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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-30C02

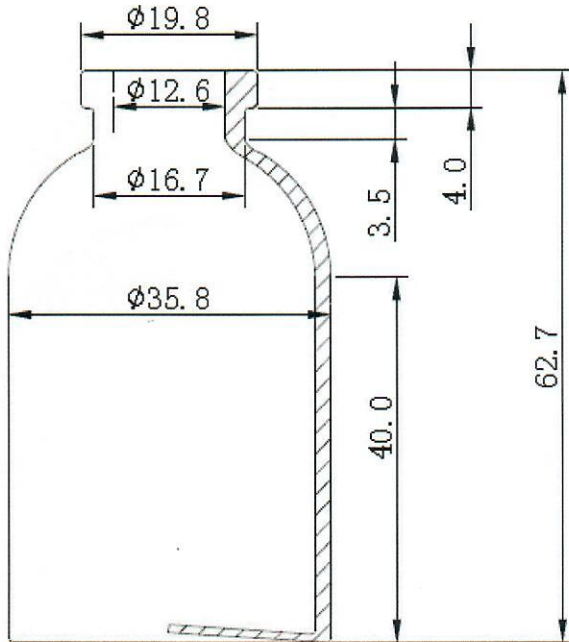
Lot No.: SV-30C02-200501

Date of Manufacturing: May, 2020

Expiry Date: May, 2022

Product Description

Unit: mm



Filling Volume: 33.0ml±1.0ml

Height: 62.7mm±0.5mm

Thickness of bottle-lip: 4.0mm±0.3mm

Height of bottle-neck: 3.5mm±0.3mm

Effective height of bottle-body: 40.0mm±1.0mm

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: 35.8mm±0.3mm

Material: Neutral borosilicate glass

(PB-011)

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: 2020.05.28

Reviewed

Siqing Lv

Date: 2020.05.28

Approved

Jie Shen

Date: 2020.05.28



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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-011	Lot No.: 1910031/2003101
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.: 1907037/1911010
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	65
Sealing Capacity	In house	No leak	No leak