**CTD PRE-SUBMISSION SCREENING CHECKLIST**

Note: Application shall be received for detailed evaluation if all the below mentioned documents are submitted.

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| 1. Form 5-F:
 |  Yes |  No |
| 1. Requisite fee:
 |  Yes |  No |
| 1. Valid DML / DSL:
 |  Yes |  No |
| 1. Evidence of GMP compliance of relevant section:
 |  Yes |  No |
| 1. Evidence of approval status in RRA:
 |  Yes |  No |
| 1. QOS (Quality Overall Summary) as per WHO QOS-PD Template:
 |  Yes |  No |
| **For Module-3, in Drug Substance Part**: |  |  |
| 3.2.S.2.1: Manufacturer(s) site address |  Yes |  No |
| 3.2.S.4.4: Certificate of Analysis (COA) of both drug substance(s) manufacturer and drug product manufacturer:  |  Yes |  No |
| 3.2.S.7: Stability data of 3 batches at accelerated and real time conditions: |  Yes |  No |
| **For Module-3, in Drug Product Part**: |  |  |
| 3.2.P.2.2.1: Product development, description of dosage form, Pharmaceutical Equivalence through Comparative Dissolution Profile (where applicable) *[Explanation:* *Pharmaceutical Equivalence is mandatory for each dosage form/product while Comparative Dissolution Profile is required as applicable]* |  Yes |  No |
| 3.2.P.3.5: Process validation: |  Yes |  No |
| 3.2.P.5.1: Specifications of drug product: |  Yes |  No |
| 3.2.P.5.3: Validation / verification of analytical procedures summary / reports: |  Yes |  No |
| 3.2.P.8.3: Stability data: |  Yes |  No |
| **FOR IMPORTED PRODUCTS (Following additional documents)** |  |
| Original, legalized and valid CoPP / Free sale and GMP certificate  |  Yes |  No |
| Sole agency agreement / authorization letter |  Yes |  No |

**Remarks (if any):**

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|  Received | Returned back to applicant for completion |

Date Name & Signature