**Quality Defects Reporting Form**

**Report No:**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 1. **Product Details:** | | | | | | | |
| **Product Name (Generic & Brand):** | | |  | | | | |
| **Strength:** | | | **Package size:** | | **Dosage Form:** | | |
| **Type of Container:** | | | | **No of Items:** | | | |
| **Batch Number:** | **Manuufacturing Date:** | | | | | **Expiry Date:** | |
| **Manufacturer:** | | | | **Registration No. (if available):** | | | |
| 1. **Type of the Quality Problem:** | | | | | | | |
| **Packaging** | | **Physical, chemical or microbial changes** | | | | | **Defective Components** |
| **Suspected Counterfeit product** | | **Suspected contamination** | | | | | **Questionable stability** |
| **Product confusion (caused by name, labelling, design or packaging)** | | | | **Labeling problems (caused by printing errors/omissions)** | | | |
| **Other:** | | | | | | | |
| **Is the product available for evaluation:  Yes  No** | | | | | | | |
| **Was the product stored according to recommendations: ☐ Yes ☐ No** | | | | | | | |
| **Description of the Problem:** | | | | | | | |
| **In case of therapeutic failure, kindly fill in the patient details: (In case of an adverse drug reaction, please additionally fill in the adverse drug reaction reporting form):**  **Patient Name: Sex: Male  Female Age: Pregnancy: Yes No NA** | | | | | | | |
| 1. **Reporter Details:** | | | | 1. **Company Representative Details:** | | | |
| **Name:**  **Job Tittle:**  **Organization:**  **Phone/Mobile:**  **Email:**  **Address:**  **Date:**  **Signature:** | | | | **Name:**  **Job Tittle:**  **Organization:**  **Phone/Mobile:**  **Email:**  **Address:**  **Date reported to Sunny PV:**  **Signature:** | | | |

**We encourage you to report any quality defect directly to us, please contact us on** [**sunnymedical@gmail.com**](mailto:sunnymedical@gmail.com)

**All the Information in this report is Confidential and protecting the patient and reporter identity**