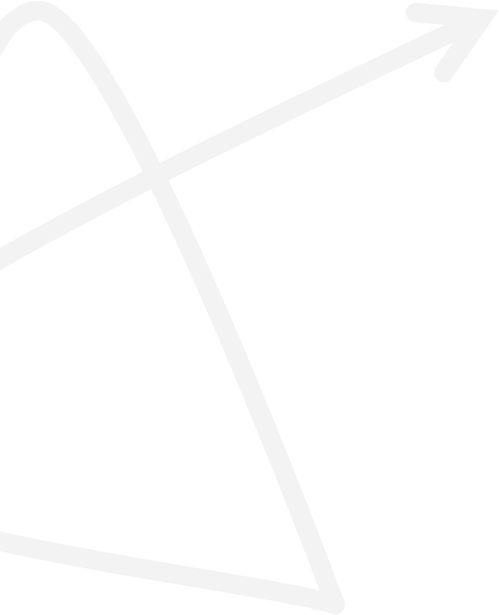
CIN NO : U33204MH2022PTC387499 **CERTIFICATE OF ANALYSIS**



|  |  |  |  |
| --- | --- | --- | --- |
| **Product Name** | 5ml Lt Glass Barrel | | |
| **Batch No** | S250011221 | | |
| **Effective date:** | 12/2021 | **Review before:** | 11/2026 |
| **Shelf Life** | 60 Months | | Page no: 1 of 2 |

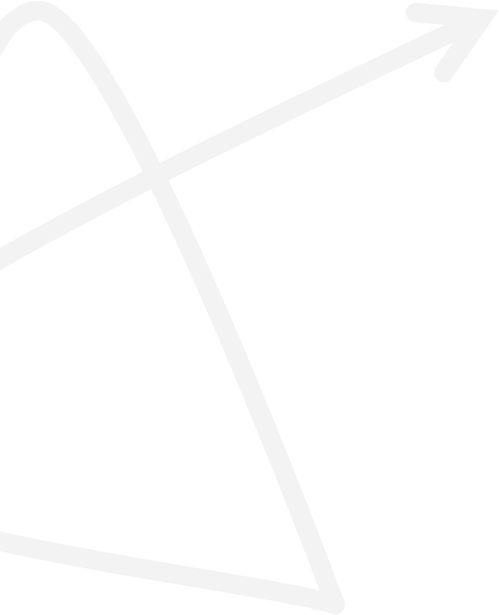
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| --- | --- | --- | --- |
| **Sr. No.** | **Tests** | **Results** | **Specifications** |
| 1 | Description | Complies | 5 ml glass barrels (USP type 1) as free as any visual defects and should be well clean & having a smooth surface free from cracks or pin holes |
| 2 | Over flow Capacity | 7.2 ml | Not less than 7.0 ml |
| 3 | Outer Diameter (*d*1) (D1) | 14.45 mm | 14.45 mm ± 0.10 mm |
| 4 | Inner Diameter (*d*2) (D2) | 11.90 mm | 11.85 mm ± 0.20 mm |
| 5 | Bottom Inner Diameter (*d*5) | 11.45 mm | 11.45 mm min |
| 6 | Length (*l*1) (L1) | 66.80 mm | 66.70 mm ± 0.75 mm |
| 7 | Total Length (*l*2) (L2) | 88.05 mm | 88.00 mm ± 0.75 mm |
| 8 | Thickness (*s*1) (*d*1-*d*2)/2 | 1.27 mm |  |
| 9 | Flange Diameter (*d*3) (D3) | 23.00 mm | 23.00 mm ± 1.00 mm |
| 10 | Flange Thickness (*h*1) (T1) | 2.40 mm | 2.40 mm ± 0.50 mm |
| 11 | Tip Top Site (*d*6) (D6) | 4.05 mm | 4.04 mm ± 0.07 mm |
| 12 | Tip Diameter (*d*7) (D7) | 4.40 mm | 4.04 mm ± 0.07 mm |
| 13 | Silicone Oil | 2.7 | Not more than 3 mg per barrel |
| 14 | Ethylene Oxide | Less than 10 ppm | Not more than 10 ppm |

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| --- | --- | --- | --- | --- |
|  | Prepared By | Reviewed By | Checked By | Approved By |
| Name |  |  |  |  |
| Signature |  |  |  |  |
| Date |  |  |  |  |
| Section | Quality Control | Quality Control | Quality Control | Quality Assurance |

210, Samruddhi Commercial Complex, Mind Space, Off Link Road, Malad (W). Mumbai – 400064. India.

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| --- | --- | --- | --- |
| 15 | Sterility Test | Complies | Should be sterile |
| 16 | Hydrolytic Resistance | | |
|  | Test 1 (Surface test) | 1.4 ml | Not more than 1.8 ml of 0.01 M hydrochloric acid should be required to neutralize the 100 ml of sample solution |
|  | Test 2 | 1.0 ml | Not more than 1.8 ml of 0.01 M hydrochloric acid should be required to neutralize the 100 ml of sample solution |
| 17 | Bacterial Endotoxins | Less than 0.25 EU/ml | Not more than 0.25 EU/ml |
| 18 | Particulate Matter | | |
|  | Particle Size: ≥ 10µm | 270 | Not more than 600 per barrel |
|  | Particle Size: ≥ 25µm | 22 | Not more than 60 per barrel |
| 19 | Gliding Force | 6.1 N | <10 Newton |
| 20 | Siliconization powder test | Complies | Should be proper, homogenized sticking of the powder in inner surface of barrel. |
| Conclusion: The sample complies with the above mention test specification. | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
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