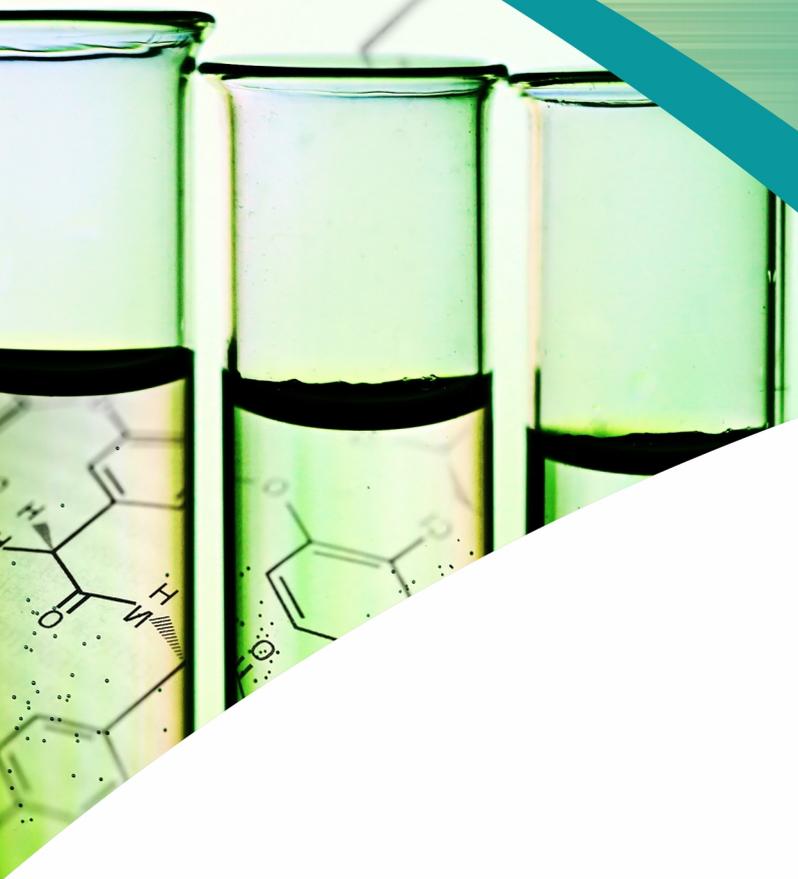


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**Disclaimer:**

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# Regulatory Requirements for Phytopharmaceuticals Under The Central Drug Standards Control Organization (CDSCO)

Kajal Chaudhary and Indu Singh

Amity Institute of Pharmacy, Amity University, Noida, Uttar Pradesh -201301

## ABSTRACT

**Background:** In India, plant based items utilized as drugs go under the class of Phytopharmaceuticals. The CDSCO notified guidelines for phytopharmaceuticals as a change to the Drugs and Cosmetic in 2015. These guidelines relate to the regulatory accommodation prerequisites, on quality, adequacy and safety to assess and allow marketing.

**Aim:** This article is intended to give explicit information on another class of drugs called phytopharmaceuticals. The gazette notification published by the Government of India published defines phytopharmaceutical medications and data generated by applicants and also incorporate administrative procedures identified applicable to this new class of drugs. This new class of medication may empower the intrigue and request of plant-based therapeutics for neglected clinical needs.

**Method:** The information collected in this article is collected from various parts and reports that relate to their authentication, source of plant used for Extraction, stability studies, manufacturing and marketing information, regulatory aspects, clinical examines and rules for the accommodation of utilization of phytopharmaceuticals.

**Result:** The proper set of documentation is required to be submitted by the applicant on the basis of set guidelines given by the CDSCO to manufacture and import the phytopharmaceutical drug.

**Conclusion:** The new phytopharmaceuticals guidelines allow the advancement of plant-based medications. CDSCO approve the NDA, the developer can bring the new phytopharmaceutical like any other chemical entity based medication in market. This is bound to advance developments and improvement of new medications from botanicals in line with the modern medication system.



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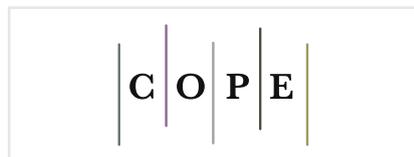
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