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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

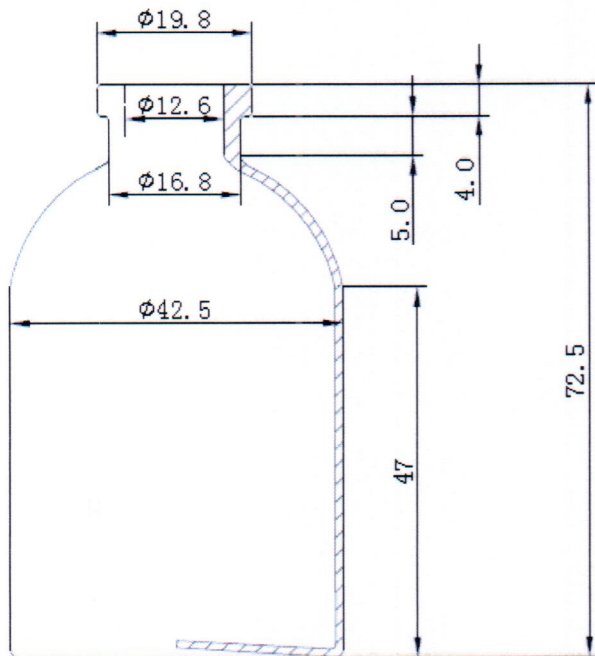
According to cGMP Requirement

Catalog No.: SV-50A04
Lot No.: SV-50A04-191101

Date of Manufacturing: Nov. 2019
Expiry Date: Nov. 2021

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-024)
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

Xingqi Huang Date: 2019.12.11

Reviewed

Siqing Lv Date: 2019.12.11

Approved

Jie Shen Date: 2019.12.11



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Certificate of Analysis

Step/Procedure	Method	Specification	Result
Materials			
Vial	Current USP<660> Current EP<3.2.1>	Neutral borosilicate glass; PB-012	Lot No.: 1803037/1810005
Stopper	Current USP<381> Current EP<3.2.9>	Chlorobutyl rubber stopper, no latex; PC-024	Lot No.: 1906025
Cap	In house	20mm central hole cap; PA-041	Lot No.: 1907037
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