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**Ayush dept issues draft notification on GCP for ASU & traditional medicines**

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Direct link to the News/Story:-

<http://www.pharmabiz.com/article/detnews.asp?articleid=56533&sectionid=>

The Department of Ayurveda, Unani, Siddha and Homoeopathy (Ayush) has recently issued a draft gazette notification informing about the guidelines for good clinical trials on Ayurveda, Siddha, Unani (ASU) medicines and other traditional medicines (TM). These guidelines are formulated based on CDSCO document on GCP guidelines for clinical trials on pharma products. The draft states that these guidelines should be followed for carrying out all ASU medicines and other TM research in India at all stages of drug development, whether prior or subsequent to product registration in India.

The draft defines ASU medicines as drugs that includes all medicines intended for internal and or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals and manufactured exclusively in accordance with the formulae described in the authoritative books of Ayurvedic, Siddha and Unani tibb systems of medicine as specified in the first schedule. Whereas, traditional medicine is defined as the sum of total of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures in India, used for the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illnesses, which do not find a mention in First Schedule of Drugs and Cosmetics Act 1940.

With the implementation of GCP for ASU and TM medicines, the government aims to ensure that the studies are scientifically and ethically sound and that the clinical properties of the ASU medicine and other TM under investigation are properly documented. The guidelines seek to establish two cardinal principles, namely, protection of the rights of human subjects and authenticity of ASU medicine/other TM clinical trial data generated.

The draft states, "The complexities of ASU medicines and other TM research necessitate a more elaborate set of guidelines that address a physician's ethical and scientific responsibilities such as obtaining informed consent or disclosing risk while involved in ASU medicines and other TM research." It further points out that the fundamental tenet of GCP is that in research on man, the interest of science and society should never take precedence over considerations related to the well being of the study subject.