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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™

Sample

Sterile Vial

According to cGMP Requirement

Catalog No.: SV-50A04

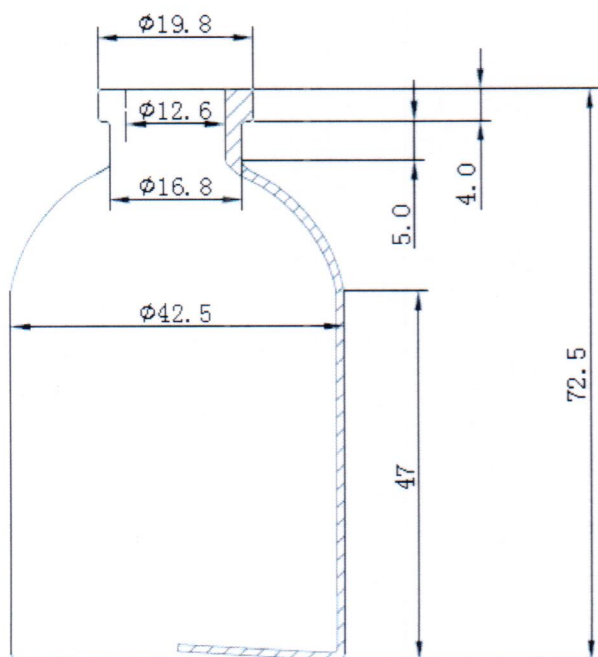
Lot No.: SV-50A04-T190401

Date of Manufacturing: Apr. 2019

Expiry Date: Apr. 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.

QC Drafted

Xingqi Huang

Date: 2019.04.22

QC Reviewed

Ying Lu

Date: 2019.04.22

QA Approved

Xiaoli Wu

Date: 2019.04.22



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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
Stopper	Current USP<381> Current EP<3.2.9>	Chlorobutyl rubber stopper, no latex; PC-024	Lot No.: 1804033
Cap	In house	20mm central hole cap; PA-041	Lot No.: 1712024
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	TBD
Bacterial Endotoxin	Current USP<85> Current EP<2.6.14>	< 0.03 IU/ml	TBD
Particles, ≥25 μm	Current USP<788> Current EP<2.9.19>	< 150	TBD
Particles, ≥10 μm	Current USP<788> Current EP<2.9.19>	< 1500	TBD
Sealing Capacity	In house	No leak	No leak