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Master File QC specification

|  |  |  |  |
| --- | --- | --- | --- |
| **File Name** | Master File Qc R Test | **Prepared by** |  |
| **QC File Code/Number** |  | **Checked By** |  |
| **QC File Code/Number** |  | **Approved By** |  |
| **Effective Date** |  |  |  |
| **Revision Date** |  |  |  |

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**R-Test raw material (Uncut sheet)**

**Sr. No: 1.1**

**Specification: Supplier Name:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Performance Test** | | | | |
| **Test description** | | **Acceptance Level** | **Criteria** | **Protocol** | |
| **1.** | **Positivity** | Blood/Serum/Urine/Fluid Positive | Positive | 1-2 Drop of Sample, 2 Drops of Buffer | |
| **2.** | **Negativity** | 50 Negative Samples | Negative | 1-2 Drops of Sample, 2 Drops of Buffer | |
| **3.** | **LOD** | L1  L2  L3  L4  L5  L6  L7  L8  L9  L10 | Positive (1/2) | Serial Dilution | |
| Positive (1/4) | Serial Dilution | |
| Positive (1/8) | Serial Dilution | |
| Positive (1/16) | Serial Dilution | |
| Positive (1/32) | Serial Dilution | |
| Positive (1/64) | Serial Dilution | |
| Positive (1/128) | Serial Dilution | |
| Positive (1/256) | Serial Dilution | |
| Positive (1/512) | Serial Dilution | |
| Positive (1/1024) | Serial Dilution | |
| **4.** | **Precision** | Uniform result | 10 Replicates | 1-2 drops of sample, 2 drops of buffer | |
| **5.** | **Buffer** | Uniform Negative result | 10 Replicates | 2 drops of buffer | |
| **6.** | **Flow time** | Within 2 Minutes | 10 Replicates | 1-2 drops of sample or 2 drops of buffer | |
| **7.** | **Serum** | Uniform Negative Result | 10 Replicates | 1-2 drops of sample, 2 drops of buffer | |

|  |  |  |
| --- | --- | --- |
| **Sr. #** | **Parameters** | **Specifications** |
| **1.** | **Physical Appearance** | The shape of the uncut sheet shall be smooth & uniform. No dislocation of pads. |
| **2.** | **Dimensions** | 300 mm \* 60 mm ± 5 |

**R-Test raw material (Diluent/ Buffer)**

**Sr. No: 1.2**

**Specification:**

**Supplier Name: **

|  |  |  |
| --- | --- | --- |
|  | **QC Inspection Parameters for Buffer** | |
| **1.** | **Parameter** | **Specification/Method** |
| **2.** | **Appearance** | Visual Inspection |
| **3.** | **Color** | Visual Observation |
| **4.** | **Odor** | Sensory check |
| **5.** | **pH** | 7.9 ±0.3 |
| **6.** | **Volume** | 1 liter |
| **7.** | **Shaking/ Mixing** | Min 1 hour |
| **8.** | **Sterility (if required)** | TSB/FTM incubation at 20–35°C |
| **9.** | **Conductivity (optional)** | Conductivity meter |
| **10.** | **Osmolality**  **(optional)** | Osmometer |
| **11.** | **Sensitivity & specificity** | No false positive or negative |
| **12.** | **Documentation Review** | COA, MSDS, etc. |

**R-Test raw material (Plastic cassette) Type D**

**Sr. No: 1.3.1**

|  |  |  |
| --- | --- | --- |
| **Sr. #** | **Parameters** | **Specifications** |
|  | **Physical Appearance** | No damage, clean, no discoloration |
|  | **Cassette Size** | ***20mm\*70mm*** with ***17mm*** reading window. |
|  | **Coordinate** | Coordination Top & Bottom |
|  | **Window Size** | 17mm × 5mm ± 0.2mm |
|  | **Fitment Check/Tightness** | Cassette pinching/ Strip fitment |
|  | **Falling Test** | Cassette should be tightly fit |
|  | **Printing** | Observe the logo on cassette |
|  | |  | | --- | | **Weight** | | |  | | --- | | 3.5g ± 0.2g | |
|  | |  | | --- | | **Flow Observation** | | Uniform flow, no leaks or blockages |
|  | **Packaging** | Intact, clean, correctly labeled |

**Specification:**

**Supplier Name: **

**R-Test raw material (Plastic cassette) Type A**

**Sr. No: 1.3.2**

|  |  |  |
| --- | --- | --- |
| **Sr. #** | **Parameters** | **Specifications** |
|  | **Physical Appearance** | No damage, clean, no discoloration |
|  | **Cassette Size** | ***28mm\*70mm*** with ***17mm*** reading window |
|  | **Coordinate** | Coordination Top & Bottom |
|  | **Window Size** | 17mm × 5mm ± 0.2mm |
|  | **Fitment Check/Tightness** | Cassette pinching/ Strip fitment |
|  | **Falling Test** | Cassette should be tightly fit |
|  | **Printing** | Observe the logo on cassette |
|  | |  | | --- | | **Weight** | | |  | | --- | | 3.5g ± 0.2g | |
|  | |  | | --- | | **Flow Observation** | | Uniform flow, no leaks or blockages |
|  | **Packaging** | Intact, clean, correctly labeled |

**Specification:**

**Supplier Name: **

**R-Test raw material (Plastic cassette) Type M**

**Sr. No: 1.3.3**

|  |  |  |
| --- | --- | --- |
| **Sr. #** | **Parameters** | **Specifications** |
|  | **Physical Appearance** | No damage, clean, no discoloration |
|  | **Cassette Size** | ***21.6mm\*69.6mm*** with **2.8\*16.6** ***mm*** reading window. |
|  | **Coordinate** | Coordination Top & Bottom |
|  | **Window Size** | 16mm × 5mm ± 3mm |
|  | **Fitment Check/Tightness** | Cassette pinching/ Strip fitment |
|  | **Falling Test** | Cassette should be tightly fit |
|  | **Printing** | Observe the logo on cassette |
|  | |  | | --- | | **Weight** | | |  | | --- | | 3.5g ± 0.2g | |
|  | |  | | --- | | **Flow Observation** | | Uniform flow, no leaks or blockages |
|  | **Packaging** | Intact, clean, correctly labeled |

**Specification:**

**Supplier Name: **

**R-Test raw material (Alu- pouch)**

**Sr. No: 1.4**

**Specification:**

**Supplier Name: **

|  |  |  |
| --- | --- | --- |
| **Sr. #** | **Parameters** | **Specifications** |
| **2.** | **Physical Characteristics** | Clean, Smooth, laminated with fine color quality |
|  | **Quality** | Pouch have ALU and looks hard Havey from normal pouch. |
| **3.** | **Dimensions & Specifications** | Length: 120mm; Width = 65mm & Weight = 1.48g |
| **4.** | **Flame Resistance Test** | The pouch must be resisting 2-3 sec not catch fire/Sustainable for sometime |
| **5.** | **Sealing Integrity Test/Leak test** | No leakage and no air release found under high pressure in Leak tester (BK-134). |
| **6.** | **Color Fastness Test** | Acidic water and sodium hypochlorite is used to check the color; no discoloration and fadedness found |
| **7.** | **Humidity & Temperature Effect** | Alu foil pouches were subjected to high humidity (60%-70%) and high temperature (50 C) independently with indicator desiccants inside. |

**R-Test raw material (Desiccant)**

**Sr. No: 1.5**

**Specification:**

**Supplier Name: **

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Test No.** | **Test Description** | **Test Condition** | **Duration** | **Measurements** |
| 1 | Initial Moisture Content | Room Temperature (25°C) and 50% RH | 24 hrs. | Weight of desiccant before and after conditioning |
| 2 | Adsorption Isotherm | Various RH levels (e.g., 10%, 30%, 50%, 70%, 90%) | Equilibrium | Moisture adsorption at each RH level |

**Inspection and Observation**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Test no.** | **Temperature (˚C)** | **Humidity (%)** | **Duration (hours)** | **Remarks** | **Observation** |
| **1** | 25 | 40 | 24 | Weight gain of 0.03 g | No Color changed |
| **2** | 30 | 53 | 24 | Weight gain of 0.15 g | No Color changed |
| **3** | 48 | 68 | 24 | Weight gain of 0.35 g | No Color changed |

|  |  |  |
| --- | --- | --- |
| Sr. No | Test Parameter | Specification |
| 1. | **Physical Appearance** | White/Blue/Orange beads,  free from dust and damage |
| 2. | **Packing integrity** | Sachets sealed properly, no leakage or tearing |
| 3. | **Sachet Weight**  **(e.g., 1g, 2g, 5g)** | 10% of label claim |
| 4. | **Moisture Indicator Color**  **(if any)** | Blue → Pink (moist), Orange → Green (moist) |
| 5. | **Adsorption Efficiency**  **(optional)** | Meets internal test for water vapor absorption |
| 6. | **Label/Printing** | Clear, legible, includes batch & expiry (if any) |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Performance Test** | | | | |
| **Sr. #** | **Parameters** | **Specifications** | |
| **1.** | **Physical Appearance** | Clean & Smooth laminated with fine color quality. |  |
| **2.** | **Dimensions & specifications** | **Width:** 120 mm; **Length:** 195mm; **Height: 9.5** mm  **Weight:** 48 g; **Thickness**: 0.4mm |  |
| **3.** | **Grammage**  **GSM** | **0.91 kg/m2**Approx  **910** gms |  |
| **4.** | **Surface area** | **52765 mm2** square mm |  |
| **5.** | **Volume** | **221400 mm3** cubic mm |  |
| **6.** | **Packing Capacity** | 50 pouches |  |
| **7.** | **Color testing** | No discoloration |  |
| **8.** | **Printing Quality** | Clear logo, correct color & alignment |  |
| **9.** | **Moisture Resistance (if laminated)** | Box should not absorb moisture or deform under normal humidity |  |
| **10.** | **Packaging Integrity** | Should remain intact after simulated transport handling |  |

**R-Test Small box**

**Supplier Name: **

**Sr. No: 1.6.1**

**R-Test Large box**

**Sr. No: 1.6.2**

**Specification:**

**Supplier Name: **

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Performance Test** | | | | |
| **Sr. #** | **Parameters** | **Specifications** | |
| **1.** | **Physical Appearance** | Clean & Smooth laminated with fine color quality. |  |
| **2.** | **Dimensions & specifications** | **Width:** 125 mm; **Length:** 230mm; **Height: 9.5** mm  **Weight:** 48 g; **Thickness**: 0.4mm |  |
| **3.** | **Grammage**  **GSM** | **1669.57 g/m²** |  |
| **4.** | **Surface area** | **287.5 cm²** |  |
| **5.** | **Volume** | **221400 mm3** cubic mm |  |
| **6.** | **Packing Capacity** | 150 pouches |  |
| **7.** | **Color testing** | No discoloration |  |
| **8.** | **Printing Quality** | Clear logo, correct color & alignment |  |
| **9.** | **Moisture Resistance (if laminated)** | Box should not absorb moisture or deform under normal humidity |  |
| **10.** | **Packaging Integrity** | Should remain intact after simulated transport handling |  |

**R-Test raw material (Dropper) 35ul**

**Sr. No: 1.7**

**Specification:**

**Supplier Name: **

|  |  |  |
| --- | --- | --- |
| **Performance Test** | | |
| **Sr. #** | **Parameters** | **Specifications** |
| **1.** | **Physical Appearance** | foreign particles, molding defects, black spots, cracks, deformation. |
| **2.** | **Dropper Functionality Test** | Test the number of drops per mL and uniformity of drops. |
| **3.** | **Volume Test** | Fill with water up to brim and measure actual capacity (e.g., 5 mL, 10 mL, etc.). |
| **4.** | **Dimensions Check** | Measure height, diameter, neck size, wall thickness (use Vernier caliper). |
| **5.** | **Color** | Transparent bottle body with white screw cap |
| **6.** | **Bottle Size** | 21.8 mm \* 66.7mm |
| **7.** | **Drop Size** | 35µl drop size |
| **8.** | **Total Capacity** | 10 ml |
| **9.** | **Coordinate** | Complete overall coordination, flexible and suitable tightness of cap |
| **10.** | **Heat Resistance test** | 10 plastic droppers were placed in thermal incubator under 50ºC temperature to check the heat resistance capacity; there shall be no damage or wrinkles due to heat effect on bottles. |
| **11.** | **Leak test** | 5 buffer filled plastic dropper bottles were placed under high pressure and temperature; result reveal there is no leakage and volume reduction found. |

**R-Test raw material (Dropper) 5ul**

**Sr. No: 1.7**

**Specification:**

**Supplier Name: **

|  |  |  |
| --- | --- | --- |
| **Performance Test** | | |
| **Sr. #** | **Parameters** | **Specifications** |
| **1.** | **Physical Appearance** | foreign particles, molding defects, black spots, cracks, deformation. |
| **2.** | **Dropper Functionality Test** | Test the number of drops per mL and uniformity of drops. |
| **3.** | **Volume Test** | Fill with water up to brim and measure actual capacity (e.g., 5 mL, 10 mL, etc.). |
| **4.** | **Dimensions Check** | Measure height, diameter, neck size, wall thickness (use Vernier caliper). |
| **5.** | **Color** | Transparent bottle body with white screw cap |
| **6.** | **Bottle Size** | 21.8 mm \* 66.7mm |
| **7.** | **Drop Size** | 5µl drop size |
| **8.** | **Total Capacity** | 3 ml |
| **9.** | **Coordinate** | Complete overall coordination, flexible and suitable tightness of cap |
| **10.** | **Heat Resistance test** | 10 plastic droppers were placed in thermal incubator under 50ºC temperature to check the heat resistance capacity; there shall be no damage or wrinkles due to heat effect on bottles. |
| **11.** | **Leak test** | 5 buffer filled plastic dropper bottles were placed under high pressure and temperature; result reveal there is no leakage and volume reduction found. |

**R-Test raw material (Box Seal)**

**Sr. No: 1.8**

**Specification:**

**Supplier Name: **

|  |  |  |
| --- | --- | --- |
| **Performance Test** | | |
| **Sr. #** | **Parameters** | **Normal Ranges** |
| **1.** | **Visual Inspection** | No defects, or Damage |
| **2.** | **Seal Strength** | |  | | --- | | ≥1.5 kgf |  |  | | --- | |  | |
| **3.** | **Printing** | No Mistake |
| **4.** | |  | | --- | | **Leak Test** |  |  | | --- | |  | | No leak |
| **5.** | **Dye Test** | No dye leakage |

|  |  |  |
| --- | --- | --- |
| Sr. # | Parameters | Specifications |
| 1. | Physical Appearance | Clean & Smooth laminated with fine color quality. |
| 2. | Dimensions & specifications | Width: 63.5mm; Length: 63.5 mm; Weight: 0.592 g  Thickness: 0.1 mm  Surface area: 80 Sq cm |
| 3. | GSM  Grammage | 733.5 g/m2  1.47 g/cm3 |
| 4. | Stickiness | Stick to r test Box |
| 5. | Color testing | No discoloration |

**Sr. No: 1.9.1**

**R-Test raw material (sticker) Box**

**Specification:**

**Supplier Name: **

**Sr. No: 1.9.2**

**R-Test raw material (sticker) Master Carton**

**Specification:**

**Supplier Name: **

|  |  |  |
| --- | --- | --- |
| Sr. # | Parameters | Specifications |
| 1. | **Physical Appearance** | Clean & Smooth laminated with fine color quality. |
| 2. | **Dimensions & specifications** | Width: 100 mm; Length: 100 mm;  Weight: 0.592 g  Thickness: 0.1 mm |
| 3. | **GSM**  **Grammage** | 59.2 g/m² |
| 4. | **Surface Area** | 0.01 m² (or 100 cm × 100 cm = 10000 mm²) |
| 5. | **Stickiness** | Stick to r test Box |
| 6. | **Color testing** | No discoloration |

**Sr. No: 1.10**

**R-Test raw material (Sterile Swab)**

**Specification:**

**Supplier Name: **

|  |  |  |
| --- | --- | --- |
| **Performance Test** | | |
| **Sr. #** | **Parameters** | **Normal Ranges** |
| **1.** | **Visual Inspection** | No defects, or Damage |
| **2.** | **Swab shaft and tip** | clean, smooth, and free from fibers/debris. |
| **3.** | **Packaging** | Intact, properly sealed, and labeled |
| **4.** | **Sterility Test** | No growth |
| **5.** | **Absorption Capacity** | 100–200 µL |
| **6.** | **Break Strength** | Breaks cleanly at breakpoint |
| **7.** | **Edges** | No sharp edges or splinters after breaking. |

**R-Test raw material (Master Carton)**

**Sr. No: 1.11**

**Specification:**

**Supplier Name: **

|  |  |  |
| --- | --- | --- |
| **Performance Test** | | |
| **Sr. #** | **Parameters** | **Specifications** |
| **1.** | **Physical Appearance** | Clean & Smooth / No damage |
| **2.** | **Ply/ Thickness** | 6.3mm |
| **3.** | **Dimensions & specifications** | Length: 46cm  Width: 40 Cm  Height: 45 Cm  Weight: 1.40 kg |
| **4.** | **Quality of Cotton** | Corrugated, strong, moisture-resistant |
| **5.** | **Water Resistance Sustainability** | No delamination or swelling 60 sec soaks |
| **6.** | **Surface Area** | 1.21 m² |
| **7.** | **Grammage** | 1157.02 g/m² |
| **8.** | **Fiber Integrity** | Should not disintegrate under light mechanical stress |
| **9.** | **Packing Capacity** | 40 R test boxes |

**R-Test raw material (Stool collection device)**

**Sr. No: 1.12**

**Specification:**

**Supplier Name: **

|  |  |  |
| --- | --- | --- |
| **Sr. No** | **Performance Test** | **Specification** |
| **1.** | **Visual Inspection** | No damage/cracks |
| **2.** | **Dimension device** | Length: 75.5  Width: 13.5 |
| **3.** | **Volume** | 5 ml |
| **4.** | **Leakage test** | No leakage |
| **5.** | **Cap Functionality** | Easy open/close |
| **6.** | **Label Adhesion** | Firmly attached |

**R-Test raw material (Alcohol Swab)**

**Sr. No: 1.13**

**Specification:**

**Supplier Name: **

|  |  |  |
| --- | --- | --- |
| **Sr. No** | **Performance Test** | **Specification** |
| **1.** | Outer Packaging | Intact, labeled |
| **2.** | Sachet Seal | No leakage, sealed properly |
| **3.** | Label Info | Batch, MFG, EXP present |
| **4.** | Alcohol Content | 70% IPA |
| **5.** | Swab Size/Material | 3x3 cm, lint-free, soft |
| **6.** | Saturation Level | Adequately moist, not dry/drip |
| **7.** | Odor/Contamination | Sharp alcohol odor, clean swab |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Role** | **Name** | **Designation** | **Signature** | **Date** |
| **Prepared By** | Muhammad Luqman | QC Analyst | \_\_\_\_\_\_\_\_ | ------------ |
| **Approved By** | Dr. Zumara | QA Manager/Head QC | \_\_\_\_\_\_\_\_ | ----------- |