

| ABC  | Pre-Requisite programme Risk Assessment                                      |   |            |          |            |   | ABC  |                  |
|--|--|---|------------|----------|------------|---|--|------------------|
|  |  |   |            |          |            |   | ISSUE NO.: 1.0   | REVISION NO.: 00 |
|  |  |   |            |          |            |   | ISSUE DATE: 01.09.2022   |                  |
| PRP Aspect   | Risk   | Root Cause  | Risk       |          |            | Existing Control  | Additional Control   |                  |
|  |  |   | Likelihood | Severity | Risk Level |   |  |                  |
| Construction and layout of buildings   | Not having proper maintenance of the building.                               | 1. Delay /Not performing the maintenance of the building as required. | 1          | 2        | Low        | Preventive maintenace of the building is performed as per schedule                  | Periodic verification of the bulding for its suitability ( Quarterly)  |                  |
| Factory Environment  | Factory sorroundings are not kept in good condition suitable for food safety | There is no schedule esatblished for cleaning the sorroundings clean. | 2          | 2        | Low        | No specific schedules are esatblished.  | Schedule for outside area will be defined and implemneted. Verification done for effectiveness                 |                  |
| Locations of establishment   | N/A  | N/A   |            |          |            |   |  |                  |
| Layout of premises and workspace   | Blender used for mixing tea is of mild steel constroction is not suitable    | Inadequate Material construction                                      | 2          | 2        | Low        | Perioic cleaning of the blender for its suitability                                 | Verification of the belnder in GMP Audit   |                  |
| Laboratory facilities  | N/A  | N/A   |            |          |            |   |  |                  |
| Storage of food, packaging materials, ingredients and non-food chemicals                     | N/A  | N/A   |            |          |            |   |  |                  |
| Water supply   | Non-potable water and potable water lines are not labelled                   | Labelling system is not esatblished                                   | 2          | 2        | Low        | No system in place  | Non-potable water and potable water lines to be labelled   |                  |
| Lighting   | N/A  | N/A   |            |          |            |   |  |                  |
| Waste management and removal   | Waste disposal records not maintained.                                       | No system of verification of waste esatblished                        | 2          | 2        | Low        | Waste collection and segregation sustems are esatblished                            | Waste dispoasal records to be implemented and verification to be done on quarterl basis.                       |                  |
| Drains and drainage  | Nil  | Nil   |            |          |            |   |  |                  |
| Equipment suitability, cleaning and maintenance  | Nil  | Nil   |            |          |            |   |  |                  |
| Management of purchased materials  | Nil  | Nil   |            |          |            |   |  |                  |
| incoming material requirements (raw/ingredients/packaging)                                   | Nil  | Nil   |            |          |            |   |  |                  |
| Measures for prevention of cross-contamination   | Nil  | Nil   |            |          |            |   |  |                  |
| Allergen management  | Nil  | Nil   |            |          |            |   |  |                  |
| Cleaning and sanitizing  |  |   |            |          |            |   |  |                  |
| Pest control   | Presence of pest in the facility   | Inadequacy in the present control system                              | 2          | 2        | Low        | Pest control is done by authorized agency. Pest application records are maintained. | Monthly verification of pest control system and its records  |                  |
| 1. Personnel hygiene and employee facilities.<br>2. Personal cleanliness/ Personal behaviour | Inadequate food safety behaviour of employees in handling food               | Not aware of the requirements by employees                            | 1          | 3        | Low        | Training sessions are planned and conducted.  | Food safety culture assessment and esatblishing posters in the plant related to food safety to be implemneted. |                  |
| Health status/ Illness and injury  | Nil  | Nil   |            |          |            |   |  |                  |
| Rework   | Nil  | Nil   |            |          |            |   |  |                  |
| Product recall procedures  | Nil  | Nil   |            |          |            |   |  |                  |
| Warehousing  | Nil  | Nil   |            |          |            |   |  |                  |
| Product information and consumer awareness   | Nil  | Nil   |            |          |            |   |  |                  |
| Food defence, biovigilance, and bioterrorism   | Nil  | Nil   |            |          |            |   |  |                  |
| Training and Competence  | required level food safety knowledge for operators                           | Not aware of the requirements by employees                            | 1          | 3        | Low        | Training programmes are planned and conducted.                                      | During GMP verification, level of awareness of operators to be verified by the persons.                        |                  |