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Voluntary Certification Scheme For ASU Products

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The worldwide categorization under which Ayurvedic products can be considered is mainly: **Unlicensed OTC (over the counter) herbal medicines**, **Prescription medicines, Herbal supplements, Food supplements, Nutraceuticals, Botanicals**; **Dietary supplements**, **Novel foods, Border line products, Traditional Remedies, Herbal extracts, Raw herbs, and Cosmetics.** The increasing use of and the growing demand in the global market for such products has raised concerns on the quality and safety of herbal materials and finished herbal products with the respective national health authorities. Although traditional systems of medicine have been recognized and accepted in most countries, concerted efforts are being made to provide validated techniques to ensure the quality, safety, and efficacy of these products. As of today (2009), the key directives/ acts/ guidelines put in place for herbals/ Ayurvedic products by different countries are: EU/UK – THMPD (Traditional herbal medicinal products directive); US – DSHEA (Dietary supplements health and education act); Canada – NHPD (Natural health products directorate); and Australia – ARGCM (Australian regulatory guidelines for complementary medicine).

The norms that require compliance for global acceptability mainly address the following issues: GACP (Good agriculture and collection practices), GMP
(good manufacturing practices), Quality, Safety, and Pharmaco-vigilance. The emphasis is on availability of separate and adequate facilities for processing raw materials of metallic, mineral or animal origin, fresh herbs, dry herbs or plant parts, excipients, volatile oils, perfumes, flavours, plant extracts, exudates and resins, etc. Herbal cleanliness is another important issue. How we handle botanical ingredient identity and quality is key to the products we manufacture. Therefore companies must evaluate their ingredient identity and quality assurance systems, and prepare for new demands expected to be in the GMP rule. In addition, health, clothing, sanitation and hygiene of workers must be ascertained.

Making Good Manufacturing Practice a part of the process sooner rather than later will ease the burden of compliance. GMP norms include: having adequate space for receiving and storing raw materials, manufacturing process areas, quality control units including in-house testing facilities, finished goods store, office, rejected goods store, etc.; a valid manufacturing instruction which takes account of the standard batch size of the finished product (if necessary, the batch size range should be stated); and the description of the manufacturing process in the processing instructions containing the critical quality process parameters (incl. acceptance limits). The norms also require In-process controls (IPC), Flow chart, Risk assessment of the manufacturing process, and Documentation. The purpose of the IPCs is to monitor whether a defined manufacturing process operates in a controlled and reproducible manner.

Appropriate acceptance limits must be set for the IPCs carried out. The flow chart, which provides a schematic overview of the manufacturing process, must indicate all the IPCs to be carried out at the appropriate point in the process. Risk assessment procedures should identify the critical manufacturing steps in relation to quality. These should also refer to how the authenticity of the starting materials is ensured, whether contamination of the finished product can occur during or following the manufacturing process (e.g. accumulation of heavy metals during the manufacturing process) and the precautions being taken to prevent impurities being transferred to subsequent batches (cross-contamination) when cleaning the machinery used. The documentation about the analytical, chemical, and pharmaceutical tests must show that the test procedures respond to the state of scientific art and have been validated. Documents tell the true story of compliance. Without good documents and document control, all of the GMP efforts may count for nothing. Learning to create, manage and control documents is necessary for good GMP practices. The documents must in particular contain information and records of the following: Composition, Manufacturing process, Control of starting materials, Control of the intermediate product, Control of the finished product, and Shelf-life studies.

An appropriate quality assurance system should be applied in the manufacture of herbal medicines. This should ensure the use of modern analytical techniques especially HPTLC (high performance thin-layer chromatography, GC (gas chromatography), HPLC (high performance liquid chromatography, CE (capillary electrophoresis), MS (mass spectrometry), and AA (atomic absorption). To characterize herbal medicines, quality assurance also requires the control of starting materials, storage, and processing. Internal

Quality assurance protocol can ensure consistent quality of herbal products through use of approved quality of all incoming raw materials; use of all approved packing material including labelling; standardized and well validated methods of processing and manufacture; and complete finished product quality control testing.

The quality of the finished herbal products is largely dependent and influenced by the quality of the raw materials used. Because herbal ingredients are of complex and variable nature, the requirements and methods for quality control of finished products especially for combination products poses additional challenges. For eg: Important Ayurvedic formulations like *Chyawanprash* are a complex combination of ingredients/ constituents which vary with source and environmental factors. Besides, no single active ingredient is responsible for the broad therapeutic effects associated with the complex formulations .Also, standardisation of individual herbs to give a defined constituent is quite difficult to achieve in every batch manufactured. Therefore, controls of starting material, storage and processing assume particular importance in

the manufacturing process and consistency of herbal medicinal products.

Unlike conventional pharmaceutical products, which are usually produced from synthetic materials by means of reproducible manufacturing techniques and procedures, herbal medicines are prepared from materials of herbal origin, which are often obtained from varied geographical and/or commercial sources. As a result it may not always be possible to ascertain the conditions to which they may have been subjected. In addition, they may vary in composition and properties. Furthermore, the procedures and techniques used in the manufacture and quality control of herbal medicines are often substantially different from those employed for conventional pharmaceutical products. Because of the inherent complexity of naturally grown medicinal plants and the often variable nature of cultivated ones, the examples of contamination with toxic medicinal plants and/or plant parts and the number and small quantity of defined active ingredients, the production and primary processing has a direct influence on the quality of herbal medicines. For this reason, application of GMPs in the manufacture of herbal medicines is an essential tool to assure their quality.

Regulatory compliance to global requirements is essential to protect our products from potential areas of vulnerability like registration (with regulatory demands escalating and registration becoming mandatory in many countries), Quality (most important aspect of registration), Labelling/ packaging compliance, etc. The Ayush products are regulated under the Drugs and Cosmetics Act, 1940 by the Drugs Controller General of India through the State Governments. The Department of AYUSH has been exploring the possibility of introducing a **voluntary product certification scheme** for selected AYUSH products to enhance consumer confidence. With this in mind the Department of AYUSH signed an agreement with QCI (Quality Council of India) to design the Scheme with Department of AYUSH being the Scheme owner and QCI being responsible for managing. The Scheme was formally launched in October '09 and simultaneously placed on the websites of Department of AYUSH and QCI for public consultation. The Scheme is being overseen by a Multi-stake holder Steering Committee (MSC) chaired by the Secretary (AYUSH) with secretariat in QCI. The MSC is supported by a Technical Committee and a Certification Committee constituted by QCI.

The objective of Quality Certification is to enhance consumer confidence with the quality mark, obtain International acceptance, encourage ASU medicine manufacturers to invest in quality, and to improve levels of compliance to regulations such as Schedule T (see annexure 1)

The Scheme is based on the **criteria for certification.** It has two levels:

a) **Ayush Standard Mark** which is based on compliance to the domestic regulatory requirements ;which is Schedule T and limits of contaminants

b) **Ayush Premium Mark** which is based on either or both of the following options;

Option A: Compliance to GMP Requirements based on WHO Guidelines and Levels of contaminants as given in Certification Criteria document

Option B: Compliance to regulatory requirements of any importing country provided they are more stringent than Option A above.

Under this scheme, each manufacturing unit would obtain a certification from an approved certification body (CB) which is accredited to appropriate international standards by the **National Accreditation Board for Certification Bodies (NABCB)** and will be under regular surveillance of the certification body. Manufacturing units may visit the qci website (www.qcin.org) and refer to Annex A, B and C and click on Conformity Assessment scheme and link to Ayush certification scheme .Even the list of approved certification bodies is provided so that manufacturers can get in touch with the CB's to understand the certification process and other formalities of the audit (see **Note**)

Annexure 1------Schedule T

- Raw materials used in manufacturing of drugs are authentic, of prescribed quality and free from contamination.
- The manufacturing process is as has been prescribed and maintains standards of purity.
- Adequate quality control measures are taken and
- The manufactured drug which is released for sale is of acceptable quality.
- To achieve these objectives each licensee shall evolve methodology and procedures for manufacture of drugs which should be documented as a manual and kept for reference and inspection

Note

i. For the time being this certification is available for Herbal products
1.1.1 For any manufacturer to qualify for Ayush Premium Mark certification, compliance to the domestic regulation is a prerequisite.
1.2 The various criteria mentioned above are as follows:
a) Domestic regulation means regulatory requirements prescribed under the Drugs and Cosmetics Act, 1940 for AYUSH products
b) GMP Requirements based on WHO Guidelines for Ayush Premium Mark (Annex A)
c) Permissible levels of contaminants for AYUSH Premium Mark (Annex B)
d) Permissible levels of contaminants for AYUSH Standard Mark (Annex C)
e) Regulations of importing countries – to be identified by the organization seeking certification and provided to the Certification Body

References for further details:

www.qcin.org; www.ayush.nic.in;
www.mhra.gov.uk ; www.who.int ;
www.fda.gov www.emea.europa.eu