**RECALL ASSESSMENT FORM**

(To be filled by licensee / representative of licensee)

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

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| --- | --- | --- |
| **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.