**Annex-II**

**INSPECTION PROFORMA FOR VERIFICATION OF STORAGE FACILITIES OF ALTERNATIVE MEDICINE AND HEALTH PRODUCTS.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Ref No.** |  | **Date** |  |

**PART – A**

1**. GENERAL INFORMATION**

|  |  |
| --- | --- |
| Name of Importer |  |
| Address of the Storage Facility |  |
| Contact Address |  |
| Phone Number |  |
| Date of inspection |  |
| Purpose of inspection |  |
| Name of inspector (s)  |  |
| Name of Firm’s Representative (s) accompanying during inspection  |  |
| Name of Qualified Person |  |

**PART – B TECHNICAL INFORMATION**

|  |  |  |  |
| --- | --- | --- | --- |
| **S. No.** | **Criteria** | **Compliant Yes/No** | **Remarks** |
| **2. PERSONNEL** |
| 2.1 | Is Organizational Chart Available |  |  |
| 2.2 | Whether a Qualified Person is Appointed and Actively Supervising the Storage Facility? |  |  |
| 2.3 | Whether the Name, Qualification and Experience of Qualified Person Provided? |  |  |
| 2.4 | Whether the Qualified Person possess adequate qualification and experience related to his/her Job Description? |  |  |
| 2.5 | Whether the staff involved in handling the Health &OTC Products is fully trained? |  |  |
| **3. PREMISES** |
| 3.1 | Is the facility situated in non-residential area  |  |  |
| 3.2 | Whether the storage area is adequately designed for better storage conditions? (i.e temperature, light, humidity & cleanliness). |  |  |
| 3.3 | Are surfaces free of flaking paint, corrosion, rust and other materials (eg., tape, Woods etc?).  |  |  |
| 3.4 | Is there any signs of vermin such as cockroaches, mice, rats, and bats? |  |  |
| 3.5 | Is floor clean, from water? |  |  |
| 3.6 | Is there a cleaning schedule in place? |  |  |
| 3.7 | Check that the storage area is not overloaded and that it is not being used to store un-authorized substances.  |  |  |
| 3.8 | Weather there is proper inventory control system? |  |  |
| 3.9 | Is there a warranty system established?  |  |  |
| 3.10 | Are all the products are properly placed or arrangements are made for systematic storage? |  |  |
| 3.11 | Check the temperature of storage area. Whether it is in the required range? |  |  |
| 3.12 | Check temperature record in the log books. (The temperature should have remained within the correct limits at all the times). |  |  |
| 3.13 | Are the temperature logs readily available for a minimum of two years? |  |  |
| 3.14 | Has all recording and monitoring equipment been calibrated in the last year? |  |  |
| 3.15 | Is there a procedure for pest control monitoring and treatment? |  |  |
| 3.16 | Are openings to doorways, vents, and drains covered to prevent the ingress of pests, etc. |  |  |
| 3.17 | Is there a fire fighting mechanism in place? |  |  |
| 3.18 | Is the space outside the room? |  |  |
| 3.19 | Check whether the emergency alarm system is working? |  |  |
| 3.20 | Whether a standby generator or alternate source of electricity is available and functional? |  |  |
| 3.21 | Whether the importer has established the Product Re-Call mechanism? Check the relevant records. |  |  |
| 3.22 | Whether the recalled products are appropriately identified and stored? |  |  |
| 3.23 | Whether a mechanism is established for handling of expired and rejected products? |  |  |
| 3.24 | Is there a separate area for expired and rejected products is provided with lock and key? |  |  |
| 3.25 | Whether a record of disposal and destruction of expired/rejected materials is available? |  |  |

**Remarks of the Company Representative:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Sign with Name & Designation Date: \_\_\_\_\_\_\_\_\_\_\_

**Concluding Remarks by the Inspector(s)**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Sign with Name & Designation of Inspecting Officer