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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

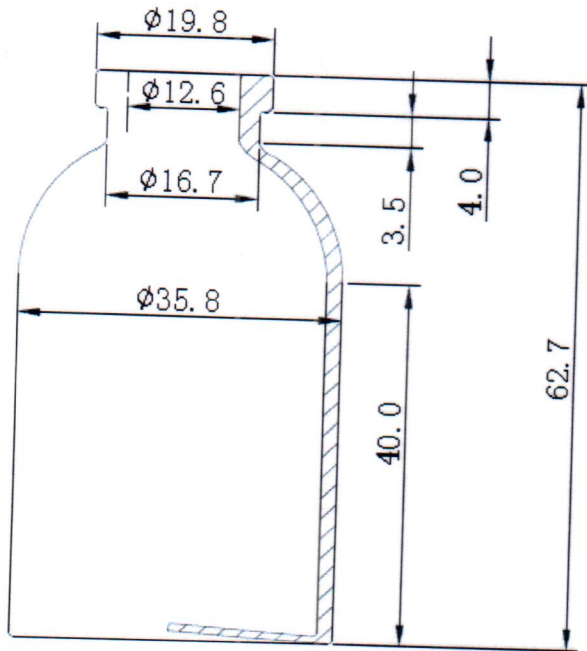
Lot No.: SV-30C02-190701

Date of Manufacturing: Jul. 2019

Expiry Date: Jul. 2021

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: 2019.08.08

Reviewed

Siqing Lv Date: 2019.08.08

Approved

Jie Shen Date: 2019.08.08



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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.: 1811025
Stopper	Current USP<381> Current EP<3.2.9>	Chlorobutyl rubber stopper, no latex; PC-024	Lot No.: 1904017
Cap	In house	20mm central hole cap; PA-041	Lot No.: 1906033
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