

Government of Pakistan
 Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan
 Division of Pharmaceutical Evaluation & Registration

CTD PRE-SUBMISSION SCREENING CHECKLIST

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

1. Form 5-F:	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
2. Requisite fee:	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
3. Valid DML / DSL:	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
4. Evidence of GMP compliance of relevant section:	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
5. Evidence of approval status in RRA:	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
6. QOS (Quality Overall Summary) as per WHO QOS-PD Template:	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No

For Module-3, in Drug Substance part:

3.2.S.2.1: Manufacturer(s) site address	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
3.2.S.4.4: Certificate of Analysis (COA) of both drug substance(s) manufacturer and drug product manufacturer:	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
3.2.S.7: Stability data of 3 batches at accelerated and real time conditions:	<input type="checkbox"/>	Yes	<input type="checkbox"/>	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)	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
3.2.P.3.5: Process validation:	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
3.2.P.4.1: Specifications of drug product:	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
3.2.P.5.3: Validation / verification of analytical procedures summary / reports:	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
3.2.P.8.3: Stability data:	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No

FOR IMPORTED PRODUCTS (Following additional documents)

Original, legalized and valid CoPP / Free sale and GMP certificate	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Sole agency agreement / authorization letter	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No

Remarks (if any):

Received

Returned back to applicant for completion

Date

Name & Signature