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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**

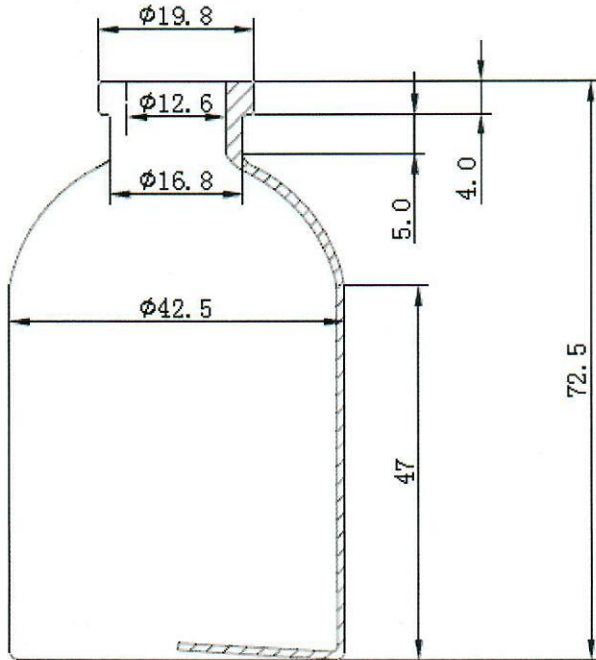
**According to cGMP Requirement**

Catalog No.: SV-50A04  
Lot No.: SV-50A04-200501

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

**Product Description**

Unit: mm



Filling Volume: 54.0ml ± 1.5ml  
Height: 72.5mm ± 0.5mm  
Thickness of bottle-lip: 4.0mm ± 0.3mm  
Height of bottle-neck: 5.0mm ± 0.5mm  
Effective height of bottle-body: 47mm ± 1mm  
Outer diameter of bottle-mouth: 19.8mm ± 0.2mm  
Inner diameter of bottle-mouth: 12.6mm ± 0.2mm  
Outer diameter of bottle-neck: 16.8mm ± 0.3mm  
Body diameter: 42.5mm ± 0.4mm  
Material: Neutral borosilicate glass  
(PB-012)  
Sealing type: Chlorobutyl rubber stopper  
(PC-024C)  
Cap: 20mm central hole cap  
(PA-041)

**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**

**Reviewed**

**Approved**

Xingqi Huang

Date: 2020.06.16

Siqing Lv

Date: 2020.06.16

Jie Shen

Date: 2020.06.16



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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-012	Lot No.: 1810005/1912015
Stopper	Current USP<381> Current EP<3.2.9>	Chlorobutyl rubber stopper, no latex; PC-024C	Lot No.: 2001023
Cap	In house	20mm central hole cap; PA-041	Lot No.: 1911010
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	41
Particles, ≥10 μm	Current USP<788> Current EP<2.9.19>	< 1500	57
Sealing Capacity	In house	No leak	No leak