

# 2<sup>nd</sup> International Conference and Exhibition on Pharmaceutical Regulatory Affairs

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# Formulation and evaluation of diclofenac sodium gels using carbopol and hpmc as gelling agents

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The present research has been undertaken with the aim to develop a topical gel formulation of Diclofenac sodium using gelling agents i.e. carbopol and HPMC in different concentration, which would attenuate the gastrointestinal related toxicities associated with oral administration. They were evaluated for physicochemical properties such as homogeneity, grittiness, viscosity, pH, Spreadability, drug content, skin irritancy, in vitro drug release, stability studies. Studies showed that drug release was decrease with increase in gelling agent concentration because polymer concentration increases, viscosity increases. Drug was absorbed from site of application as long as it remains in higher concentration gelling agent in solution form.

### **Biography**

M. ASADANSARI completed B. Pharma in 2011 from Kota College of Pharmacy, Kota (RAJASTHAN.). Presently he is an M. Pharma. (Pharmaceutics) Student in Kota College of Pharmacy, Kota (Rajasthan). ASAD has attended 1 National conference IPC in Ahmedabad (Gujrat). His Research Guide is Dr. M. P. Khinchi is having 15 International Research Articles, 20 International Review Articles and he is Attended 12 National Conferences.

# New drug application (NDA) filling and submission

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Por decades, the regulation and control of new drugs is based on New Drug Application(NDA).NDA is a submission to the USFDA (United States Food & Drug Administration) or concerned regulatory authority of the country containing clinical and non-clinical test data / analysis reports along with drug chemistry information.NDA is submitted by Innovator Company to the FDA for the purpose of review of various activities carried out during the various phases of clinical studies before final marketing, authorization to the new pharmaceutical product. The goals of NDA are to provide enough information to satisfy FDA review team to take decisions regarding safety and efficacy of drug in its proposed use, appropriate proposed labeling and package insert, confirming the methods and controls used in manufacturing and maintaining the quality of new drug. The NDA to be submitted to FDA is prepared in multiple copies such as Archival copy, Review copy, Field copy containing as many as 20 different sections. The content of every NDA may be variable based upon the nature of drug and volume of information available at the time of submission. Now-a-days electronic submission of NDA is done to speed up the review process of new drugs.

## **Biography**

M.Prashanth is pursuing his B.Pharm IV year from CMR College of Pharmacy, Jawaharlal Nehru Technological University, Hyderabad. He participated and gave presentations in many national level seminars held at various colleges in Hyderabad. He got 2<sup>nd</sup> price for oral presentation on "Resealed Erythrocytes-Golden eggs in novel drug delivery system" in a national level symposium held at Sitha Institute of pharmaceutical sciences. Participated in international conference "3<sup>rd</sup> World Congress on Bioavailability & Bioequivalence: Pharmaceutical R & D Summit" conducted by OMICS group at Hyderabad and presented our project work done under the guidance of Dr.T.Vedavathi.

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