|  |  |
| --- | --- |
| **Product Name:** | **Batch No.:** |

**Quality Assurance**

Withdraw the sample for physical appearance and fill the following table. Decide for visual inspection of entire batch or release for packing based on the criteria given below.

|  |
| --- |
| Acceptable Quality Level |
| Tick mark whichever is applicable | Batch Size/ Lot size | Sample Qty. | Acceptable Defects |
| Critical(0 .010%) | Major(0.40 %) | Minor(1.50 %) |
| Accept | Reject | Accept | Reject | Accept | Reject |
|  | 10,001 to 35,000 Tablets/Capsules | 315 | 0 | 1 | 3 | 4 | 10 | 11 |
|  | 35,001 to 150,000 Tablets/Capsules | 500 | 0 | 1 | 5 | 6 | 14 | 15 |
|  | 150,001 to 5,00,000 Tablets/ Capsules | 800 | 0 | 1 | 7 | 8 | 21 | 22 |
|  | 5,00,001 to 10,00,000 Tablets/ Capsules | 1250 | 0 | 1 | 10 | 11 | 21 | 22 |
|  | More than 10,00,000 Tablets/ Capsules | 2500 | 0 | 1 | 10 | 11 | 21 | 22 |

√ **Tick ‘’ mark whichever is applicable**

|  |  |
| --- | --- |
| **Inspection** | **Date** |
| Inspection Tray ID:  |  |
| Checkpoints |  |
| Total No of Containers  |  |
| Total No of Containers to be selected for AQL |  |
| Containers No. from which sample withdrawn |  |
| CRITICAL | **Observation** |
| Foreign material |  |
| Size variation |  |
| Missing/Wrong Embossing |  |
| Contaminated Tablets |  |
| Abnormal discoloration of products |  |
| Layer Separation |  |
| **TOTAL** |  |
| MAJOR | **Observation** |
| Tablet is not fully coated |  |
| Bridging |  |
| Peeling/Orange Peel Roughness |  |
| Capping |  |
| Cracked/Broken tablet |  |
| Soft Tablets |  |
| Film Cracking |  |
| Black speck/particles |  |
| Illegible embossing |  |
| Mottling |  |
| **TOTAL** |  |
| MINOR | **Observation** |
| Tablet is not free of chipping/ Edge chipping |  |
| De-bossing or score is not well defined |  |
| Shade variation |  |
| Twinning |  |
| Logo Bridging |  |
| Edge Erosion/Surface Erosion |  |
| Picking/Sticking |  |
| Dusted Tablets |  |
| Rough surface |  |
| Color variation |  |
| **TOTAL** |  |
| **Performed By (QA Officer):****(Sign & Date):** | **Acknowledged By (Production Officer):****(Sign & Date):** |

**Comments:**