

**GOVERNMENT OF INDIA  
MINISTRY OF AYURVEDA, YOGA & NATUROPATHY,  
UNANI, SIDDHA AND HOMOEOPATHY  
(AYUSH)**

**LOK SABHA  
UNSTARRED QUESTION NO. 07  
TO BE ANSWERED ON 2<sup>ND</sup> FEBRUARY, 2018**

**GOOD CLINICAL PRACTICE**

**7. SHRI ANTO ANTONY:**

Will the Minister of **AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH)** be pleased to state:

- (a) whether the Government has published Good Clinical Practice (GCP) Guidelines for Ayurveda, Siddha and Unani Medicines;
- (b) if so, the details and the salient features thereof;
- (c) whether the Government has received any proposal for amending the GCP guidelines and if so, the details thereof;
- (d) whether the Government proposes to amend the GCP guidelines; and
- (e) if so, the details thereof and if not, the reasons therefor?

**ANSWER**

**THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYURVEDA,  
YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY  
(SHRI SHRIPAD YESSO NAIK)**

(a) to (e): Yes, the erstwhile Department of AYUSH in the year 2013 published 'Good Clinical Practice Guidelines for Clinical Trials in Ayurveda, Siddha and Unani (ASU) Medicine (GCP-ASU)'. The salient features of these guidelines include protection of human rights as a subject in clinical trial. It also provides assurance of the safety and efficacy of the newly developed as well as conventionally used ASU formulations. These guidelines include standards of how clinical trials should be conducted; and define the roles and responsibilities of clinical trial sponsors, clinical research investigators, monitors etc. The objective is to inculcate the culture of conducting ASU intervention-based clinical studies in the country in accordance with requisite scientific standards and appropriately designed methodologies. It is also intended that results and findings of clinical trials are properly recorded, analyzed and reported. As of now, there is no proposal for making any amendment in the GCP guidelines since the regulatory requirement of clinical trial is not mentioned in the extant provisions of the Drugs & Cosmetics Act, 1940 and Rules thereunder for granting license to the manufacturing of Ayurveda, Siddha and Unani medicines.