LIST OF DOCUMENTS REQUIRED FOR APPLICATION FOR WHO-GMP/ CoPP FOR A.S.U. HERBAL DRUGS

DRAFT CHECKLIST

The proposed checklist is for applicants for submission of APPLICATION FOR WHO-GMP/ CoPP FOR A.S.U. HERBAL DRUGS are being uploaded for information and public comments. The comments should be reached to Office of DCG(I) by 5:00 pm on 31st May 2018 at CDSCO, FDA Bhavan, Kotla Road, New Delhi – 110002 through post and email at dci@nic.in.

14TH MAY.2018

Copy to: All Ayurvedic Drugs Manufacturers Associations

LIST OF DOCUMENTS REQUIRED FOR APPLICATION FOR WHO-GMP/ CoPP FOR A.S.U. HERBAL DRUGS

1. Application for: WHO-GMP certification & issuance of COPP.
2. Name of the applicant with address, telephone, fax, e-mail etc.
3. Copy of Manufacturing Licence.
4. List of approved products.
5. List of products for which the firm has valid CoPP.
6. List of products applied for issuance of COPP & their composition.
7. Site Master file (as specified under WHO TRS 823).
8. Data on Finished Formulation:
   - **8.01** Master manufacturing formula, manufacturing process.
   - **8.02** Finished product specification and Method of Analysis .
   - **8.03** Stability study evaluation (Accelerated and Real Time) for 3 batches including details batch size, Batch No., Date of manufacturing, Date of Expiry, stability study condition (Accelerated/ Real time), Name of Drug etc **(as per Format-A)**
   - **8.04** Process validation report for 3 batches.
   - **8.05** Validation report of analytical method.
9. List of technical staff, their qualification, and experience and approval status.
10. List of equipment and instrument.
11. List of SOPs and STPs.
12. Manufacturing Plant layout.
13. Schematic diagram of water system specifying circulation loop and MOC.
14. Schematic diagram of HVAC system specifying terminal filter configuration.
15. Export data of last 2 years, in case of re-validation of CoPP.
16. Product summary sheet **(as per Format B).**
17. Actual labels of the products applied for WHO-CoPP.
18. Proof of safety and effectiveness as per Rule 158B of Drugs & Cosmetic Rules, 1945.
19. Reference standards of the ingredients / formulation of the products applied for WHO-CoPP
20. Certificates of Analysis for three batches of each product
21. Undertaking regarding absence of any non-herbal ingredients including metals/ minerals, etc. in the products applied for WHO-CoPPs.
22. Undertaking regarding compliance to the provisions of domestic regulations *inter-alia* Drugs & Cosmetics Act, 1940 and Rules thereunder, Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules thereunder, etc.

Note: *The application for grant/ renewal of WHO-GMP/ CoPP along with all the supporting documents as per the check list is to be addressed to the Office of DCG(I), CDSCO(HQ), New Delhi with a copy to the Drug Control Cell, Ministry of AYUSH.*

CDSCO
CENTRAL DRUGS STANDARD CONTROL ORGANISATION
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

#Format-A : Stability Study Data

Name of the Product: **Batch No:** **Batch Size:**

Manufacture Date: **Study Initiation Date:** **Storage Condition:**

Pack style:

Accelerated Study: Time Points (Month)

Test	Specification	Initial	3 month	6month
01				
02				

Real Time Study: Time Points (Month)

Sufficient to establish the Stability profile of the drug

Test	Specification	Initial	6 month	12month	18 month	24month	36 month	48 month	60 month
01									
02									

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Format-B : Product summary sheet

Sr No	Name of Products (along with its composition)	No of batches manufactured in last 2years (with scale	Stability Data period (Maximum completed)		Process Validation (Completed/ Not Completed)	Status of Cleaning validation/Verification	Status of Analytical method validation (Completed/ Not	Availability of Reference & Working Standard	Annual product review	Mfg Lic / Product permission	COPP issue date
			Accelerated	Real Time							
01											
02											