**TEMPLATE A**

*(Submit in both hard copy and soft copy in .docx format)*

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| 1. **REGISTRATION DETAILS**   **[As per issued marketing authorization (MA), e.g., Certificate of Product Registration (CPR)]**  *Encode data. Otherwise, type “****Not applicable****”.* | | | | | |
| **Generic Name**  **Dosage Form Dosage Strength**  **Route of Administration** | ……… | **Brand Name, *if any*** | ……… | **Pharmacologic Category** | ……… |
| **Classification** | *Choose an item.* | **Storage Conditions** | ……… | **Packaging** | ……… |
| **Approved Shelf-life** | *Choose an item.* | **Finished Product Manufacturer, *with complete address*** | *Choose an item.*  ……… | **Registration Status** | *Choose an item.*  ……… |
| **Registration No.**  *Choose an item.* | ……… | **MA Issuance** | *Click or tap to enter a date.* | **MA Validity** | *Click or tap to enter a date.* |
| *If there are other affected Principal CPR or Certificate/s of Listing of Identical Drug Product (CLIDP/s), fill-out and attach* ***TEMPLATE B****.*  *If various active pharmaceutical ingredients (APIs) are affected, fill-out and attach* ***TEMPLATE C****.* | | | | | |
| **Remarks, *if any*** | ……… | | | | |

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| 1. **LICENSING DETAILS**   **[As per issued License to Operate (LTO)]**  *Encode data. Otherwise, type “****Not applicable****”.* | | | | | | | |
| **Marketing Authorization Holder (MAH)** | ……… | **Complete Address of MAH** | ……… | | | **LTO No.** | LTO- |
| **Application Type** | *Choose an item.* | **LTO Activity** | *Choose an item.*  *Click or tap here to enter the activity/ies if not included above.* | | | **LTO Validity** | *Click or tap to enter a date.* |
| **B.1. FOR ANOTHER ESTABLISHMENT SEEN ON THE MA, i.e., not mentioned  in Sections A & B** | | | | | | | |
| **Applicable  Not Applicable** | | | | | | | |
| **LTO Activity** | **Complete Name & Address of Establishment** | | | | | | |
| *Choose an item.*  *Click or tap here to enter the activity/ies if not included above.* | ……… | | | | | | |
| **B.2. FOR LOCAL MANUFACTURER**  **[As per issued Certificate of Current Good Manufacturing Practice (GMP)]** | | | | | | | |
| **Applicable  Not Applicable** | | | | | | | |
| **Certificate No.:** | ……… | | | **Name of Products, *list all*** | ……… | | |
| **CGMP Issuance** | *Click or tap to enter a date.* | | | **CGMP Validity** | *Click or tap to enter a date.* | | |
| **B.3. FOR FOREIGN MANUFACTURER**  **(As per issued Certificate of GMP Compliance)** | | | | | | | |
| **Applicable  Not Applicable** | | | | | | | |
| **Certificate No.:**  *Choose an item.* | CDRR-CGMP-……… | **Registration Status** | *Choose an item.* | | | **Dosage Forms Manufactured, *list all*** | ……… |
| **CGMP Issuance** | *Click or tap to enter a date.* | **CGMP Validity** | *Click or tap to enter a date.* | | |
| **Remarks for whole Section B, *if any*** | ……… | | | | | | |

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| 1. **TRIGGER OR HAZARD**   **Document Tracking Number/s (DTN): *Click or tap here to enter DTN. Use semi-colon (;) to separate numerous DTNs.***  *Encode data. Otherwise, type “****Not applicable****”.* | | | | | | | | | |
| **Full Name of Reporter; *if any, type the designation*** | | *Choose an item.*  ……… | **Organization or company with complete address, *if any*** | | ……… | | **Contact Details** | | *Encode telephone number/s and/or mobile number/s* |
| *Encode e-mail address/es* |
| **Date of Report** | | *Click or tap to enter a date.* | **Type of Trigger** | | *Choose an item.*  *Click or tap here to enter other reason/s not included above.* | | **Issues, *choose all applicable*** | | Efficacy  Quality  Safety |
| **C.1. BATCH/LOT DETAILS**  *Insert additional rows if needed.* | | | | | | | | | |
| **Registration No.** | **Batch/es or  Lot/s**  *(one batch or lot per row)* | | | **Mfg. Date/s** | | **Exp. Date/s** | | **Total Affected Quantity, *state in pack size, e.g., “Boxes (Box of 100 tablets)”*** | |
| ……… | ……… | | | *Click or tap to enter a date.* | | *Click or tap to enter a date.* | | ……… | |
| ……… | ……… | | | *Click or tap to enter a date.* | | *Click or tap to enter a date.* | | ……… | |
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| ……… | ……… | | | *Click or tap to enter a date.* | | *Click or tap to enter a date.* | | ……… | |
| ……… | ……… | | | *Click or tap to enter a date.* | | *Click or tap to enter a date.* | | ……… | |
| **C.2. HISTORY OR INVESTIGATION OF TRIGGER/HAZARD AND ACTIONS TAKEN** | | | | | | | | | |
| *Click or tap here to enter text.* | | | | | | | | | |

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| 1. **CHECKLIST**   **Core Requirements**  *Submit and attach all the* ***complete and necessary documents/evidence (hard and/or soft copies)****. Encode remarks, if necessary.* | | |
|  | **API *\*CHOOSE\** with complete address/es** | ……… |
|  | **Corrective and Preventive Action Plan (CAPA)** | ……… |
|  | **Certificate/s of Analyses**  \*For cases needed with testing/analyses | ……… |
|  | **Copy of recall communications to clients** | ……… |
|  | **Marketing Authorization, *e.g., CPR, CLIDP*** | ***Refer to Section A; submit copy of MA*** |
|  | **Direct Healthcare Professional Communication (DHPC)** | ……… |
|  | **Distribution Records, *showing total quantity distributed deducted with each quantity provided to every client*** | Total quantity distributed, ***state in pack size, e.g., “Boxes (Box of 100 tablets)”***: *Click or tap here to enter text.*  ……… |
|  | **GMP Certificate** | ***Refer to Section B; submit copy of GMP Certificate*** |
|  | **Importation Records, *e.g., airway bill, bill of lading, etc.***  \*For imported products only | Total quantity imported, ***state in pack size, e.g., “Boxes (Box of 100 tablets)”***: *Click or tap here to enter text.*  List importation documents, *if any (separate with a semi-colon or “;”):* *Click or tap here to enter text.*  ……… |
|  | **LTO** | ***Refer to Section B; submit copy of LTO*** |
|  | **Manufacturing, *e.g., batch manufacturing record***  \*For local manufacturers only | ……… |
|  | **Photograph/s of Actual Samples**  ***(refer to Annex-*** ***Standards on Data Capture of Actual Commercial Samples)*** | ……… |
|  | **Preventive Measures, *e.g., quarantine of stocks*** | Total quantity left in the warehouse, ***state in pack size*, *e.g., “Boxes (Box of 100 tablets)”***: *Click or tap here to enter text.*  ……… |
|  | **Root Cause Analysis (RCA)** | ……… |
| **D.1. Supplemental Requirements**  *Choose all applicable evidence. Submit and attach all the* ***complete and necessary documents/evidence (hard and/or soft copies)****. Encode remarks, if necessary.* | | |
|  | **Adverse Event (AE)/Adverse Drug Reaction (ADR) Report** | ……… |
|  | **Countries exported with the product/s, *if any*** | ……… |
|  | **Inspection Report of FDA-Regional Field Office (RFO)** | DTN/s: *Click or tap here to enter text.*  ……… |
|  | **Laboratory Test Report/s** | Laboratory Number/s: *Click or tap here to enter text.*  ……… |
|  | **Post-Approval Change/s on MA** | ……… |
|  | **Two-Way Alert Report, i.e.,** *Choose an item.* | **ASEAN PMAS** Report Ref. No. or **WHO-RAS** Ref. RPQ/REG/ISF/Alert No.: *Click or tap here to enter text.*  ……… |
|  | **Variation/s on LTO** | ……… |
|  | **Others, *if any*** | ……… |

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| 1. **HAZARD EVALUATION**   *Choose all applicable. Encode remarks, if necessary.* | | |
| Is the problem associated with any adverse event? | *Choose an item.* | *Elaborate, if needed…* |
| Is the problem associated with any complaint? | *Choose an item.* | *Elaborate, if needed…* |
| Is there gross deception to the public? | *Choose an item.* | *Elaborate, if needed…* |
| Is there adulteration of the product/s? | *Choose an item.* | *Elaborate, if needed…* |
| Are there risks to any of the following segments of the population?  Children  Elderly  Immuno-compromised  Infants  Nursing Mothers  Pregnant Women  Surgical Patients  Others: *Click or tap here to enter text.* | *Choose an item.* | *Elaborate, if needed…* |
| Are the effects of the health hazards acute (short-term) or chronic (long-term)? | *Choose an item.* | ***Choose applicable hazard:***  Life-threatening (i.e., death has or could occur)  Results in permanent impairment of a body function or permanent damage to a body structure  Necessitates medical or surgical intervention to preclude or reverse permanent damage to a body structure or permanent impairment of a body function  Temporary or reversible (with medical intervention)  Temporary or reversible (without medical intervention)  Limited (transient, minor impairment, or complaints)  No adverse health consequences  Remarks, *if any: Click or tap here to enter text.* |

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| 1. **ASSESSMENT**   *Choose the condition that applies for each row.*  ***NOTE: Any changes in this section after submission of this report must be notified accordingly  to the FDA for the approval of the agency.*** | |
| **Classification of Recall** | Class I: Product defects or conditions that are potentially life threatening or could result into severe health risk, health impairment or effects such as permanent damage to health or death.  Class II: Product defects or conditions that could cause poisoning or temporary/medically reversible adverse health problem or mistreatment.  Class III: Product defects or conditions that may not pose a significant hazard to health, but withdrawal may have been initiated for other reasons.  Remarks, *if any: Click or tap here to enter text.* |
| **Depth of Recall** | Manufacture  Wholesale  Retail  Household/Consumer  Remarks, *if any: Click or tap here to enter text.* |
| **Frequency of Recall Status Reporting** | *Encode the frequency here (e.g., weekly, every 2 weeks, every Thursday, etc.)* |
| **Completion of Recall** | *Click or tap to enter actual date of recall completion.*  **NOTE:** Complete nationwide retrieval (i.e., rural and urban area), of all stocks to be recalled and secured in your official warehouse under lock & key. Thereafter, stocks are ready for disposal. |
| **Advisory** | ***Please attach the advisory with this report.***  **NOTE:** Regardless of the classification of recall, an advisory must be provided by your company with your own letterhead or company logo containing the following minimum details and must observe correct grammar, sentence construction, and with cohesive information. This shall be submitted to the FDA for posting in our website:   * Product/s details, e.g., brand name, registration no., etc.; * Affected batch/es or lot/s with its mfg. date and exp. date; * History of trigger/hazard or reason for recall and actions of your company; * Indications of the product/s; * Instructions to the general public regarding the recall of the product/s, e.g., consumers with product on hand, patients taking the product, etc.; * Contact details of your company or reporting channels; and * FDA ADR Reporting Statement, “**For suspected adverse drug reaction, report to the FDA:** [**www.fda.gov.ph**](http://www.fda.gov.ph) **or through https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH**”. |
| **Disposition** | Destruction method, *e.g., pyrolysis*: *Click or tap here to enter text.*  Shipped out to Country of Origin  Others, please specify: *Click or tap here to enter text.*  Remarks, *if any: Click or tap here to enter text.* |
| **Other Actions to be Taken, *as deemed necessary*** | …… |