**RFO/CO:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**CORRECTIVE ACTION AND PREVENTIVE ACTION PLAN**

|  |  |
| --- | --- |
| **Name of Establishment:** | **Address:** |
| **Inspector/s:** | **Inspection dates:** |
| **Prepared by :**  **(Name & Designation of establishment’s authorized representative)** | **Date prepared (dd/mm/yyyy):** |

***Note: Establishment to fill columns 3 to 5.***

| **Deficiency number**  **(1)** | **Description of deficiency**  **(2)** | **Corrective Action /Preventive Actions (CAPA)**  **(3)** | **Evidence of compliance**  **(4)** | **Completion or proposed completion date dd/mm/yyyy**  **(5)** | **Inspector(‘s) Comment(s)**  **(6)** | **Response accepted (Yes / No)**  **(7)** |
| --- | --- | --- | --- | --- | --- | --- |
| **CRITICAL** | | | | | | |
|  |  |  |  |  |  |  |
| **MAJOR** | | | | | | |
|  |  |  |  |  |  |  |
| **OTHERS** | | | | | | |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

**For FDA use only:**

|  |
| --- |
| **Remarks** |

|  |  |  |  |
| --- | --- | --- | --- |
| **Recommendation(to FDA office)**: | | | |
| Reviewed by: | **Name /Designation and Signature of FDRO(s)** | Date: |  |
| Noted by: | **Name and Signature Team Leader/Supervisor** | Date: |  |

1. Provide the company with soft and hard copies of the close out and deficiency report.
2. Summary and conclusion and recommendations will be provided after the verification of closure of all deficiencies.