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P.O. Box 29475  
San Francisco, CA 94129

**Huayi Isotopes Co.**

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

## FILL-EASE™

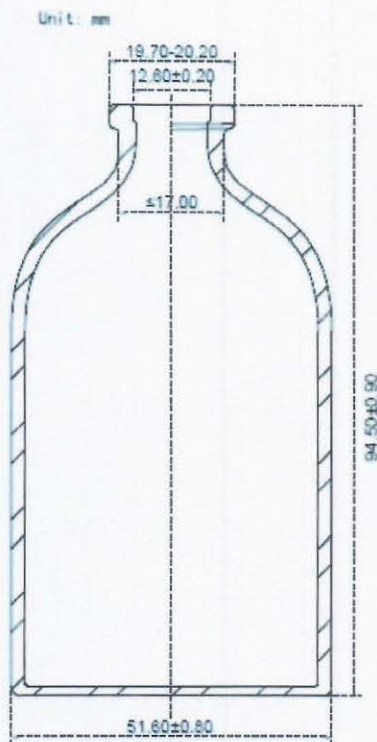
### Sterile Vial

### According to cGMP Requirement

Catalog No.: SV-100B  
Lot No.: SV-100B-231101

Date of Manufacturing: Nov. 2023  
Expiry Date: Nov. 2025

### Product Description



Filling Volume: 107.0ml ± 2.0ml  
 Height: 94.50mm ± 0.90mm  
 Outer diameter of bottle-mouth: 19.70mm-20.20mm  
 Inner diameter of bottle-mouth: 12.60mm ± 0.20mm  
 Outer diameter of bottle-neck: ≤ 17.00mm  
 Body diameter: 51.60mm ± 0.80mm  
 Material: Neutral borosilicate glass  
 (PB-138)  
 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.

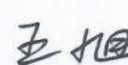
Drafted

  
Xingqi Huang Date: 2024.01.02

Reviewed

  
Ying Lu Date: 2024.01.02

Approved

  
Xu Wang Date: 2024.01.02



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**Sterile Vial**

**According to cGMP Requirement**

Catalog No.: SV-100B  
Lot No.: SV-100B-231101

Date of Manufacturing: Nov. 2023  
Expiry Date: Nov. 2025

**Certificate of Analysis**

Step/Procedure	Method	Specification	Result
<b>Materials</b>			
Vial	Current USP<660> Current EP<3.2.1>	Neutral borosilicate glass; PB-138	Lot No.: 2307003
Stopper	Current USP<381> Current EP<3.2.9>	Chlorobutyl rubber stopper, no latex; PC-003	Lot No.: 2311033
Cap	In house	20mm aluminum cap; PA-013	Lot No.: 2306008
Appearance	Visual inspection	Integrity, no obvious spots and scratches, essentially free of visible particulate	Integrity, no obvious spots and scratches, essentially free of visible particulate
Test for sterility	Current USP<71> Current EP<2.6.1> Current ChP<1101>	Passed test	Passed test
Bacterial Endotoxin	Current USP<85> Current EP<2.6.14> Current ChP<9251>	≤ 0.25 EU/mL	Conforms
Particles, ≥25 μm	Current USP<788> Current EP<2.9.19> Current ChP<0903>	< 150	30
Particles, ≥10 μm	Current USP<788> Current EP<2.9.19> Current ChP<0903>	< 1500	59
Sealing Capacity	In house Current USP<1207.2>	No leak	No leak