2](#).

3.2.P.7.2. Vial Stopper

The vial stopper is an elastomeric closure composed of 4.2 1 ind. gray bromobutyl rubber that is not manufactured from dry natural rubber (latex).

3.2.P.7.2.1. Vial Stopper Manufacturing Sites

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 1 ind.	Stopper manufacture
	Stopper manufacture

3.2.P.7.2.2. 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 1 ind.
Plug Outside Diameter	
Flange Thickness	

3.2.P.7.2.3. 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

For informational purposes, a representative schematic drawing of the vial stopper is illustrated in [Figure 3.2.P.7-4](#).

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.

3.2.P.7.3.1. Vial Seal Manufacturing Sites

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 1 ind.	Vial seal manufacture
	Vial seal manufacture
	Vial seal manufacture

3.2.P.7.3.2. Vial Seal Dimensions

The dimensions of the vial seals are provided in [Table 3.2.P.7-9](#).

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

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

3.2.P.7.3.3. Vial Seal Quality Control

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

For informational purposes, a representative schematic drawing of the vial seal is illustrated in [Figure 3.2.P.7-5](#).

3.2.P.7.4. Secondary Packaging Components

Drug product vials are placed into corrugated boxes with lids.

Figure 3.2.P.7-1. Drawing of 4.2 1 ind. Vial

4.2 1 ind., 4.1(b)

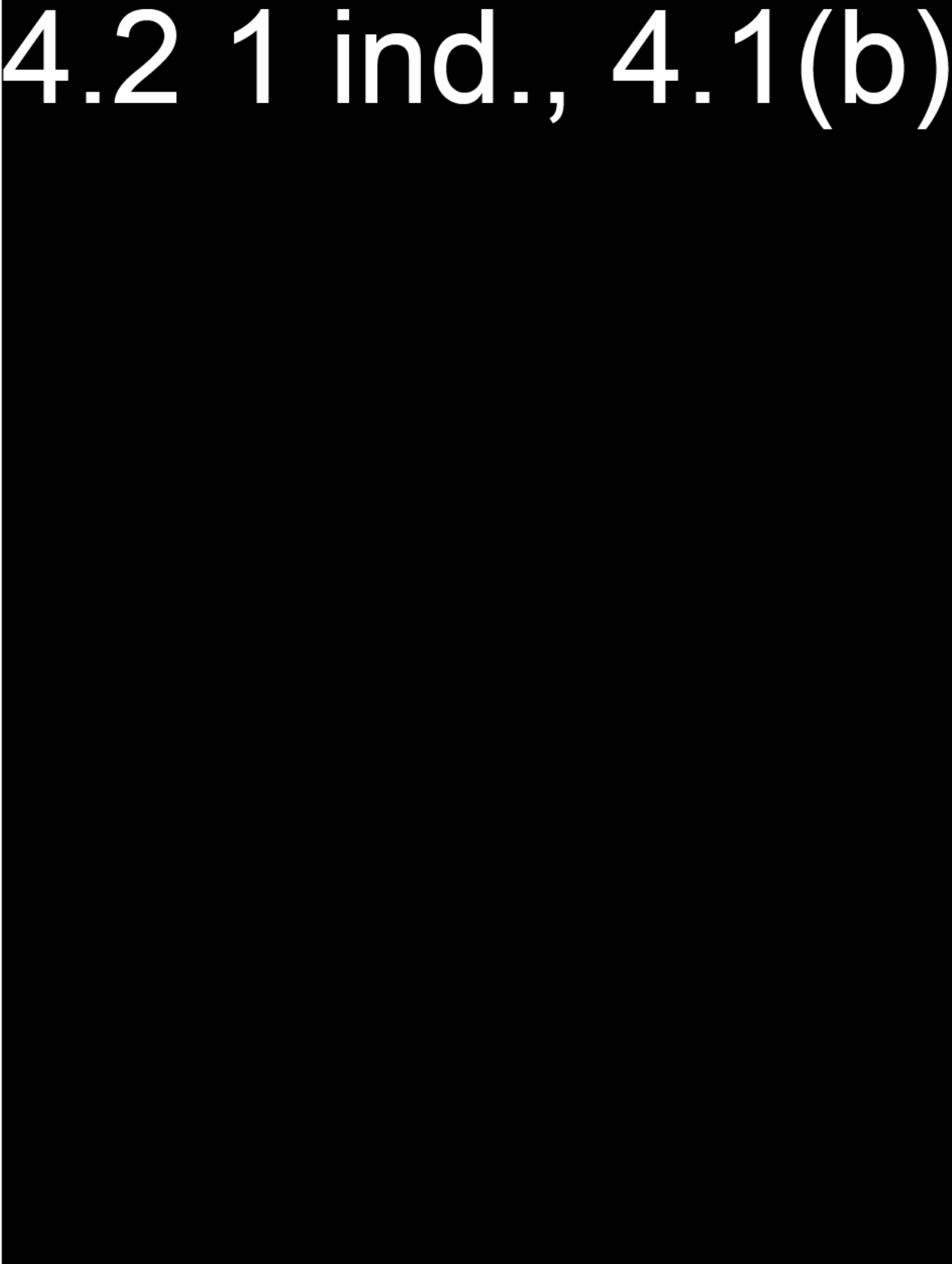


Figure 3.2.P.7-2. Drawing of  **Vial**

4.2 1 ind., 4.1(b)

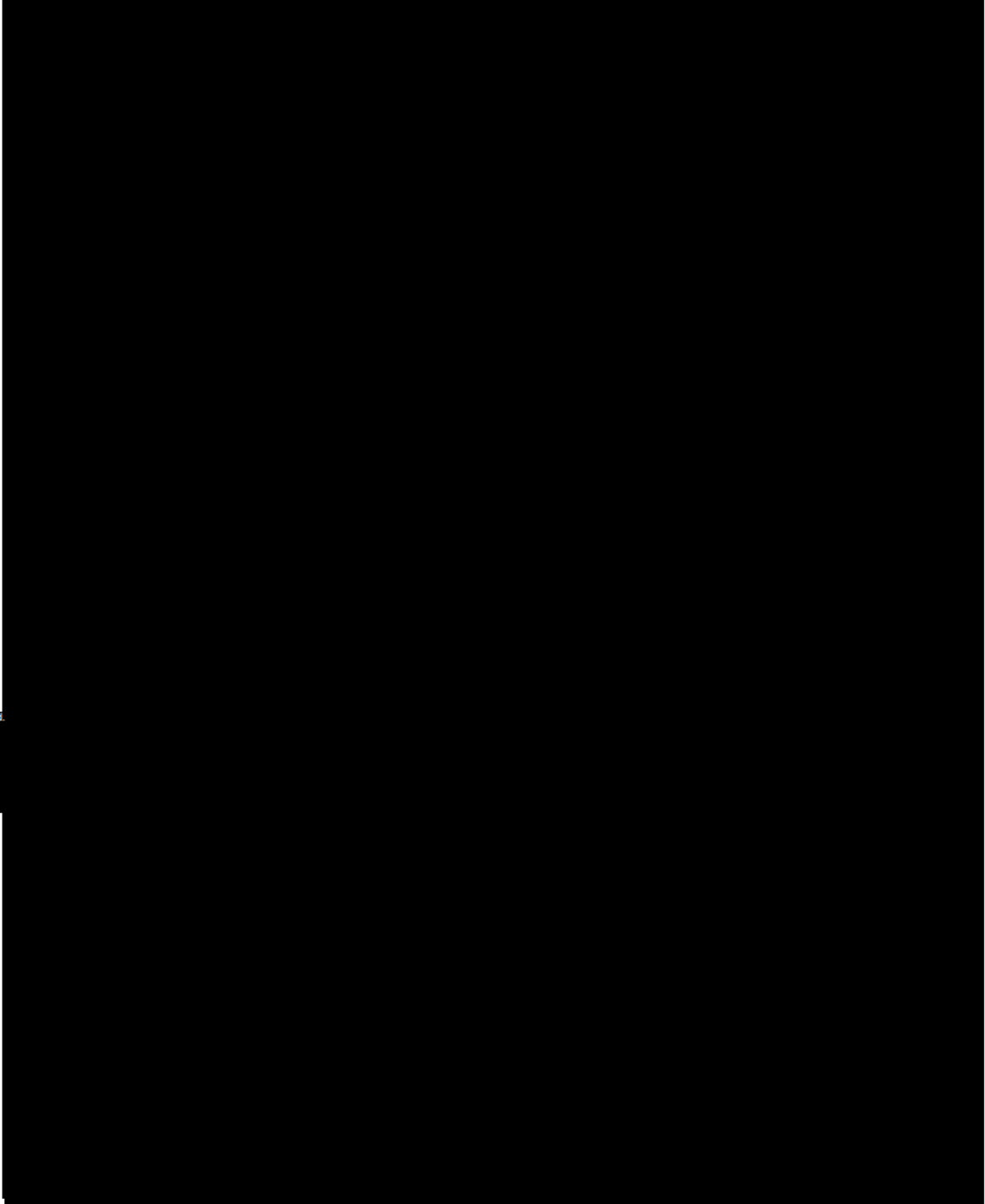


Figure 3.2.P.7-3. Drawing of 4.2 1 ind. Vial

4.2 1 ind., 4.1(b)

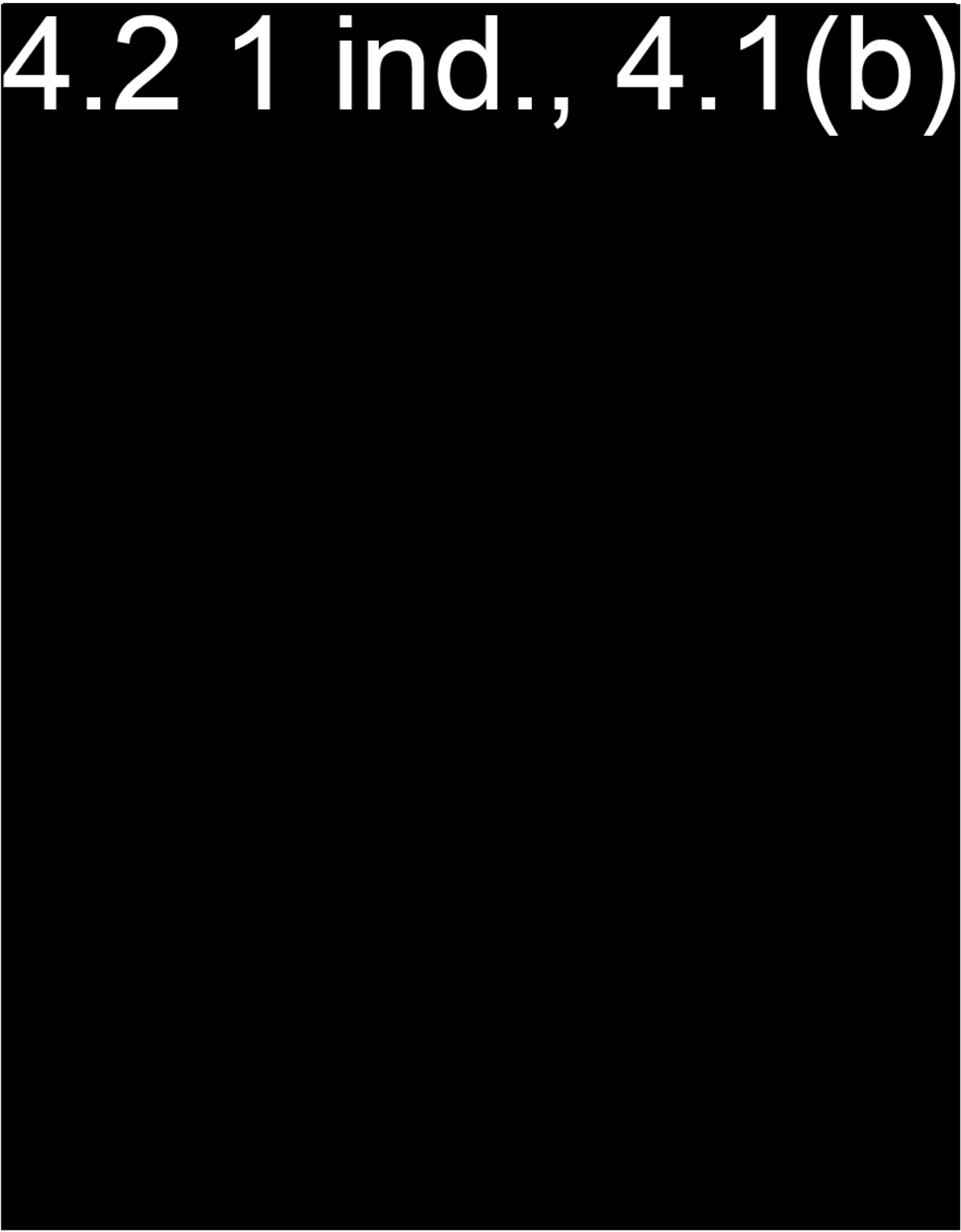


Figure 3.2.P.7-4. Drawing of 4.2 1 ind. Vial Stopper 4.2 1 ind.

4.2 1 ind., 4.1(b)

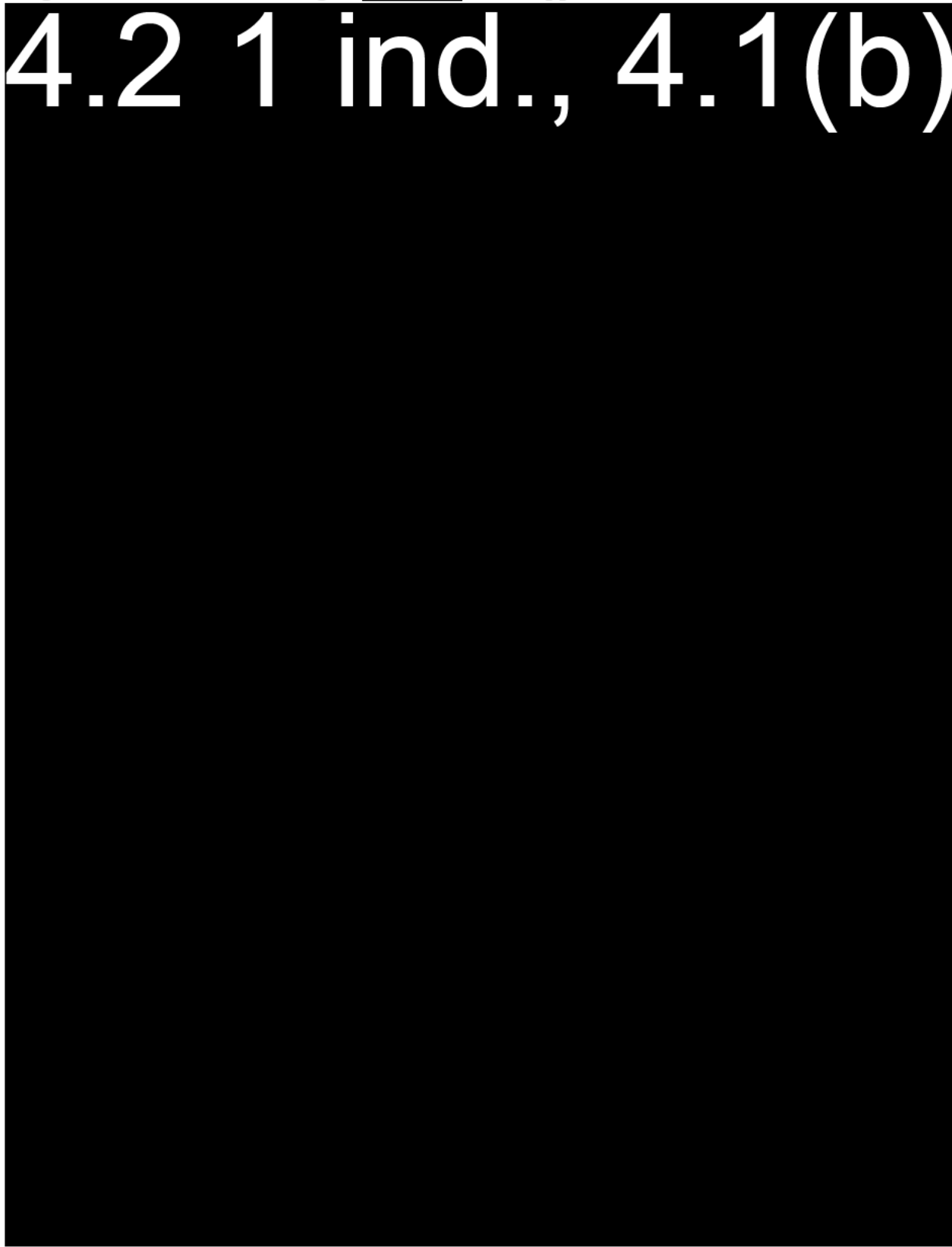


Figure 3.2.P.7-5. Drawing of 4.2 1 ind. Seal

4.2 1 ind., 4.1(b)

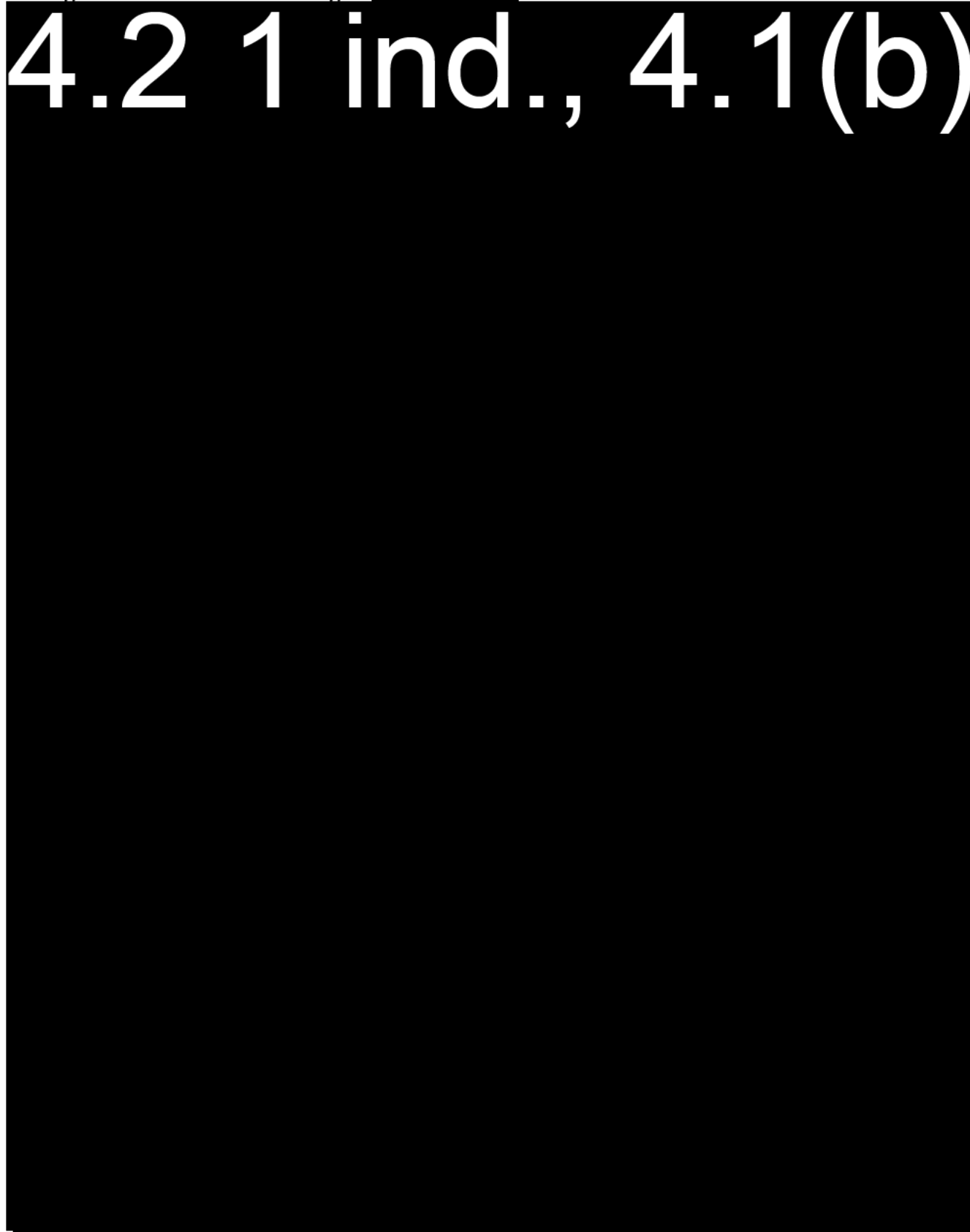


Figure 3.2.P.7-6. Drawing of 4.2 1 ind. Seal

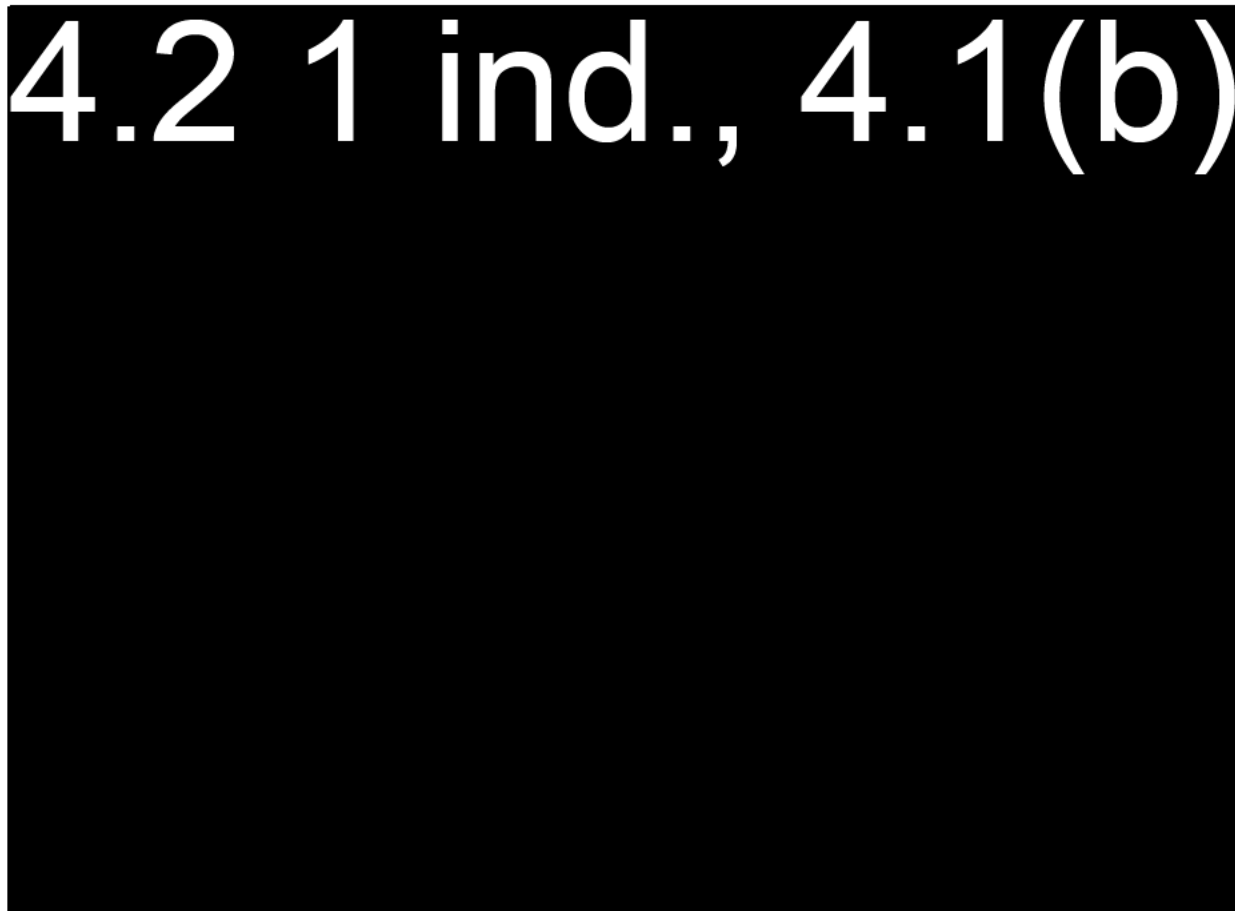


Figure 3.2.P.7-7. Drawing of 4.2 1 ind. Seal

