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P.O. Box 29475  
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**Huayi Isotopes Co.**

*The leading manufacturer of Oxygen 18 Water & PET Precursors*

**FILL-EASE™**

**Sterile Vial**

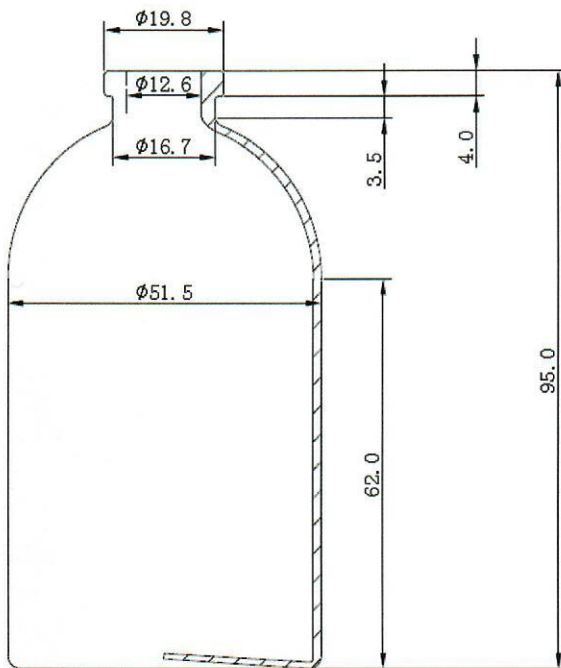
**According to cGMP Requirement**

Catalog No.: SV-100B  
Lot No.: SV-100B-200401

Date of Manufacturing: Apr. 2020  
Expiry Date: Apr. 2022

**Product Description**

Unit: mm



Filling Volume: 107.0ml ± 2.0ml  
Height: 95.0mm ± 1.0mm  
Thickness of bottle-lip: 4.0mm ± 0.3mm  
Height of bottle-neck: 3.5mm ± 0.3mm  
Effective height of bottle-body: 62.0mm ± 2.0mm  
Outer diameter of bottle-mouth: 19.8mm ± 0.2mm  
Inner diameter of bottle-mouth: 12.6mm ± 0.2mm  
Outer diameter of bottle-neck: 16.7mm ± 0.5mm  
Body diameter: 51.5mm ± 0.6mm  
Material: Neutral borosilicate glass  
(PB-053)  
Sealing type: Chlorobutyl rubber stopper  
(PC-003)  
Cap: 20mm aluminum cap  
(PA-013)

**Note**

- The product should be stored at room temperature.
- Manufactured according to requirements of cGMP, ISO 9001 and ISO 13485.
- We certify that all test results meets the acceptable criteria of Huayi specification current QS-SV.
- Tested for sterility and Bacterial endotoxins.

**Drafted**

Xingqi Huang Date: 2020.05.20

**Reviewed**

Siqing Lv Date: 2020.05.20

**Approved**

Jie Shen Date: 2020.05.20



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### Certificate of Analysis

| Step/Procedure      | Method                                 | Specification                                   | Result                                       |
|---------------------|--|---|--|
| <b>Materials</b>    |  |   |  |
| Vial                | Current USP<660><br>Current EP<3.2.1>  | Neutral borosilicate glass;<br>PB-053           | Lot No.: 1910030/1912014                     |
| Stopper             | Current USP<381><br>Current EP<3.2.9>  | Chlorobutyl rubber stopper, no<br>latex; PC-003 | Lot No.: 1912035                             |
| Cap                 | In house                               | 20mm aluminum cap; PA-013                       | Lot No.: 1910037                             |
| Appearance          | Visual inspection                      | Integrity ,no obvious spots and<br>scratches    | Integrity ,no obvious spots and<br>scratches |
| Test for sterility  | Current USP<71><br>Current EP<2.6.1>   | Passed test                                     | Passed test                                  |
| Bacterial Endotoxin | Current USP<85><br>Current EP<2.6.14>  | ≤ 0.25 EU/mL                                    | Conforms                                     |
| Particles, ≥25 μm   | Current USP<788><br>Current EP<2.9.19> | < 150   | 49   |
| Particles, ≥10 μm   | Current USP<788><br>Current EP<2.9.19> | < 1500  | 57   |
| Sealing Capacity    | In house                               | No leak   | No leak                                      |