Annex A

VOLUNTARY CERTIFICATION SCHEME FOR AYUSH PRODUCTS Section IV

INTERNAL QUALITY ASSURANCE PROTOCOL

1. This document describes the controls over process and the product at various stages of production, and the hygienic conditions for ensuring the consistent production of AYUSH products meeting the specified certification criteria. T

2. An Inspection and Test plan has been documented defining the controls over the incoming herbal starting material, in process controls and the final AYUSH product.

3. **Batch** – For the purpose of this Internal Quality Assurance Protocol for AYUSH Products, a ***batch*** (***or lot***) is a defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it is expected to be homogeneous. It may sometimes be necessary to divide a batch into a number of sub- batches, which are later brought together to form a final homogeneous batch. In the case of terminal sterilization, the batch size is determined by the capacity of the autoclave. In continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity. The batch size can be defined either as a fixed quantity or as the amount produced in a fixed time interval.

4. The manufacturer shall test the products in the laboratory, which shall be suitably equipped and staffed. The inspection and testing shall be shall be carried out in accordance with the methods given in the relevant Pharmacopeia API/UPI /SPI/HPI/Internationally recognized methods / the relevant Regulation of the importing country. Records of all tests performed shall be maintained for a minimum period of 3 years .

4.1 All the testing equipment shall be periodically checked for continued suitability and calibrated at least once in year from NABL accredited Calibration laboratories. Calibration certificates issued by the Equipment manufacturer indicating traceability to National / International standards may be acceptable as initial calibration. Calibration of analytical equipment's like Gas Liquid chromatograph, Atomic Absorption Spectrophotometer, etc., may be done as specified in the respective instrument manuals or the test methods. Records of such checks and calibration shall be maintained. The Certified reference materials used for instrument calibration and other standardization purposes shall be procured from and shall be traceable to national or any other internationally acceptable sources as applicable.

5. The entire production of the product for which the manufacturer has been certified shall be subject to these controls as defined in Table II – Inspection and testing Plan and evaluated for its conformance to the applicable certification criteria.

6. The decision regarding conformity or otherwise of a Batch to the prescribed requirement shall be made on the basis of tests and analysis results, and review of Batch Processing Records and Batch Packaging Records

7. In respect of all other clauses of the Standard, other than those mentioned under Inspection and Testing Plan – Table II of this Internal Quality Assurance Protocol, the factory shall maintain appropriate controls and checks to ensure that their product conforms to the various requirements of the standard.

8. All products conforming the criteria shall be legibly marked with the specific Certification mark awarded to them. The manufacturer shall apply the Certification Mark and dispatch only after the completion of satisfactory corrective actions and availability of satisfactory results of all tests as applicable for each Batch has been achieved.

9. Finished products should be held in quarantine until their final release, after which they should be stored as usable stock under conditions established by the manufacturer.

10. Incoming materials

10.1 Incoming starting herbal material shall be checked for compliance to criteria defined in the API/UPI/SPI/HPI. Each consignment shall be subjected to Inspection and testing and only those found conforming shall be used for processing. If the herbal material for processing does not

comply with its quality specifications, the material shall be rejected, stored separately and disposed of.

10.2 When consignments are accompanied by a suppliers Test certificate the same maybe accepted as means of establishing conformance, and in such cases the manufacturing organization shall test samples from every 10th consignment. However if sample fails on independent testing then sample from every consignment shall be tested till confidence is assured.

10.3 Other raw materials and Packaging material - All incoming products and packaging materials to be used shall be checked on receipt for quantity, identity and conformity with the packaging instructions. The conformity assessment shall be carried in accordance with the levels of controls as given under Table I.

10.4 Packaging material shall be checked for identity and condition while issuing for packaging of the product. Outdated or obsolete primary packaging material or printed packaging material shall not be issued for use. It shall be destroyed and its disposal recorded.

10.5 Water (from any given source) if used for processing shall be initially tested for Colour, Odour, Taste, Turbidity, pH, Total Dissolved Solids, Microbiological and Chemical requirements including Toxic Elements and Pesticides Residues. Subsequently, its quality may be regularly assessed at least once in three months through in-house testing for Colour, Odour, Taste, Turbidity, pH, Total Dissolved Solids and Microbiological requirements. If the water source is changed then all the initial tests shall be carried out before its use .

11. Non Conforming Products

11.1 As and when a Batch of finished Product is reported non-conforming to specified requirements with respect to the Microbiological Requirements, the Batch shall not be dispatched. The Batch shall be rejected. The previous Batches made from the same consignment of incoming starting herbal material or those Batches in which the material of this Batch has been blended, and is available in stock shall be released into the market only after reinspection and testing confirming compliance to specified requirements.

11.2 As and when a Batch of AYUSH Products is reported non-conforming to specified requirements with respect to the requirements of Heavy Metal Contaminant , Pesticide residues and Aflatoxins, the Batch shall not be dispatched. The manufacturer shall immediately investigate the reasons for contamination and nonconformity, undertake a root cause analysis, do a correction, initiate corrective actions. The manufacturer may reprocess the material including blending .

11.3 The previous Batches made from the same consignment of incoming starting herbal material or those Batches in which the material of this Batch has been blended , and available in stock shall be released into the market only after reinspection and testing.

11.4 As and when a Batch of AYUSH Products is reported non conforming to specified requirements with respect to the other physio chemical requirements of the standard or Regulatory requirements, the Batch shall not be dispatched The Batch should be clearly marked as such and stored separately in restricted areas.

11.5 The manufacturer shall immediately investigate the reasons for the nonconformity, undertake a root cause analysis, do a correction, initiate corrective actions. The manufacturer may reprocess the material including blending. A reprocessed batch shall be identified by a new batch number, and all appropriate records of Batch processing and packaging maintained.

11.6 Whenever, the quality of herbal materials / AYUSH product is found to be not meeting the requirements of the certification criteria, the incoming raw materials records, in process records namely Batch processing records and Batch packing records shall be checked again for identifying and deciding upon the necessary controls to be exercised for conformance of quality of the AYUSH product.

12. Hygienic conditions- The herbal material and AYUSH products shall be processed, handled, stored, packed and marketed in accordance with the hygienic practices given in the applicable relevant Regulation, domestic or international, and the GMP Requirements Based On WHO Guidelines. Compliance to these requirements shall be checked and recorded on the check list for good hygienic practices.

13. Rejected Material - Rejected materials and products should be clearly marked as such and stored separately in restricted areas. They should either be returned to the suppliers or, where appropriate, reprocessed or destroyed in a timely manner. Whatever action is taken, should be approved by authorized personnel and recorded. A separate record providing the detailed information regarding the rejected materials and Batches of AYUSH Products and mode of their disposal shall be maintained. Such material shall in no case be stored together with that conforming to the certification criteria.

14. Samples- The manufacturer shall permit the drawal and collection of samples from their facility for independent evaluation of the product quality by the CB. No fee shall be levied for the same.

15. Replacement- Whenever a complaint is received soon after the goods with AYUSH Certification Mark have been purchased and used, and if there is adequate evidence that the goods have not been misused, defective goods are replaced free of cost by the licensee, in case the complaint is proved to be genuine and the best before period (where applicable) has not expired. The final authority to judge conformity of the product to the Certification criteria shall be with the CB. The manufacturer shall have its own complaint investigation system.

16. In the event of any damages caused by the goods bearing the Certification mark, or claim being filed by the consumer against AYUSH Certification Mark and not "conforming to" the relevant Certification Criteria, entire liability arising out of such non conforming products shall be of the certified unit and the CB shall not in any way be responsible in such cases.

17. Labelling - The finished AYUSH products shall be marked legibly on the label of the bottle / package …;

a) Name of the AYUSH Product;
b) Dosage form (Tablet or vegetarian capsules or any other)
c) List of active Ingredients and other ingredients , showing the amount of each present and a statement of the net contents (e.g. number of dosage units, weight, volume);
d) Batch number assigned by the manufacturer;
e) the expiry date in an uncoded form;
f) any special storage conditions or handling precautions that may be necessary;
g) directions for use, and warnings and precautions that may be necessary;
h) the name and address of the manufacturer or the company or the person responsible for placing the product on the market;
i) Any others as required by the Regulation;
j) The appropriate AYUSH Certification mark;
k) Customer care number or Helpline or Consumer complaint number

18. Suspension - The manufacturing unit shall suspend the certification voluntarily under intimation to the CB if, at any time, there is some difficulty in maintaining the conformity of the AYUSH product(s) to the relevant certification criteria, or the testing equipment goes out of order. The suspension may be revoked as soon as the deficiencies are removed under intimation to the CB. The use of Certification Mark on the product shall be stopped during the suspension period.

Table I

Raw Material Testing and Inspection Plan

Sl. No.	Parameters	Acceptance Criteria	Method of test	Frequency of test	No. Of Samples
1	Description	Compliance to relevant API / UPI / SPI / HPI Specification / Importing country Regulation. Test certificate with each consignment from supplier's laboratory is acceptable for establishing conformance, and in such cases every 10th consignment to be tested.	Visual (macroscopic) and / or Microscopic	Each Consignment	One
2	Identification		Visual examination and/or TLC	Each Consignment	One
3	Physio Chemical Parameters		As prescribed in API /UPI /SPI /HPI / Importing country Regulation	Each Consignment	One
4	Microbiological contaminants			Each Consignment	One
5	Pesticide residues (including Agricultural and veterinary substances)			Each Consignment	One
6	Aflatoxins			Each Consignment	One
7	Heavy Metals and Non-Metals			Each Consignment	One
8	Water	WHO guidelines form drinking water	As prescribed in WHO guidelines for drinking water	Once in a week	One
9	Packaging Material	As per documented in-house specifications / specifications of the importing country . Test certificate with each consignment from supplier's	As prescribed laboratory is acceptable for establishing conformance, and in such cases every 10th consignment to be tested.	Each Consignment	One

Table II

Finished Product Testing and Inspection Plan

Sl.No.	Parameters	Acceptance Criteria	Method of test	Frequency of test	No. of Samples
1	Description	Compliance to relevant API /UPI /SPI /HPI / Importing country Regulation	As prescribed in API /UPI /SPI /HPI / Importing country Regulation	Each Batch	One
2	Identification		Microscopic; TLC	Each Batch	One
3	Physio Chemical Parameters and assay, where applicable.		As prescribed in API /UPI /SPI /HPI / Importing country Regulation	Each Batch	One
4	Microbiological Contaminants	Compliance to relevant API/UP/SP/HP Specification / Importing country Regulation	Internationally recognized methods	Each Batch	One
5	Pesticide residues (including Agricultural and veteri		Internationally recognized methods	Each Batch	One
6	Aflatoxins (B1, B2, G1 and G2)		Internationally recognized methods	Each Batch	One
7	Heavy Metals and Non Metals	As per Govt order no .F.No.K - 11020/5/97- DCC (AYUSH) / WHO Limits /Importing country regulations	Internationally recognized methods	Each Batch	One