21076/05.06.2018

**F.No. AYUSH/Misc-23/2018-DC**
**Government of India**
**Directorate General of Health Services**
**Central Drugs Standard Control Organization**
**(AYUSH Division)**

**Tele. No. : 011-23236965**
**Fax No. : 011-23236973**

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 02 AUG 2018

**Office Memorandum**

**Subject:** List of documents required with the application and its processing by both the agencies to expedite the grant/ revalidation of WHO-GMP/CoPP of ASU drugs-regarding.

This is with reference to the O.M. vide no K11020/03/2002-DCC(AYUSH)-Pt. Dated 28.06.2018 received from the Ministry of AYUSH on the subject matter.

In this regard it is stated that the complete list of documents required for grant/revalidation of WHO-GMP/CoPPs of ASU drugs as per WHO guidelines has been finalised as annexed.

In order to expedite the process of Issuance of WHO-GMP/CoPP certificate by this office in a time bound manner it is appropriate to consider that Ministry of AYUSH will perform the product evaluation from the angle of quality, safety & efficacy whereas this office will examine the tenets of the GMP applied for manufacturing of products.

The following timelines has been prescribed for processing and disposal of such applications by both the agencies:

| Sr No | Type | Proposed Timelines |
|---|---|---|
| 01 | Initial processing and disposal of application | 30 days |
| 02 | Processing of query response applications | 15 days |
| 03 | Processing by default for Joint inspection of the site | 90 days |

This is for your information and necessary action.

**Encl: As above**

**(Dr. S. Eswara Reddy)**
**Drugs Controller General (I)**

**To:** Dr. D. C. Katoch,
Advisor (Ayush),
AYUSH Bhawan,
'B' Block, GPO Complex, INA
New Delhi 110023

**Copy to:**

1. JS(R), Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi
2. PS to JS, Ministry of AYUSH, AYUSH Bhawan, 'B' Block, GPO Complex, INA, New Delhi 110023.
3. Shiela Tirkey, Under Secretary to Govt of India, Ministry of AYUSH, AYUSH Bhawan, 'B' Block, GPO Complex, INA, New Delhi 110023

## 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. (Applicable for revalidation of 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)**
     **(Minimum 06 months period for Accelerated Stability data and 12 months for Real time Stability data shall be submitted at the time of initial application.)**
   - **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. List of Reference standards/ marker for all active ingredients / formulation of the products applied for WHO-CoPP
19. Certificates of Analysis for three batches of each product
20. Undertaking regarding absence of any non-herbal ingredients including metals/ minerals, etc. in the products applied for WHO-CoPPs.
21. 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 and simultaneously to the Drug Control Cell, Ministry of AYUSH.*

# #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 | | | | | | | | | |



# # 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 | | | | | | | | | | | |