

CHECKLIST

Form Name: Certificate of Pharmaceutical Product(COPP)

Fresh

Section no.	Checklist Name	Is Mandatory
1.0	Site Master file (as specified under WHO TRS 823)	Yes
2.0	Copy of Manufacturing Licence	Yes
3.0	List of Approved products	Yes
4.0	List of Products applied for issuance of Certificate of Pharmaceutical Product	Yes
5.0	List of SOPs	Yes
6.0	List of STPs	Yes
7.0	Stability Data(3 batches,6 Months) Accelerated/Real Time	Yes
8.0	List of equipment and Instrument	Yes
9.0	List of technical staff, their qualifaction, experience and approval status	Yes
10.0	Manufacturing Layout	Yes
11.0	Process validation for 3 batches of each product	Yes
12.0	Schematic Diagram of water system specifying circulation loop and MOC(Material of Construction)	Yes
13.0	Schematic Diagram of HVAC system specifying terminal filter configuration	Yes
14.0	Export Data of last 2 years in case of revalidation	Yes
15.0	Product Summary Sheet	Yes
16.0	Application Form For Certificate of Pharmaceutical Product	Yes
17.0	Fee Challan	Yes