GOA – CENTER FOR EXCELLENCE IN INTELLECTUAL PROPERTY

3rd Annual International Conference
on

Intellectual Property: Prosecution to Litigation

Part II: Protecting Inventions and Copyrights

Nov. 15-16, 2018
Goa College of Pharmacy
Panaji, Goa - INDIA

G-CEIP

GOA – CENTER FOR EXCELLENCE IN INTELLECTUAL PROPERTY

Research Showcase Presentation

Abstracts

3rd Annual International Conference

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Message …….

At the outset, it is my distinct privilege to welcome you to the 3rd Annual International Conference on Intellectual Property organized by the **Goa – Center for Excellence in Intellectual Property [G-CEIP]** in association with **Goa College of Pharmacy [GCP]**. Global experts in IP have gathered here to share their rich and extensive experience in IP matters.

The industrial sector, including the pharmaceutical and healthcare sector in India is yet to recognize the full potential of the IP rights in all its dimensions – from generation to preservation and protection. The pharmaceutical community – academia and industry – have a limited understanding of IP and the rights associated with them. Additionally, the scientists/professionals, the very IP generators, have limited to no understanding of IP rights let alone their protection and preservation. As a result, it is time to address the immediate need(s) with respect to IP considerations with an appropriate balance of academic training, continuous updating and upgradation of knowledgebase in IP matters.

G-CEIP completes three years, as of date !! I will be presenting a ***Report Card*** on the accomplishments of the Center during this journey. Of the many "***first of its kind***" the Center, in June 2018, presented its first (of its series) 2-Day Professional Advancement Focus Program: **Understanding Basics of Intellectual Property for Scientists: *The IP Generators*** which was well supported and equally well received by industry and academia. This program is now available for on-site presentation to reach wider research groups and audience.

The principal focus of G-CEIP continues to be ***Recognize and Protect Scientific Discovery with the Rights it Deserves !!*** In keeping with this focus, G-CEIP will bring forth a series of international conferences over the coming years that will address the recent advances related to various aspects of IP from generation to preservation and protection. The central theme of **G-CEIP 2018 International Conference on Intellectual Property** is entitled:

Intellectual Property: Prosecution to Litigation - Part II: *Protection of Inventions and Copyrights*

We have added a new and unique feature (first of its kind) to this event: ***Research Showcase Presentation [RSP].***
It presents an opportunity for research scientists to present their research findings in a poster format. Additionally, the scientists will be able to network with IP experts (some of the best minds in IP) and assess the IP potential of their research findings. Thus, this opportunity, I believe, will be a very positive experience for the scholars and a long term positive impact in image building for the Center - a truly win-win situation for all concerned !!!! G-CEIP will be, in the future, looked upon as a breeding site to nurture innovation that ***Recognizes and Protects Scientific Discovery with the Rights it Deserves*** - the very guiding principle of the Center !!

I, personally, welcome each and every one of you to take maximum advantage of this opportunity, not only to listen to these experts in IP, but also to interact one-on-one with them. I hope this program will be a professionally enriching and rewarding experience which will go a long way in your professional development.

Warm wishes,

Umesh Banakar, Ph.D.
Professor & President

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Affix passport- size photograph

TITLE: FORMULATION DEVELOPMENT OF CARVEDILOL *IN SITU* GEL BY QUALITY BY DESIGN APPROACH

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ABSTRACT:

The main aim of present study was to formulate and develop novel *in situ* gelling system of Carvedilol by Quality by Design approach. A GastroRetentive Drug Delivery System of Carvedilol was formulated to increase the resident time in stomach and to modulate the release behavior of the Carvedilol. Carvedilol has half-life of 6-7 hours and required dose is 12 mg day. Initially Critical Quality Attributes (CQA) were identified from Quality Target Product Profile (QTPP) and risk analysis was done. Formation of *in situ* gel was done by mixing of gelling agent with suitable pH. For optimization of *in situ* gelling system 2^3 full factorial design was employed to study the effect of independent variables, concentration of HPMC (X1) and concentration of sodium alginate (X2) and dependent variables like viscosity, % drug content and % drug release. Formulation containing 0.50% of sodium alginate, 0.25% of HPMC showed the best gelling ability.C3 batch was selected as optimized batch based on viscosity(3.13 Pa.s), drug content (93%) and CPR (92%) at 12 hr. Formulation was studied for FT-IR study and DSC study showed there is no interaction between drug and excipients. The sustained release of Carvedilol from *in situ* gelling system was observed and hence *in situ* gelling system increase the gastric transient time and ultimately bioavailability of Carvedilol. Stability shown that there was no noticeable change in characterization. Thus, *in-situ* gel formulation is promising approach for gastro retentive sustained delivery of Carvedilol.

Keywords: *In Situ* Gel, Carvedilol, Quality by Design

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TITLE: Formulation, Development and Evaluation of Drug Loaded Niosomal Gel of Raloxifene Hydrochloride

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ABSTRACT:

Osteoporosis is a common disease characterized by a decrease in the density of bone, resulting in fragile bones. Raloxifene hydrochloride is a selective estrogen receptor modulator belonging to BCS class II. The objective of the study involves formulation and characterization of raloxifene hydrochloride niosomes by thin film hydration technique using non-ionic surfactants and cholesterol; thereby improve its solubility and bioavailability. The other basic idea was to avoid the first pass metabolism and formulate a cost effective dosage form viz. a topical gel to administer raloxifene hydrochloride niosomes. The niosomes were characterized using scanning electron microscopy and zeta potential and further evaluated for entrapment efficiency and *in-vitro* release studies and stability studies. Also the raloxifene hydrochloride noisome was modelled using molecular modelling techniques and evaluated *in-silico* using molecular dynamics simulations to establish the 3D-stability of the complex. *In-vitro* release of niosomal dispersion showed constant delivery of the drug for the period of 24 hours and followed zero order kinetics with Non-Fickian diffusion. Stability studies indicated that the niosomal dispersion remained more stable at refrigerated temperature compared to room temperature. *In-vitro* release data of gel formulations showed similar release as that of niosomal dispersion indicating that the release is not altered by incorporation into the gel base. This concludes that the gel formulation acts as a vehicle for application of niosomal dispersion. Amongst the gel formulation batches, gel prepared with 3% Hydroxypropyl methyl cellulose (HPMC) K15M showed highest release.

KEYWORDS: Raloxifene hydrochloride, Niosomes, Spans, Cholesterol, Gel, Molecular Dynamics Simulation.

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TITLE: Mechanistic Insights of the Penetration Enhancement Effect of Physical and Chemical Enhancers on Transdermal Delivery of Rizatriptan

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ABSTRACT:

Rizatriptan, an antimigraine drug is a selective 5-HT_1 receptor agonist. On administration by oral route, it undergoes extensive first pass metabolism showing bioavailability of about 40% and half-life of 1.5-2h which results in increased dosing frequency due to recurrence of migraine attack every 2h after the dose. Transdermal drug delivery system forms an alternative to such limitations. Rizatriptan being a hydrophilic drug does not possess ideal characteristics required for transdermal permeation, hence a suitable permeation enhancement technique is required for its delivery. The objective of this study is to assess the effect of Chemical enhancers (Isopropyl Myristate, Span 80, Tween 20 and Eucalyptus oil) and Physical enhancer (Microneedle 0.500mm & 0.75mm) on transdermal permeation of Rizatriptan. Transdermal patches were prepared by solvent evaporation technique using HPMC K4M, HPMC K15M & Eudragit RL100 as polymers and PEG 400 as plasticizer. Various evaluation parameters like physicochemical properties, release studies, stability studies, thickness, folding endurance, drug content, percentage moisture content, water vapor transmission rate and tensile strength were determined and found to exhibit satisfactory results. *In-vitro* drug release studies performed were seen to follow zero order kinetics thus proving IPM being most effective chemical enhancer. *Ex-vivo* skin permeation studies conducted using goat skin showed approximately 6.5 and 7.2 fold increase in steady-state flux. Formulations were found to be stable for a period of 3 months at 40 °C and 75% RH. Overall, the study suggests that use of penetration enhancers promises a practical way for treating migraine by transdermal delivery system of Rizatriptan.

KEYWORDS: Transdermal Drug Delivery, Rizatriptan Benzoate, Chemical Enhancers, Microneedle

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TITLE: DRY POWDER INHALATION OF VORICONIAZOLE FOR THE TREATMENT OF PULMONARY ASPERGILLOSIS: FORMULATION AND *IN-VIVO* EVALUATION

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ABSTRACT:

Aim: Dry powder for inhalation of voriconazole for the treatment of pulmonary aspergillosis: Formulation and in vivo evaluation.

Objective: The aim of the present study was to develop a dry powder inhalation formulation of VZ for the treatment of pulmonary aspergillosis.

Method: Hydroxy propyl-β-Cyclodextrin (HP-β-CD) complex of Voriconazole (VZ) was prepared by spray drying method. Based on results of phase solubility analysis, the formulations of VZ:HP-β-CD inclusion complex were prepared at molar ratio of 1: 2.5 with and without 10% and 20% of leucine as dispersing agent. The spray dried formulations were characterized for morphology by FESEM, FTIR, DSC, XRD, drug content, *in vitro* dissolution and particle size. In vivo lung distribution of optimized formulation was compared with oral and pure VZ inhalation formulation in Wistar rats.

Results: The optimized formulation with VZ: HP-β-CD molar ratio of 1:2.5 and 10% leucine exhibited markedly enhanced dissolution rate as compared to VZ pure drug. FTIR studies confirmed the absence of chemical interaction between VZ and HP-β-CD suggesting possibility of hydrophobic interactions. The absence of endotherm of VZ in inclusion complex with and without leucine further confirms formation of inclusion complex of VZ and HP-β-CD. XRD studies indicated change of drug from crystalline to amorphous form during process of formulation. VZ-HP-β-CD inclusion complex showed significant increase in the lung distribution than VZ pure drug inhalation (3.6 fold) and oral formulation (9.6 fold) when administered in Wistar rats. Histopathological studies revealed lower toxicity by VZ on lungs when administered as inclusion complex formulation than when it is in given in free form by oral or inhalation route.

Conclusion: VZ-HP-β-CD inclusion complex formulation is a promising alternative approach for pulmonary delivery of VZ with improved bioavailability of antifungal drug for treatment of Pulmonary Aspergillosis.

KEYWORDS: Voriconazole, HP-β-CD, Spray drying, pulmonary delivery, in-vivo tissue distribution study.

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TITLE: FORMULATION AND EVALUATION OF BILAYERED TABLET OF SUMATRIPTAN SUCCINATE AND IBUPROFEN

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ABSTRACT:

Bi-layered tablet refer to tablet which contain subunits which are separated by alayer. Study is planned such that, one-layer of tablet provides immediate release and other acts as sustained release. Our objective is to formulate and evaluate bilayer tablet containing sumatriptan succinate, 250 mg and ibuprofen, 200 mg. In the present case 50 mg of sumatriptan succinate and 200 mg of ibuprofen are supposed to release immediately by constituting a unit and the remaining 200 mg of sumatriptan succinate has to be released in a sustained manner from the other unit. Earlier studies indicate that the combination of sumatriptan and ibuprofen increases the serum concentration of ibuprofen, hence the study is planned to get optimum analgesic effect of ibuprofen. Immediate release unit of tablet was prepared with sodium starch glycolate and sustained release unit with HPMC K15, HPMC E15, eudragit S 100 and sodium alginate polymers. The different concentrations of above polymers were considered as variables and are optimized. Pre compression and post compression parameters were studied. Drug, HPMC K15 and HPMC E15 in the ratio of 1:0.125:0.125 was the optimized formulation. Drug release at 8th hour was found to be 60.67%. The compatibility studies and stability studies were proved good. This preparation had released the drugs in an appropriate manner and found suitable in the management of Migraine.

KEYWORDS: 5-HT 1B 1D receptors, Bi-layered tablet, API, HPMC K15, HPMC E15.

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TITLE: DEVELOPMENT AND CHARACTERIZATION OF FLOATING MICROSPHERES CONTAINING RASAGILINE MESYLATE USING NATURAL POLYMERS

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ABSTRACT:

Floating microspheres of Rasagiline mesylate were prepared to prolong gastric residence time, to achieve controlled delivery of drug and to improve bioavailability of the drug. The floating microspheres were prepared by solvent evaporation method using 2^3 factorial design. Guar gum was used as a polymer and ethyl acetate was used as gastro retentive and coating material. Microparticles were characterized for physical characteristics such as micromeritic properties, particle size, particle shape, %yield, drug entrapment efficiency. Further %CDR and surface morphology by scanning electron microscopy, in-vitro buoyancy, in-vitro release studies, in-vitro release kinetics, in-vivo X-ray radiographic studies were performed. Stability studies were carried out on selected formulation according to ICH guidelines. The obtained microspheres were free flowing, spherical in shape and had a mean particle size ranging from 5-65µm suitable for oral delivery. All the microspheres showed good buoyancy and drug was entrapped into the microspheres with an efficiency of 83.4%, % drug release was 88.99%. Upon fitting of in-vitro release data into various kinetic models, the release was found to follow first order kinetic model. The in-vivo radiographic study results revealed that the drug was retained in the stomach for a period of 8h. The results obtained suggested that Rasagiline mesylate microspheres floating delivery system can be successfully designed to provide controlled drug release.

KEYWORDS: Floating microspheres, Rasagiline mesylate, Guar gum, solvent evaporation, controlled release.

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TITLE: FORMULATION AND EVALUATION OF FAST DISSOLVING TABLETS CONTAINING A MODEL ANTI-MIGRAINE DRUG

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ABSTRACT:

Eletriptan hydrobromide is a second generation Triptan drug, intended for the treatment of acute Migraine attacks. It is selective 5 Hydroxytryptamine (5HT 1β/1δ) receptor agonist with intensely bitter taste. Formulation of Eletriptan hydrobromide into fast dissolving tablets (FDT's) can provide rapid dissolution, absorption and quick onset of action with better patient compliance. In the present study, an attempt has been made to mask the bitter taste of Eletriptan hydrobromide by complexing with β-Cyclodextrin (1:3 ratio) using physical mixture method, along with addition of suitable sweetness and flavors. This was in turn successfully formulated into FTD's by direct compression method using suitable diluents and superdisintegrants. The 3 superdisintegrants- crospovidone (CP), croscarmellose sodium (CCS) and sodium starch glycolate (SSG) were taken in different ratios 4%, 8% and 12% to study the influence of these three different superdisintegrants and % ratio on the prepared FDT's. The prepared blends were examined for the taste masking efficiency by the selected human volunteers, along with the pre-compression parameters which were in permissible limits. All the formulated FDT's were examined for hardness, drug content, friability, *in vitro* disintegration time, *in vitro* dissolution rate, release kinetics model and stability studies. The formulation F3 containing 12% CP showed best disintegration time of 0:32± 0.006 mins and drug release of 94.71± 0.163% (10 mins) and was found to follow first order release kinetics models. This study concluded, that nature and concentration of the superdisintegrants influenced the *in vitro* disintegration time and *in vitro* dissolution rate.

KEYWORDS: Eletriptan hydrobromide, Fast dissolving tablets, Superdisintegrants, Taste masking, *In vitro* disintegration time, *In vitro* dissolution rate, First order release kinetics.

TITLE: FORMULATION AND EVALUATION OF MICROSPONGES FOR TOPICAL DRUG DELIVERY OF BUTENAFINE

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ABSTRACT:

Butenafine hydrochloride topical microsponges were prepared in order to sustain the drug release and minimize the associated side effects of topical delivery such as burning, itching, contact dermatitis, erythema and irritation. Microsponges were prepared by quasi-emulsion solvent diffusion method by applying factorial design. From the preliminary trials, the constraints for independent variables Eudragit S-100 (A), Polyvinyl alcohol (B), stirring rate (C) and stirring time (D) were set and experimental runs were generated to prepare microsponges. The prepared microsponges were evaluated for surface morphology, particle size and shape by scanning electron microscopy, micromeritic properties, percentage yield, entrapment efficiency and *in-vitro* release studies. Optimized butenafine hydrochloride microsponges were then incorporated into carbopol gel. The prepared gel was evaluated for pH, viscosity, drug content, *in-vitro* drug permeation study, *in-vitro* and *in-vivo* antifungal study. Stability studies were carried for the gel according to ICH guidelines. The obtained microsponges were spherical, free flowing particles with diameter ranging from 47.36 to 65.76 µm. All the microsponge formulations showed controlled release of drug. Drug release of the optimized formulation followed Korsmeyer Peppas model. There was good co-relation between *in-vitro* and *in-vivo* antifungal activity. Butenafine hydrochloride microsponges showed better activity when compared to the marketed formulation.

KEYWORDS: Fungal infection, Butenafine hydrochloride, Topical microsponges, Eudragit S-100, polyvinyl alcohol, quasi-emulsion solvent diffusion method.

TITLE: PREPARATION AND OPTIMIZATION OF QUERCETIN LOADED LIPID NANOPARTICLES FOR COLON TARGETING IN ULCERATIVE COLITIS

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ABSTRACT:
Quercetin loaded lipid nanoparticles (QTLNs) were prepared by emulsification followed by high speed homogenization and spray drying using min run screen design. From the preliminary trials, the constraints for independent variables, drug, stearic acid, soya lecithin, tween 20, pectin and homogenization speed were set and experimental runs were generated by min run screen design to prepare QTLNs. The prepared nanoparticles were characterized for particle size, particle shape and surface morphology by scanning electron microscopy, zeta potential, micromeritic properties, percentage yield, drug entrapment efficiency, *in vitro* release studies, *in vitro* release kinetics, *in vivo* radiography and *in vivo* pharmacodynamic study. The optimized formulation had poor flow property and SEM images depicted spherical shaped particles with slight rough surface. The average particle size and zeta potential of the optimized formulation was found be 86.64 nm and -62.4 mV respectively which indicated the suitability of formulation for oral delivery with good physical stability. The optimized formulation showed controlled release of drug with enhanced release in colon, indicating colon specific release. Upon fitting of *in vitro* release data into various kinetic models, the drug release mechanism followed non-Fickian diffusion (anomalous transport) model. The *in vivo* radiographic study results revealed that the drug was retained in the colon for a period of 16h. Pharmacodynamic results demonstrated the improved therapeutic efficiency of the QTLNs nanoparticles in comparison with pure drug in the management of ulcerative colitis. These findings demonstrate the feasibility of min run screen design in successfully developing pectin coated QTLNs for colon targeting.

KEYWORDS: stearic acid, high speed homogenization, pectin, spray drying, min run screen design

TITLE: Formulation, characterization and monitoring crystallization of of atorvastatin calcium in fast dissolving oral film

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ABSTRACT:

Background: Atorvastatin calcium, a lipid lowering agent, exhibits poor aqueous solubility. The aim of the present study was to incorporate atorvastatin calcium in two different drug loadings into a fast dissolving oral film. Furthermore, the films were evaluated of physiochemical properties and examined for crystallization during its stability period.

Method: Hydrophillic polymers such as different grades of hydroxyl propyl methyl cellulose (HPMC) and polyvinyl pyrrolidone (PVP) were used as film formers. The film was formulated by employing solvent casting method. The films were evaluated for physiochemical and mechanical properties including in-vitro disintegration and in-vitro dissolution. Optimized films were subjected for stability studies. The films were monitored for crystallization during their storage period and analysed using scanning electron microscopy (SEM) and X-ray diffraction (XRD).

Results: The results obtained showed that in-vitro disintegration time and drug release was affected by the presence and amount of superdisintegrants. Films analysed after stability studies, displayed no visible crystals in the SEM images. The XRD diffractograms proved the conversion of crystalline atorvastatin calcium to its amorphous state and the peaks remained consistent even in the consequent stability samples. There was no much difference observed in the drug release profiles of stability samples.

Conclusion: The oral film formulation with two different drug loadings of atorvastatin calcium was possible. The formulations were found to be stable during its stability period and the drug exhibited amorphous stability at the end of three months.

KEYWORDS: Atorvastatin Calcium, fast dissolving films, HPMC E-15, HPMC-E5, HPMC E-3, in-vitro dissolution, crystallization, stability study

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TITLE: FORMULATION OF ALOE VERA GEL IMMEDIATE TABLETS

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ABSTRACT:

Aloe vera gel finds wide applications therapeutically and is also used extensively in cosmetic preparations. Aloe vera gel is used as a nutraceutical and in food applications. It is used either as a liquid or in the dried form[4]. Not much work is reported on the tablet formulation of aloe vera gel. The present work is to formulate aloe vera gel powder (AVGP) into immediate release tablets. Preformulation studies have been carried viz. micromeritic properties, hygroscopicity, compactibility testing and excipient selection study. AVGP has been found to be hygroscopic and had poor flow characteristics. It formed good compacts when subjected to compression force. 1:1 Blend of AVGP with magnesium oxide and with Aerosil remained dry and had good flow while those with other excipients formed an aggregate. Tablet formulation has been tried by wet granulation and direct compression methods. The tablets were evaluated for hardness, thickness, friability, assay, disintegration and dissolution. Tablets could be prepared by wet granulation method with starch as binder but the yield was very low. These tablets took more than 30 minutes to disintegrate. Direct compression method was tried. Blends were tried to get good flow. AVGP direct compression tablets without stabilizers showed mild discoloration upon storage. These tablets were compression coated to confer physical stability. % disintegrant to be incorporated had to be increased because of the hygroscopic nature of the material being compressed. Assay was performed based on estimation of polysaccharide content employing congo red. Evaluation parameters for AVGP direct compression tablets and compression coated tablets were within standard limits.

KEYWORDS: Aloe vera gel, immediate release tablets, wet granulation, direct compression, hygroscopic, compression coating, aerosil, Magnesium oxide.

TITLE: Targeting Cholinesterases: Virtual Screening of Chemical Libraries for Potential Anti-Alzheimer's Candidates

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ABSTRACT

Alzheimer's disease (AD) is the most common cause of dementia characterized by gradual decline of the cognitive functions in the elderly people, accounting for around 50%-60% of the overall cases amongst population over 65 years of age. Dementia is presumed to be arise from the progressive deterioration of widespread and dense cholinergic innervation of the human cerebral cortex, that is responsible for the cognitive and behavioral disturbances in AD, marked the decreased levels of the neurotransmitter, acetylcholine (ACh). Acetylcholine is hydrolyzed by acetylcholine esterase (AChE) and butyrylcholinesterase (BuChE). AChE regulates the levels of ACh in a health brain while BuChE has a minor role to play. But the process practically reverses in patient with AD where the levels of AChE activity declines drastically leading to an increased activity of the BuChE increases. The ratio between BuChE and AChE can change from 0.6 in the normal brain to as high as 11 in the plaque affected areas of the cortex. Looking at this events dual inhibition strategy of AChE and BuChE is a resourceful approach to increase the efficacy of treatment and broaden the indications.

Through virtual screening of chemical libraries using docking, we have identified a preliminary set of potential candidates that can simultaneously inhibit Acetylcholine Esterase (AChE) and Butyrylcholine Esterase (BuChE). During virtual screening the molecules have been pre-filtered through ADME/Tox parameters. The strength of binding for shortlisted molecules has been established using intense and prolonged molecular dynamics simulations on the protei-inhibitor complexes.

ACKNOWLEDGEMENT

This research work is supported by Department of Science, Technology and Environment, Goa.

KEYWORDS

Alzheimer's Disease, QSAR, Docking, Virtual Screening, Chemical Databases

TITLE: Insights into the binding of inhibitors to Dengue Virus Protein Target RNA dependent RNA polymerase (RdRp): A Molecular Dynamics Simulations Study

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ABSTRACT

Many RNA viruses have been "re-discovered", including the life-threatening flaviviruses viz. Dengue and Zika. Dengue is a mosquito-borne viral infection. DENV-infected patients exhibit symptom ranging from a mild fever to severe plasma leakage and hemorrhagic shock. Dengue has grown dramatically in recent decades worldwide. Actual numbers of dengue cases are underreported with many being misclassified. The recent estimate of occurrence is 390 million dengue infections in a year (95% credible interval 284–528 million), with 96 million (67–136 million) clinical manifestation (with any severity of disease); in another report, 3.9 billion people, in 128 countries, are at risk.

Four serotypes of DENV are reported, spread across the world in tropical and subtropical regions, specially in urban and semi-urban areas. Dengue (severe) is a leading cause of serious illness and death among children in some Asian and Latin American countries. There is no specific treatment for dengue/ severe dengue, but early detection and access to proper medical care can save lives; decreasing mortality rates from more than 20% to less than 1%.

DENV NS5 RNA-dependent RNA polymerase (RdRp) is an attractive anti-viral target; since (i) viral polymerases are clinically proven therapeutic targets; no human analogs and (ii) RdRp is the conserved viral protein amongst the DENV serotypes; the probability of one compound with pan-serotype activity is higher than individual compounds targeting other viral proteins. DENV polymerase activity resides in the C-terminal (two-thirds of the viral nonstructural protein 5), while the remaining one-third of NS5; the N-terminal, encodes a methyltransferase. Number of DENV NS5 RdRp inhibitors have been reported; however none have passed efficacy/safety tests in animals or in clinical trials.

Through virtual screening of chemical libraries using docking, we have identified a preliminary set of potential inhibitors of DENV NS5 RdRp. During virtual screening the molecules have been pre-filtered through ADME/Tox parameters. The strength of binding for shortlisted molecules has been established using intense and prolonged molecular dynamics simulations on the RdRp-inhibitor complexes along with activity predictor models generated in-house.

KEYWORDS

Dengue Virus, QSAR, Docking, Virtual Screening, Molecular Dynamics Simulations

TITLE: ROLE OF PROSECUTION DURING LITIGATION

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ABSTRACT:
Litigation in the pharmaceutical domain has been exploited as a meaningful tool for safeguarding any earliest entry by generic player in well regulated markets like US, Europe etc. The entry barriers like patents/applications/trademarks etc. by innovator companies creates value addition to the products in the market and provides long term existence of revenue generation. However, these entry barriers are meaningfully interdependent on their prosecution including admissions by applicant, declarations given by any inventors/experts, quality of response and amount/length of prosecution etc.,

For generic company, the drug regulatory pathway provides significant opportunity by way to elect drug product dossier submission i.e. Abbreviated New Drug Application (ANDA) via pathway like PARAGRAPH- IV electing either non-infringing strategy or invaliditory pathway [505 (j)]. Irrespective of any elective pathway for paragraph -IV submission by generic players, it is well evidenced by the facts that the valid and enforceable patent by innovator companies are enforced as a matter of litigation and such patents are often worked out in detail by generic companies to make a litigation strategy in case litigation is enforced on the generic company.

More often these patents have been worked out for strategy in detail primarily based on their prosecution and responses submitted by the applicant leading to prosecution estoppel, assertion on demerits on prior disclosure, reason on long felt need, inventors declarations etc. besides many other factors. These strategies are often devised in such a way to secure benefit of particular generic player only, by avoiding immediate submissions of IPRs or PGRs, since generic to generic competition itself govern the bigger revenue for first few entrants.

KEYWORDS: ANDA, PARA IV

TITLE: Quality by Design (QbD) Approach for the formulation Formulation Development of Indapamide Fast Dissolving Tablets

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ABSTRACT:

The main objective of the present study was to develop fast dissolving tablet formulation of Indapamide using quality by design (QbD) approach. In the present study, the Critical Process Parameters and the Critical material attributes were investigated and related to the Critical Quality Attributes of the product or the tablet formulation. Fast dissolving tablet of Indapamide was developed by using the factorial design technique. In the factorial design the effect of two variables Sodium starch glycollate and Lactose monohydrate was studied at 3 different levels. Ultra-violet (UV), Fourier-transform infrared (FTIR), differential scanning calorimetry (DSC) analysis were conducted as a part of the formulation evaluation. Direct compression method was used to prepare the tablet.

The λ_{max} of the drug was found to be 240 nm. The FTIR studies revealed that there were no possible interactions between drug and the formulation excipients. DSC studies revealed that the drug was present in crystalline form showing sharp peaks. The *in-vitro* dissolution studies indicated which formula was the best among the nine batches chosen. Therefore, the present study indicates that fast dissolving tablets of indapamide were successfully developed using the QbD approach.

KEYWORDS: Indapamide, Fast dissolving tablet, Quality by Design, Factorial design.

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TITLE: DEVELOPMENT AND VALIDATION OF ANALYTICAL METHOD FOR THE SIMULTANEOUS ESTIMATION OF METFORMIN HYDROCHLORIDE AND LOSARTAN POTASSIUM

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ABSTRACT:
A simple, sensitive, precise, rapid and accurate reverse phase high performance liquid chromatography (RP-HPLC) method was developed and validated for simultaneous estimation of Metformin Hydrochloride and Losartan Potassium. The chromatographic separation was achieved by usingCosmiosil®100, C18 (250mm×4.6mm, 5µm) as stationary phase and mobile phase consisting of Acetonitrile:Water (75:25% v/v) with pH 3 adjusted with *Orthophosphoric* acid. Flow rate was maintained at 0.8ml/min. The analysis was performed at room temperature and the eluent was monitored at 254nm using UV detector. The retention time of Metformin Hydrochloride and Losartan Potassium were found to be 2.4min and 4.4min respectively and the calibration curves were linear (r^2=0.9982 & 0.9996) over a concentration range of100-500µg/ml for Metformin Hydrochloride and 10-100µg/ml for Losartan Potassium. The developed method was validated as per International Conference on Harmonization (ICH) guidelines using parameters like linearity, specificity, system suitability, sensitivity, precision, ruggedness, robustness and accuracy. All the validated parameters were found to be well within the acceptance criteria. Hence the proposed method can be used for the routine analysis of Metformin Hydrochloride and Losartan Potassium simultaneously.

KEYWORDS: Metformin Hydrochloride, Losartan Potassium, RP-HPLC, Simultaneous estimation, ICH guidelines.

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TITLE: DEVELOPMENT OF A NOVEL RP-HPLC METHOD FOR TIZANIDINE HYDROCHLORIDE TO ACHIEVE SHORTER RETENTION TIME AND ITS VALIDATION

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ABSTRACT:

The main objectives of the present research study was to develop a novel RP-HPLC method for tizanidine hydrochloride to achieve shorter retention time (RT), to minimize human error by avoiding usage of buffers for the adjustment of pH. The few methods of analysis for tizanidine hydrochloride is available having more RT and usage of buffers leads to turnout sample were less, usage of mobile phase is more, tedious and chance of human error are more thereby the available methods are not economical. The developed method utilizes a column Phenomenex Gemini NX C18 (25cmX4.6mm) 5 µm which is readily available with low cost also makes developed method is much economical than existing methods. The present method was developed in HPLC (Shimadzu) comprises of mobile phase acetonitrile and HPLC grade water (70:30 v/v) and pH was adjusted to 4 by dilute *Ortho*-phosphoric acid. The analysis was carried out at a flow rate of 0.8 ml/min and the UV detection wavelength was 228 nm. The developed method was validated as per the International Conference on Hormonization [ICH Q2 (R1)] guidelines. The parameters considered were system suitability, specificity, linearity, range, precision, robustness, accuracy and solution stability. The newly developed method had shorter RT of 2.46 min thereby turnout samples are more, consumption of mobile phase less, non-tedious, not utilization of buffers and utilization of C18 column makes the method economical and free from human error. The results of validation parameters lies within the acceptable limits suggested that the method become precise, accurate and robust.

KEYWORDS: RP-HPLC, Tizanidine hydrochloride, ICH guidelines, Validation.

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TITLE: PREPARATION AND EVALUATION OF PHYTOSOMES CONTANING GRAPE SEED EXTRACT

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ABSTRACT:

Grape seed extract (GSE) is a supplement derived from grape seeds which is a vessel for proanthrocyanidin/procyanidin molecules. Procyanidins are chains of catechin molecules, which are polyphenolic compounds found in tea and collectively referred to as green tea catechins. Present investigation was aimed at formulation, characterization and evaluation of phytosomes containing Grape seed extract for better antioxidant activity. It was achieved through the preparation of phytosomes by rotar evaporation method. The prepared phytosomes were characterized by particle size, scanning electron microscopy, Fourier transfer infrared spectroscopy, %DEE and *in-vitro* drug release. The results showed that the average particle size of optimized grape seed extract phytosomes formulation were 25.11µm.The *in-vitro* drug release study revealed that optimized formulation sustained the drug release for 8hr(with 76.26%). SEM study revealed phytosomes were irregular in shape. Upon fitting of *in-vitro* drug release data into various kinetic models, the release was found to follow higuchi model. Antioxidant property of Grape seed extract phytosomes was evaluated by *in-vitro* radical scavenging activity by DPPH model. The antioxidant activity showed controlled activity. The results obtained suggested that grape seed extract phytosomes can be successfully designed to provide controlled drug release and to give better antioxidant property.

KEYWORDS: Phytosomes, Grape seed extract, cholesterol, soyalecitin, rotary evaporation method, antioxidant activity

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TITLE: Development and evaluation of herbomineral effervescent delivery system using factorial design

AUTHORS: Kitty Rodrigues, Santoshi Chodankar, Shailendra Gurav, Arun Joshi, Anant Bhandarkar, Mythili Krishna Jeedigunta

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ABSTRACT:

Present research work reports the preparation of a stable herbo-mineral effervescent drug delivery using QbD approach and its evaluation on physicochemical and pharmacological grounds (in-vitro and in-vivo gastro protective effect). On the basis of reported literature, different herbs and minerals were selected as drug candidate and effervescent granules were formulated with different proportions of acid to base ratio, concentration of binder and effervescent mixture in the formulation using wet granulation technique. Factorial design was employed to study the effect of independent variables such as sodium bicarbonate, PVP and effervescent mixture in the formulation on dependent variables like disintegration time and percent moisture absorption in high relative humidity. Optimized formulation batches of effervescent granules were then evaluated for their physicochemical parameters (particle size, flowability, effervescence time, disintegration time, moisture content, carbon dioxide content, pH and water sorption assay) and based on their in-vitro antacid activity, the formulation showing the prominent activity was further subjected for the in-vivo pharmacological evaluation. Therapeutic evaluation of developed and optimized formulation at the dose of 400mg/kg and 800mg/kg body weight by pylorus ligation in rat method showed significant reduction in the volume of gastric secretion, free acidity and total acidity of gastric juice as compared to control.

KEYWORDS: Effervescent granules, QbD, factorial design, herbomineral preparation, gastro protective effect

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TITLE: FORMULATION AND EVALUATION OF ALGINATE COATED GAUZE INCORPORATED WITH ANTIOXIDANT POTENTIAL TERMINALIA PANICULATA EXTRACT.

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ABSTRACT:

Terminalia paniculata (Combretaceae) is an ethanomedicinal plants used in the treatment of wounds. Ethanolic extract of *T. paniculata* was evaluated for total phenolic, total flavonoidal content and *in-vitro* antioxidant activity. Preformulation studies were carried out prior to the incorporation of extract in to the alginate (AG) coated gauze. Different concentrations of alginate in distilled water with various immersion times were evaluated. 0.025, 0.5 and 0.1% of extract was loaded in AG coated non woven gauze. Swelling behavior, oxygen permeability and i*n-vitro* diffusion studies were carried out. *T. paniculata* extract has shown significant radical scavenging potential (DPPH: IC50=10.62 µg/ml, H2O2: IC50=33.22 µg/ml, NO: IC50= 37.24µg/ml). 0.5% w/ v concentration of Na-AG with immersion time of 120 sec was considered ideal for the formulation of AG wound dressings. All Formulations (F1 to F3) were found to be ideal and showed a drug release of more than 99 % in 24h.

KEYWORDS: *Terminalia paniculata,* Alginate coated gauze, Swelling behavior, oxygen permeability, i*n-vitro* diffusion studies.

TITLE: PHARMACONOSTICAL STUDIES ON AN ENDANGERED PLANT SPECIES *ATUNA INDICA* (CHRYSOBALANACEAE)

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ABSTRACT:

Herbs have provided the basis for the great medical systems in human history. We know that until the early 20th century, therapeutically potent drugs such as Digitalis, Atropine, Morphine, Ergot and Quinine were of plant origin and still Pharmaceutical scientists derive therapeutically useful leads from plant sources.

This presentation is the Pharmacognostical investigation on the leaves of scientifically under explored species *Atuna indica* (Bedd.) Kosterm (rediscovered about 150 years later) of the family Chrysobalanaceae, distributed in the Southern Western Ghats of India which has been studied for its antioxidant potential, primary metabolites and presence of the coumarin derivative, Umbelliferone which has increasing the scientific evidence for the upgradation of the species from unexplored wild plant to a medicinal plant category. Umbelliferone is an active coumarin with a varied number of reported Pharmacological activities such as an antioxidant compound (Dhalwal et al. 2008), prevent the complications of Type 2 diabetes (Okada et al. 1995), reduction of cellularity and eosinophil count in asthmatic mice (Juliana et al. 2009), antihyperglycemic effect (Ramesh & Pugalendi 2007) and is also known to be used in Cancer prevention therapy.

Different Pharmacognostical studies viz. Macro and Microscopical (Anatomical, Quantitative and Powder studies) have been carried out that may contributes towards the relevant data for Pharmacognostical Drug Standardization. India has established as a niche of natural products chemistry through the works of internationally honored Indian natural products chemists as that of Sir Shanti Swaroop Bhatnagar (1894 – 1955) and Shanti Swaroop Bhatnagar Awardee Professor T.R. Govindachari (1915 – 2001).

KEYWORDS: *Atuna indica*, Umbelliferone, Macro and Microscopic Studies.

TITLE: Comparative study of Patent Opposition Procedures in USA, Europe and India.

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ABSTRACT:

The patent opposition scenario in the United States of America (USA) has changed with the implementation of America Invents Act (AIA) in 2013. Similarly in India with the amendment of 'The Patents Acts' in 2005, the patent opposition scenario changed, while in Europe since the establishment of European Patent Office (EPO), the region has widely used opposition procedures. The South Korean patent office has implemented changes in the opposition procedures bringing about post grant opposition in picture. One of the objectives of this paper is to study the patent opposition procedures in the USA, India and Europe and compare the differences across these geographies. It is important to explore the potential of both pre and post grant opposition processes. There exists substantial differences in the patent opposition procedures in the USA, India and Europe in terms of timelines, basis of opposition, who can oppose, where to oppose, different procedures, estoppel provisions and patentability criteria. Hence, it is necessary to study the administrative structure, and compare and contrasts the patent opposition systems in these regions. The study of opposition procedures is particularly more important in the pharmaceutical sector as society benefits when frivolous patents do not block the entry of cost effective medicines; this is particularly important for the generic pharma industry across different regions. Patent Opposition procedures might enable access to affordable medicines for millions of people in the developing world. It may alsohelp the easy and early access of generic medicines in different regions.

KEYWORDS: Patent Opposition, India, USA, European Patent Office (EPO), generic

TITLE: Studies on phytoplankton community in tropical estuary (Chapora) of Goa, west coast of India

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ABSTRACT:

Estuaries are the supportive grounds for phytoplankton (microalgae) growth as they receive constant supply of nutrients from rivers and other land based discharges. Lot of studies are been carried out on microalgae which states its wide range of application in pharmaceutical industries, as they are known to be rich in several pharmacologically active compounds (phlorotannin, fatty acids, polysaccharides, peptides and terpenes) which combat bacterial invasion. In the present study, phytoplankton communities are studied along the salinity gradient in Chapora estuary (North Goa). This is to better understand its ecological conditions in which they proliferate so that its production can be optimized accordingly in a controlled culture. Water samples were collected during July-December, 2016 comprising both monsoon and non-monsoon season. A total of 119 species belonging to 8 different groups (Bacillariophyceae, Dinophyceae, Chlorophyceae, Cyanophyceae, Chrysophyceae, Xanthophyceae, Euglenophyceae and Dictyophyceae) were reported. From our observations it was noted that, physico-chemical parameters (water temperature, salinity and concentration of nutrients) play a vital role in the distribution of phytoplankton.

KEYWORDS: Phytoplankton; tropical estuary; pharmacologically active compounds

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TITLE: EVALUATION OF ANTIOXIDANT POTENTIAL OF PLANT PARTS OF *ANNONA MURICATA* L. (ANNONACEAE)

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ABSTRACT:

In the recent years, the quest for natural food additives and efforts to gain extensive knowledge regarding the power of antioxidants from plants to tap their potential is up-surging. Bioactive principles present in medicinal plants attribute to therapeutic efficacy with a potential to be incorporated into modern medicine system for development of newer drug formulations. *Annona muricata* L. belonging to Annonaceae family and found widely distributed in tropical and subtropical regions possesses multifarious curative benefits. All parts of tree are used in natural medicine including twigs, leaf, root, fruit and seeds. The fruits and leaves are recognized as an efficient agent for cancer chemotherapy. The present study was conducted to evaluate the free radical scavenging potential along with its correlation to phenolic and flavonoid contents to validate the therapeutic efficacy of plant parts. Results highlights the possible use of *A. muricat*a plant parts as a source of antioxidants where the highest scavenging activity of leaf extracts reached 91.54% compared to standard with 95.69% scavenging activity with inhibitory concentration (IC_{50}) close to ascorbic acid. The extracts radical scavenging activity were effective in following decreasing order ascorbic acid> Leaf> Rind> Bark> Seed> Pulp and Root. Standards and all extracts showed a dose dependent inhibition of DPPH radicals. The plant parts with higher free radical scavenging effect also showed greater content of both phenols and flavonoids, suggesting positive correlation between polyphenolic content and antioxidant activity. Further research is addressed on application of *A. muricata* as natural food preservative to protect against peroxidative damage in living systems related to aging and carcinogenesis.

KEYWORDS: *Annona muricata*, antioxidant, cancer, carcinogenesis, DPPH, inhibitory concentration, peroxidation

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TITLE: PHYTOCHEMICAL ANALYSIS OF CRUDE BARK EXTRACTS FROM SELECTED DYE-YIELDING PLANT SPECIES

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ABSTRACT:

The attractive colors and fragrance produced by the plants are due to the presence of specific phytochemicals in them. Phytochemicals are the chemicals produced by plants through primary and secondary metabolism. The present study reports an investigation of the phytochemical constituents present in the crude plant extract of selected dye yielding plants viz. *Ceriops tagal*, *Mammea suriga*, *Rhizophora mucronata* and *Phyllanthus acidus*. The phytochemical analysis were performed for water and ethanol extracted plant species to identify the presence of colour compounds responsible for dyeing the silk fabrics. The phytochemical analysis revealed the presence of tannins, flavonoids, alkaloids and saponins in the crude bark extracts of all the dye-yielding plant species. The tannins constituted the most common colour component in all the bark extract which is responsible for dark brown color shades to the silk fabrics. The presence of saponins, alkaloids, steroids and terpenoids in all the plants species showed that the extracts are of various pharmacological importance.

KEYWORDS: Phytochemicals, *Ceriops tagal*, *Mammea suriga*, *Rhizophora mucronata*, *Phyllanthus acidus*, dye-yielding plants.

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TITLE: INTELLECTUAL PROPERTY PROTECTION FOR TRADITIONAL KNOWLEDGE

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ABSTRACT:

International IP law began emerging as an important tool for trade between Africans and Europeans long before the intellectual property developments of the nineteenth century. Pre colonial trade "involved Africans and Europeans in complex relationships that required them to hammer out systems of accountability and process of dispute. On March20, 1833, during both the Industrial Revolution and the peak of European influence over Africa, the Paris Convention for the Protection of Industrial Property was created. The object of the document was to protect patent, utility models, industrial designs, trademarks, service marks, trade names, indications of source or appellation of origin, and the repression of unfair competition Changes in the Berne Convention reflected the importance of addressing developing countries needs within international IP laws. The Berne Convention was modified in Stockholm in 1967. One suggested alternative to imposing the current system of international IP law on developing countries is to allow a "threshold level of economic development "before increasing intellectual property protection.

DEVELOPING CONTRIES USE TRADITIONAL KNOWLEDGE FOR OBTAINING CONCESSION UNDER THE TRRIPS: Many developing countries use the protection of traditional knowledge is in the public domain, encouraging the idea that nobody is harmed and no rules are broken when research institution and corporation use it freely.

- **THE DISTINCTIVE EFFECT:** It has been said that ,in a very contemptuous way, that pharmaceutical industries have little, if any, interest in the "jungle pharmacy", and attractive drug discovery might be more promising, if research did not have to comply with benefit sharing.
- **MAKING OF IPR FOR TRADITIONAL KNOWLEDGE:** Internationally, the agreement on TRIPS mandate the level of protection of IPRs in national law. As a basis premise, the TRIPS agreement requires that all countries, whether they are developed/developing adopt the same level of protection for IPRs.

KEYWORDS: PROTECTION, TRADITIONAL KNOWLEDGE,TRIPS

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Affix passport- size photograph

TITLE: Traditional Knowledge Digital Library as an effective tool against Bio-piracy of Traditional Knowledge of India - Protection of the usage of Ginger usage in Ayurveda and Unani Medicines

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ABSTRACT:

Ginger –the thick tuberous rhizome (termed also as the healing spice of India) plays an important role in traditional Indian Ayurvedic medicine and its wide usage in Ayurveda makes itself an entire medicine chest. Ginger has a long history of medicinal use for more than 2000 years as most versatile medicinal plant having wide spectrum of biological activity and also known for its antimicrobial and antioxidant properties. In India, one will find its usage as an ingredient in traditional Indian drinks, as a main spice in indian cuisine and as a traditional medicinal remedy for cough and asthma and also finds its usage in curing of other ailments.

However over the last decades, there have been several patents concerning indigenous system of medicine that have been granted at the international level on account of lack of sufficient evidence by India. This paper focuses on the analysis of how Traditional Knowledge Digital Library is an effective tool against Bio-piracy of Traditional Knowledge of India**.** Traditional Knowledge Digital Library (TKDL) has been a pioneer initiative of India to prevent misappropriation of country's traditional medicinal knowledge at International Patent office. A classic example would be the Indian struggle and effort to revoke the patent on the wound healing properties of turmeric at the USPTO. Traditional Knowledge Digital Library has been a real boon to India. This paper also highlights the study of the case of Nicholas John Larkin, London who filed a patent application (GB2436063) titled "Pharmaceutical Composition for the treatment of access mucous product" on March 16, 2006 at the British Patent Office claiming the usefulness of Ginger (Zingiber Officinale) and Kutki Plant (Picrorhiza Kurroa) for the treatment of cough and lung disease considering it as a novel The said patent was struck down by the UK Patent Office in 2011 upon India submitting it's prior art evidence through the Traditional Knowledge Library (TKDL) on 25th April, 2011 as the examiner terminated the patent application before Grant.

Keywords: *In Situ* Gel, Carvedilol, Quality by Design