**RECALL ASSESSMENT FORM**

(To be filled by licensee / representative of licensee)

|  |  |  |
| --- | --- | --- |
| To, | ………………………………………….……………………. | Recall Ref No: …………………..Date: ……………….. |

|  |  |  |
| --- | --- | --- |
| **Recall information** | **Information by the Holder of Certificate of registration/Distributor/wholesaler** | **Comments from DRAP (expert committee, concerned Board / competent forum)** **(For DRAP use only)** |
| **Origin of report** |  |  |
| 1. Name of person/organization reporting the problem

(State whether it is a complaint, quality defect, lab report, voluntary or statutory) |  |  |
| 1. Date of report
 |  |  |
| 1. Name of recalling firm (Registration/Enlistment holder/manufacturer)

(Specify separately for finish import / contract manufacturing as the case may be.)  |  |  |
| 1. Physical address of recalling firm
 |  |  |
| 1. Telephone number of recalling firm
 |  |  |
| 1. Alternate number of recalling firm
 |  |  |
| 1. E-mail address of recalling firm
 |  |  |
| 1. Name of Quality head/QA Incharge recalling firm
 |  |  |
| **Product(medicine) details** |  |  |
| 1. Name of product affected
 |  |  |
| 1. Registration number
 |  |  |
| 1. Dosage form
 |  |  |
| 1. Strength
 |  |  |
| 1. Pack size/type
 |  |  |
| 1. Batch number and expiry date
 |  |  |
| 1. Date manufactured
 |  |  |
| 1. Date released
 |  |  |
| 1. Total quantity prior to distribution
 |  |  |
| 1. Quantity released for distribution prior to the recall
 |  |  |
| 1. Date of distribution (s)
 |

|  |  |  |
| --- | --- | --- |
| **Sr. No.** | **Distribution Name** | **Date** |
|  |  |  |
|  |  |  |
|  |  |  |

 |  |
| 1. Local distribution (give full details and quantity)
 |  |  |
| 1. Overseas distribution (give full details and quantity)
 |  |  |
| **Nature of defect** |  |  |
| 1. Source of problem

(e.g. SS/OOS test report, patient/ hospital/pharmacy/ manufacturer, etc |  |  |
| 1. Details of problem
 |  |  |
| 1. Number of complaints received if any
 |  |  |
| 1. Action taken so far (if any)/ Proposed action and its urgency
 |  |  |
| 1. Type of hazard/health risk and assessment of risk to the user
 |  |  |
| 1. Proposed recall classification and level of recall
 |  |  |
| 1. Other relevant information
 |  |  |

The form should be signed and dated appropriately.