CIN NO : U33204MH2022PTC387499 **CERTIFICATE OF ANALYSIS**



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| **Product Name** | 1 ml LT COC Barrel |
| **Batch No** | P310011221 |
| **Mfg. Date:** | 12/2021 | **Exp. Date:** | 11/2026 |
| **Shelf Life** | 60 Months | Page no: 1 of 2 |

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| **Sr. No.** | **Tests** | **Results** | **Specifications** |
| 1 | Description | Complies | Transparent plastic barrel of 1 ml, free from any visual defects and should be well clean and having smooth surface, free from cracks and pin holes |
| 2 | Leakage Test | Complies | There should not be any signs of leakage from any container observed after 24 hours. |
| 3 | Appearance of solution | Complies | Solution S should be clear and colorless and should practically be free from foreign particles. |
| 4 | Acidity or Alkalinity | 0.1 ml | Not more than 0.3ml of 0.01M sodium hydroxide or 0.01 M hydrochloric acid should be required to change the color of indicator. |
| 5 | Absorbance | 0.10 | The absorbance at 230 nm to 360 nm should not be more than 0.40 |
| 6 | Reducing substance | Complies | The difference between the titration volumes should not be more than 3.0 ml |
| 7 | Transparency | Complies | The cloudiness of the suspension should be perceptible when viewed through the container and compared with a similar container filled with water. |
| 8 | Nonvolatile Residue | Complies | The difference between the amounts obtained from the sample and the blank should not exceed 15 mg |
| 9 | Residue on Ignition | Complies | The difference between the amounts of residue on ignition obtained from the sample and the blank does not exceed 5 mg |

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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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| 10 | Heavy Metals | 0.6 ppm | Not more than 1 ppm |
| 11 | Buffering Capacity | Complies | The difference between the two volumes should not be greater than 10 ml, and if acid was required for either the sample or blank and alkali for the other, the total of the two volumes required should not be greater than 10 ml |
| 12 | Total length (*l)* (L2) | 46.10 mm | 46.05 mm ± 0.20 mm |
| 13 | Length of barrel (*l*1) (L1) | 35.95 mm | 35.90 mm ± 0.20 mm |
| 14 | Outer diameter (*d*1) (D1) | 10.90 mm | 10.85 mm ± 0.10 mm |
| 15 | Inner diameter (*d*2) (D2) | 8.65 mm | 8.65 mm ± 0.10 mm |
| 16 | Flange diameter (*d*3) (D3) | 17.75 mm | 17.75 mm ± 0.10 mm |
| 17 | Flange cut diameter (*d*4) (D4) | 14.70 mm | 14.70 mm ± 0.10 mm |
| 18 | Flange Thickness (*h*1) (T1) | 2.20 mm | 2.20 mm ± 0.10 mm |
| 19 | Over Flow Capacity | 13.72 ml | Not less than 1.8 ml |
| 20 | Safety Test | Complies | During the observation period none of the animals treated with the extract shows a significantly greater biological reactivity than the animals treated with the blank. |
| 21 | Bacterial Endotoxin Test | Less than 0.25 EU/Barrel | Not more than 0.25 EU/barrel |
| 22 | Sterility Test | Sterile | Should be sterile |
| 23 | Particulate Matter |
|  | Particle Size: ≥ 10µm | 250 | Not more than 600 per barrel |
|  | Particle Size: ≥ 25µm | 18 | Not more than 60 per barrel |
| 24 | Ethylene Oxide | Less than 1 ppm | Not more than 1 ppm |
| 25 | Residue of Silicone Oil | 0.7 mg/barrel | Not more than 1mg/barrel |
| 26 | Gliding Force | 5.0 N | <10 Newton |
| 27 | 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 Specifications |

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