**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**

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