Pharmaceut Reg Affairs 2012, 1:4
http://dx.doi.org/10.4172/2167-7689.S1.007

OMICS Group Conferences
Accelerating Scientific Discovery

2nd International Conference and Exhibition on
Pharmaceutical Regulatory Affairs

November 23-24, 2012 Hyderabad International Convention Centre, India

## Gudavarti- an ayurvedic, cost-efficient treatment for management of constipation

**Mukesh R. Hire[1], Lalit V. Patil[1] and Aparna A .Raut[2]**
[1]Infectious diseases department, kem hospital, India
[2]Department of shalya-tantra, shree saptashrungi ayurved college &hospital, India

The above Study was done to check the efficacy of Gudavarti in minimizing symptoms and Cost-effectiveness in the Treatment of Constipation. Gudavarti was prepared with herbal ingredients with help of preparation guideline mentioned in Bhaishjay-Kalpana Vidnyan of Ayurved. Patients diagnosed with the Constipation for six symptoms related to Constipation were taken as subjects for study. Gudavarti was inserted rectal route to patients. The diagnosis was done based on the four stages of symptom viz. Often (O), Sometimes (S),Most of times (M), Always (A).On diagnosis for symptom-1,45% of the patients showed Sometimes of Hard and Lumpy stools, 10% patients showed Often of Symptom 25% showed Most of times and 20% showed Always of Hard and Lumpy stools. On completion of the treatment after 3 days, 1 % showed Sometimes of Symptom, 2 % showed Often of symptom, 1% of patients showed symptom always of symptom. The overall results show that overall 96% of patients showed total relief from symptom at end of treatment. Accordingly for Symptom-2, Symptom-3, Symptom-4, Symptom-5, Symptom-6-95%, 95%, 94%, 93%, 98% of patients showed total relief from symptom respectively. The Gudavarti was prepared with herbal ingredients and it is safe, easy for preparation, Cost effective. Thus, the result shows that Gudavarti is having high commercial potentials for the treatment of Constipation.

mukeshhire@gmail.com

## Drug registration in Asean countries

**Munugoti Suman and Saikatroy**
Vaagdevi College of Pharmacy, India

A regulatory process, by which a person/organization/sponsor/innovator gets authorization to launch a drug in the market, is known as drug approval process. Every country has its own regulatory authority, which is responsible to enforce the rules and regulations and issue the guidelines to regulate the marketing of the drugs. In the present scenario, countries have different regulatory requirements for approval of a new drug. The single regulatory approach for marketing authorization application (MAA) of a new drug product applicable to various countries (on the basis of single dossier) is utmost difficult. Therefore, the knowledge of exact and detailed regulatory requirements for MAA of each country should be known to establish a suitable regulatory strategy. Asean Common Technical Dossier ACTD is common application format that will be submitted to ASEAN regulatory authorities for the registration of pharmaceutical products for human use. Even though some of the Individual ASEAN Countries have their own drug registration formats, all ASEAN countries accept the ACTD. The Asean countries are Brunei Darussalam, Cambodia, Indonesia, Lao's, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam. The main objective of the work is to prepare high level documentation of Overview of the ASEAN Countries Drug Registration Process with each country's process and produce common Technical Document for ASEAN countries with a Comparison study of ACTD and ICH CTD. To provide additional guidance to DRA and industries on technical difficulties encountered in the ACTD implementation and to exchange expertise and experiences among member countries. It's a study of Drug Dossier Preparation with a brand name **FEROFUME** and the Drug Registration Process - Time Line (country specific) procedures.

munugoti.suman@gmail.com