

DOCUMENT REQUIRED TO OBTAIN AN AYUSH LICENSE

- Applicant's details such as Name, Address, E-mail, Contact Number
- A copy of the Manufacturing License,
- Complete product list applied for issuance of COPP and their composition,
- Site Master file/ Manufacturing Plant Layout,
- Submit the manufacturing formula along with the manufacturing process,
- Method of analysis and finished product specification Report,
- Approved products list,
- Stability study analysis based on batch, along with the Date of manufacturing, Date of Expiry, stability study condition, the name of the Drug
- Process validation report for three batches,
- Technical staff list along with the information like experience, qualification, and approval status,
- List of equipment and instruments used or to be used,
- Water System Diagram,
- HVAC System Diagram,
- Export data for the last two years, wherever re-validation of COPP is applicable,
- A proof of safety and effectiveness as mentioned in Rule 158B of Drugs & Cosmetic Rules, 1945.
- Undertaking related to the absence of any non-herbal such as metals/ or minerals etc. in the products applied for WHO-COPPs (Applicable in case of herbal products)

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- Undertaking related to compliance with the provisions of domestic regulations inter-alia Drug and Cosmetics Act, 1940 and Rules thereunder, Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954 and rules thereunder, (Applicable in case of herbal products).

