

VOLUNTARY CERTIFICATION SCHEME FOR AYUSH PRODUCTS

Section I

Introduction

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. The matter was discussed in a series of meetings taken by the Secretary (AYUSH) beginning 24 Dec 2008 and the Quality Council of India (QCI) offered to develop a concept paper on the subject.

On approval of the concept, the Department of AYUSH signed an agreement with the QCI on 27 July 2009 to design the Scheme with **Department of AYUSH being the Scheme owner and QCI being responsible for managing the Scheme.**

The draft Scheme was given to the Department of AYUSH on 3 Aug 2009 and simultaneously placed on the websites of Department of AYUSH and QCI for public consultation.

The Scheme will be overseen by a **Multistakeholder Steering Committee (MSC)** chaired by the Secretary (AYUSH) with secretariat in QCI. The MSC will be supported by a **Technical Committee** and a **Certification Committee** constituted by QCI.

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

- a. **Ayush Standard Mark** which is based on compliance to the domestic regulatory requirements
- b. **Ayush Premium Mark** which is based on GMP requirements based on WHO Guidelines and product requirements with flexibility to certify against any overseas regulation provided these are stricter than the former criteria.

Under this scheme, each manufacturing unit would obtain a certification from a 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.

The documentation of the Scheme is as follows:

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III	Certification Criteria
III A	GMP Requirements Based On WHO Guidelines for Ayush Premium Mark
III B	Permissible Levels of Contaminants for Ayush Premium Mark
III C	Permissible Levels of Contaminants for Ayush Standard Mark
IV	Certification Process
IV A	Internal Quality Assurance Protocol
V	Requirements for Certification Bodies
VI	Obtaining and Maintaining Certification
VII	Approval for use of Certification Mark to Certified Units