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| **Fresenius Kabi India Private Ltd.**Ninth Floor, AP81, S No 83, North Main Road,  Mundhwa, Pune 411036, Maharashtra, India **QUALITY MANAGEMENT- MU****Product Complaint Report Form****Contact details of Complaint Officer**- fkipl.vigilance@fresenius-kabi.com **Office Phone Number:** +91 20 67649000**Customer Care Number:** +91 9158898288 |

**Please mark which is applicable.**

* **Pharmaceutical Product Name of Manufacturer:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* **Medical Devices**

**Name of Sender** (Name, Address, Phone, Fax): \_\_\_

 \_\_\_

1. **Product:**  **Pack size**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**Qty Complained:** \_\_\_\_\_\_\_\_\_\_\_\_\_

**Batch Number**: **Mfg. Dt.:** *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*\_ **Exp. Dt.:** \_\_\_\_\_\_\_\_\_\_\_\_\_

**Material No: (For Medical device Only)** \_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Date of Event:**  \_\_\_\_\_\_\_\_\_
2. **Date reported to Fresenius Kabi:** \_\_\_\_\_\_\_\_\_\_\_\_
3. **Name / Address of Customer**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 \_\_\_

**Phone No.** **E-mail:**  \_\_\_

1. **Samples:**

🞏 Unused 🞏 Used

1. **Nature of complaint / Description:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Remarks:**

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**Is there any Adverse Drug Reaction? Yes No**

**If Yes, please fill in ADR Form as per annexure 2 of SOP No: INMU-PV-003**