VOLUNTARY CERTIFICATION SCHEME FOR AYUSH PRODUCTS
Section I
Introduction

The AYUSH products are regulated under the **Drugs and Cosmetics Act, 1940 and Rules 1945** by the Drugs Controller General of India through the State Governments. Regulations for Ayurveda, Siddha and Unani (ASU) products is followed as per schedule T and Regulations for homeopathy products is followed as per schedule M1.

The Ministry of AYUSH was 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) in Dec 2008 and the Quality Council of India (QCI) offered to develop a concept paper on the subject.

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

The draft Scheme was given to than Department of AYUSH, under Ministry of Health and Family Welfare on 3 Aug 2009 and simultaneously placed on the websites of the Ministry of AYUSH and QCI for public consultation.

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

The Scheme is based on **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 using WHO Guidelines and product requirements with flexibility to certify against any overseas regulation provided these are more stringent than the former.

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.

SECTION I: PADD: AYUSH MARK: INTRODUCTION

The documentation of the Scheme has been structured as given below:

Section	Title
I	Introduction
II	Governing Structure
III	Certification Criteria
III A	GMP Requirements based on WHO Guidelines for herbal medicines 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