**Blood Establishment Inspection Reply**

**Sector: Operation**

**Executive Department: Inspection Support**

**Department: Factories Inspection Support**

**Section: Pharmaceutical and Cosmetic Factories**

**Code: OPS-F-210-037-V2**

**Related SOPs: Policy and Procedure of Blood Establishment Inspection Process**

**Approval Date: 05/02/2021**

**Version Control**

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision Date** | **Version NO.** | **Reason of change** | **Describe the change** |
| **08/12/2020** | **1** | **Organization Identity & Change the title** | **Organization Identity & Change the title from Arabic to English** |

**BLOOD ESTABLISHMENT INSPECTION REPLY**

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| --- | --- |
| **Reference No.: For SFDA use only** | **Inspection Date: For SFDA use only** |
| **Inspected Site:**  **For SFDA use only** | |

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| **Description of Deficiency** | **The blood bank will fill this space with the findings as written in the report** |
| **1ST Responses & Actions** | **The blood bank will write a full and detailed corrective/preventive action plan~~.~~ ~~W~~ith any attachment supporting the correction** |
| **1ST Inspector remarks** | **For SFDA use only** |
| **2ND Responses & Actions** | **If the first blood bank response ~~was~~ not satisfactory or more clarification was needed from the inspection team the blood bank should respond as above** |
| **2ND Inspector remarks** | **For SFDA use only** |
| **3RD Responses & Actions** | **If the first blood bank response ~~was~~ not satisfactory or more clarification was needed from the inspection team the blood bank should respond as above** |
| **3RD Inspector remarks** | **For SFDA use only** |

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| **Description of Deficiency** | **The blood bank will fill this space with observation as it was written in the report** |
| **1ST Responses & Actions** | **The blood bank will write a full and detailed corrective/preventive action. With any attachment supporting the correction** |
| **1ST Inspector remarks** | **For SFDA use only** |
| **2ND Responses & Actions** | **If the first blood bank response ~~was~~ not satisfactory or more clarification was needed from the inspection team the blood bank should respond as above** |
| **2ND Inspector remarks** | **For SFDA use only** |
| **3RD Responses & Actions** | **If the first blood bank response ~~was~~ not satisfactory or more clarification was needed from the inspection team the blood bank should respond as above** |
| **3RD Inspector remarks** | **For SFDA use only** |

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| **Description of Deficiency** | **The blood bank will fill this space with observation as it was written in the report** |
| **1ST Responses & Actions** | **The blood bank will write a full and detailed corrective/preventive action. With any attachment supporting the correction** |
| **1ST Inspector remarks** | **For SFDA use only** |
| **2ND Responses & Actions** | **If the first blood bank response ~~was~~ not satisfactory or more clarification was needed from the inspection team the blood bank should respond as above** |
| **2ND Inspector remarks** | **For SFDA use only** |
| **3RD Responses & Actions** | **If the first blood bank response ~~was~~ not satisfactory or more clarification was needed from the inspection team the blood bank should respond as above** |
| **3RD Inspector remarks** | **For SFDA use only** |

**Recommendations:**

**For SFDA use only**

**Conclusions:**

**For SFDA use only**

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| --- | --- | --- |
| **Inspector Name’s** |  |  |
| **Signature** |  |  |
| **Date** |  |  |

1. **Approvals**

|  |  |
| --- | --- |
| **Date:**  **-----------------------** | **Issued By:** Marae Al-Qarni & Fahad Al-Battal  **Position:** Inspection Operations Support Expert & Inspection Expert of Products and Facilities  **Signature: -----------------------** |
| **Date:**  **-----------------------** | **Approval:** Mohammad Dahhas  **Position:** Executive Director for Inspection Support  **Signature: -----------------------** |