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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

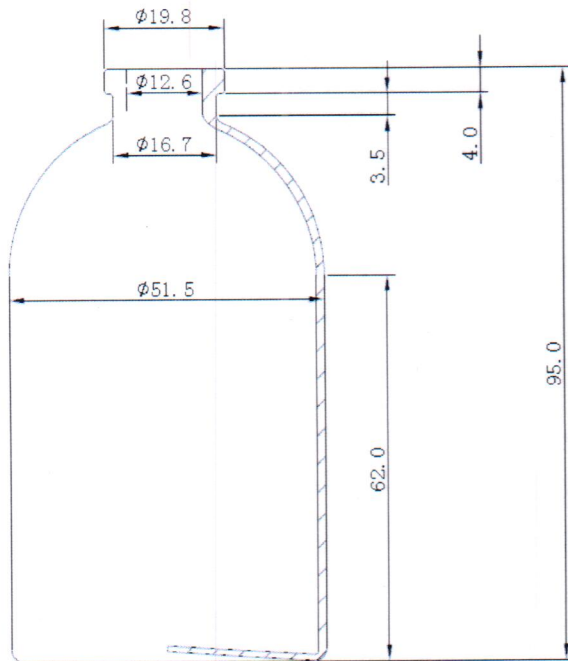
According to cGMP Requirement

Catalog No.: SV-100B
Lot No.: SV-100B-191101

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

Product Description

Unit: mm



Filling Volume: 107.0ml ± 2.0ml
Height: 95.0mm ± 1.0mm
Thickness of bottle-lip: 4.0mm ± 0.3mm
Height of bottle-neck: 3.5mm ± 0.3mm
Effective height of bottle-body: 62.0mm ± 2.0mm
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: 51.5mm ± 0.6mm
Material: Neutral borosilicate glass
(PB-053)
Sealing type: Chlorobutyl rubber stopper
(PC-003)
Cap: 20mm aluminum cap
(PA-013)

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: 2019.12.19

Reviewed

Siqing Lv

Date: 2019.12.19

Approved

Jie Shen

Date: 2019.12.19



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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-053 | Lot No.: 1910030 |
| Stopper | Current USP<381> Current EP<3.2.9> | Chlorobutyl rubber stopper, no latex; PC-003 | Lot No.: 1905022 |
| Cap | In house | 20mm aluminum cap; PA-013 | Lot No.: 1907039 |
| 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 |