



# Huayi Isotopes Co.

The leading manufacturer of Oxygen 18 Water & PET Precursors

## FILL-EASE™

### Sterile Vial

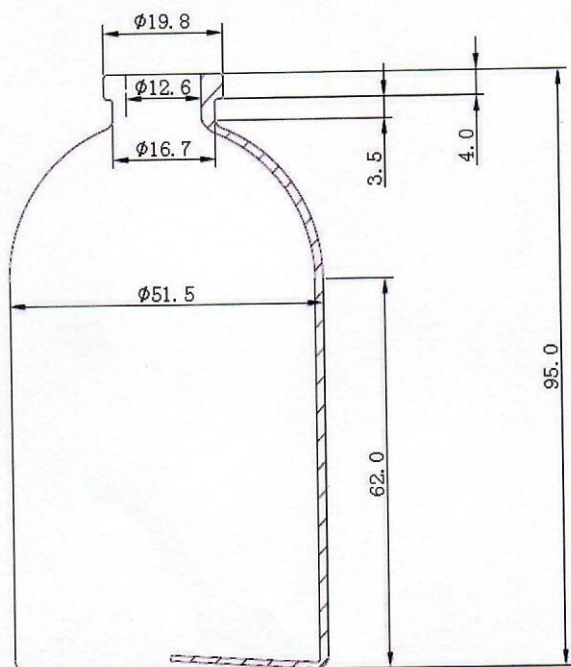
### According to cGMP Requirement

Catalog No.: SV-100B  
Lot No.: SV-100B-210501

Date of Manufacturing: May. 2021  
Expiry Date: May. 2023

### 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.
- 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: 2021.05.29

Reviewed

Siqing Lv

Date: 2021.05.29

Approved

Jie Shen

Date: 2021.05.29





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### Certificate of Analysis

Step/Procedure	Method	Specification	Result
<b>Materials</b>			
Vial	Current USP<660> Current EP<3.2.1>	Neutral borosilicate glass; PB-053	Lot No.: 2003102/2010011
Stopper	Current USP<381> Current EP<3.2.9>	Chlorobutyl rubber stopper, no latex; PC-003	Lot No.: 2012014
Cap	In house	20mm aluminum cap; PA-013	Lot No.: 2011037
Appearance	Visual inspection	Integrity ,no obvious spots and scratches	Integrity ,no obvious spots and scratches
Test for sterility	Current USP<71> Current EP<2.6.1>	Passed test	Passed test
Bacterial Endotoxin	Current USP<85> Current EP<2.6.14>	≤ 0.25 EU/mL	Conforms
Particles, ≥25 μm	Current USP<788> Current EP<2.9.19>	< 150	33
Particles, ≥10 μm	Current USP<788> Current EP<2.9.19>	< 1500	57
Sealing Capacity	In house	No leak	No leak