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Convener: Dr. N. M. PatelChief Coordinator: Dr. A. A. PatelCoordinator: Dr. D. Prajapati

Abstract of the Poster Presentation Gujcost/Ceutics/01 - Gujcost/Ceutics/36

GUJ/Ceutics/01

A Stupendous Pulmonary Drug Delivery of Proteins and Peptides

Jay Joshi, V.A.PATEL,

Dept of Pharmaceutics, A. R College of Pharmacy, V.V.Nagar

Abstract

Peptides and therapeutic proteins have been the target of intense research and development in recent years by the pharmaceutical and biotechnology industry. Preferably, they are administered through the parenteral route, which is associated with reduced patient compliance. Formulations for non-invasive administration of peptides and therapeutic proteins are currently being developed. Pulmonary drug delivery is a developing technology in which medication is inhaled through the lungs and enters the bloodstream through the alveolar epithelium. Pulmonary drug delivery provides a non-invasive, alternative method to subcutaneous injection, and also intravenous injection. Pulmonary delivery of proteins requires particles for delivery to be in the aerodynamic size range $1-5 \mu m$ for deep lung deposition. Advanced techniques such as spray drying, spray freeze drying and the use of supercritical fluid technology have been developed to produce particles in the suitable size range. The emphasis in this review will be on targeting of drugs by inhalation using carriers such as liposomes, microspheres, micro particles.

GUJ/Ceutics/02

Development & Characterization of Colon Targeted Hydrogel Tablet of Methotrexate.

Soni Ravi P.*, Bhavsar Jalpesh, Dr. Mukesh R. Patel, Dr. Kanu R. Patel, Shri, B. M. Shah College of Pharmaceutical Education and Research, MODASA

Abstract

Aim of the present study was to develop and characterize the colon targeted formulation of methotrexate using various hydrophilic and biodegradable polymers for the treatment of colorectal cancer and irritable bowel syndrome (IBS). The influence of various excipients was studied during study. The optimized batches were subjected to ensure that the formulations remain stable on storage. Tablets were prepared by using hydrogel principle. The colon targeted tablet of methotrexate can be formulated by optimized proportion of hydroxyl propyl cellulose and excipients in coating as well as in core tablet.

GUJ/Ceutics/03

Development and Characterization of Colon Targeted Enteric Coated Matrix Tablet of Tegaserod Maleate

Ashishkumar V. Patel, Jalpesh Bhavsar, Vishal Brahmbhatt, Ravi Soni, Dharmendra Patel. Shri B. M. Shah College of Pharmaceutical Education and Research, Modasa, Gujarat, India

Abstract

The aim of the study was to develop and evaluate enteric-coated matrix tablet of Tegaserod maleate(TM) for colonic delivery by exploiting prolonged release characteristics of Eudragit RSPO and Eudragit RLPO with pH dependent solubility property of a Eudragit S100. Extended release matrix tablet were prepared by direct compression of freely permeable and less permeable polymers like Eudragit RLPO and Eudragit RSPO respectively and other ingredients. The pH dependent release was achieved by coating matrix tablet with Eudragit S 100, a methacrylic acid co-polymer soluble at pH.

GUJ/Ceutics/04

Development and *In-Vitro* Characterization of Gastro Retentive Floating Tablets of Famotidine

Anandkumar K. Patel¹*, Vishnu M. Patel², Research Scholar, JJT University, Jhunjhunu, Dept. of Pharmaceutics, APMC College of Pharm. Edu.and Research, Himatnagar.

Abstract

Famotidine has a short elimination half-life, a narrow absorption window and is mainly absorbed in proximal areas of GIT. The purpose of this study was to develop a gastro retentive controlled-release drug delivery system with swelling, floating, and adhesive properties. Eight tablet formulations were designed using hydroxypropylmethylcellulose (HPMC K15M), HPMC K100M and sodium alginate (Na alginate) as release-retarding polymer(s) and sodium bicarbonate (NaHCO₃) and anhydrous citric acid as a gas former. Swelling ability, floating behavior, in vitro adhesion period and drug release studies were conducted in 0.1 N HCl (pH 1.2) at $37 \pm 0.5^{\circ}$ C. The tablets showed acceptable physicochemical properties. Drug release profiles of all formulae followed non-Fickian diffusion. Statistical analyses of data revealed that tablets containing HPMC K100M (30.0% w/w), Na alginate (25.0%, w/w), NaHCO₃ (18.75%, w/w) and anhydrous citric acid (6.25%, w/w) (formula F6) was promising systems exhibiting excellent floating properties, extended adhesion periods and sustained drug release characteristics(>12 h).

GUJ/Ceutics/05

Development and validation of dissolution method of Tolperisone HCl film coated tablets, and comparative *in vitro* dissolution study of Tolperisone HCl.

Patel Komal, APMC college of Pharmacy, Himmatnagar

Abstract

The aim of this work is to develop and validate a dissolution method for 150mgTolperisone hydrochloride film coated tablets using a UV spectroscopic method. Tolperisone HCl as a frequently used as centrally muscle relaxants has no dissolution method in its monograph in Japanese pharmacopeia. After test sink conditions, dissolution medium, the best conditions were: Basket apparatus at 75 rotations per minute (rpm) stirring speed, 0.1 N HCL as dissolution medium volume of 900 ml. The quantization method was also adapted and validated. More than 95% was achieved over 30 min in the basic one. The dissolution profile for tablets was considered satisfactory. And in comparative study three marketed brands of Tolperisone HCl 150mg tablets have been evaluated using dissolution test in 0.1N HCL media with the aim to assess bioequivalence. The dissolution test developed was adequate for its purpose and could be applied for quality control of Tolperisone hydrochloride tablets. Minutes. The in vitro release profiles of various tests were compared for their similarity using the f2 test. Results of this test indicate that in most cases dissolution profiles of the different marketed brands were significantly different from each other. The first objective of this study was to assess the interchangeability of the available Tolperisone HCl products on the basis of their in vitro dissolution characteristics using USP Apparatus 2(Basket type). The second objective was to compare dissolution profiles in simulated fasted and fed states and determine whether there is a change in the mechanism of drug release. Dissolution test results were subjected to further analysis by difference factor (f1), similarity factor (f2) and dissolution efficiency (% DE).

GUJ/Ceutics/06

Floating Pulsatile Drug Delivery System for Chronotherapy

S.R. Patel^{*}, M.K. Modasiya, A.K. Patel, V.M.Patel APMC College of Pharmaceutical Education and Research, Himatnagar, Gujarat-India.

Abstract

In the recent years, scientific and technological advancements have been made in the research and development of novel drug delivery systems by overcoming physiological troubles such as short gastric residence times and unpredictable gastric emptying times. Several approaches are currently utilized in the prolongation of the gastric residence times, including floating drug delivery systems, swelling and expanding systems, polymeric bioadhesive systems, modified shape systems, highdensity systems and other delayed gastric emptying devices. Recent trends indicate that drug delivery systems are especially suitable for achieving controlled or delayed release oral formulations with low risk of dose dumping, flexibility of blending to attain desirable release patterns with less inter- and intra-subject variability. A blend of floating and pulsatile principles of drug delivery system seems to present the advantage that a drug can be released in the upper GI tract after a definite time period of no drug release. Floating pulsatile drug delivery system (FPDDS) concept was applied to increase the gastric residence of the dosage form having lag phase followed by a burst release. Diseases wherein FPDDS are promising include asthma, peptic ulcer, cardiovascular diseases, arthritis, and attention deficit syndrome in children. To overcome limitations of various approaches for imparting, buoyancy and lag controlling were prepared by floating pulsatile delivery systems, for which time controlling system like swelling and rupturable membranes, soluble or erodible coating, capsule shaped system, and multiparticulate system are primarily involved in the control of release.

GUJ/Ceutics/07

Formulation and evaluation of self-micro emulsifying drug delivery system of Valsartan

M. J. Patel¹, S. S. Patel¹, N. M. Patel¹, M. M. Patel², Shri B. M. Shah College of Pharmaceutical Education and Research, Modasa. Kalol Institute of Pharmacy, Kalol

Abstract

The main purpose of this study was to prepare lipid-based self-micro emulsifying drug delivery system (SMEDDS) to improve water solubility of Valsartan. Solubility of drug and emulsification efficiency was determined in various vehicles. SMEDDS is mixture of oils (Sunflower oil), surfactant (Acrysol K 140) and Co-surfactant (Capmul MCM C8), which are emulsified in aqueous media under condition of gentle agitation. Pseudo-ternary phase diagrams were constructed to identify the efficient self-emulsification region, particle size distribution and zeta potential of resultant micro emulsions were determined using particle size analyzer. In vitro release was investigated by using phosphate buffer pH 6.8 as a dissolution media in dissolution apparatus and compare with pure drug. From the result, the release of Valsartan from SMEDDS was 91.78% in 60 min, which compare with pure drug.

GUJ/Ceutics/08

Formulation development and *In vitro* evaluation of mucoadhesive Microcapsules of Captopril.

Jalpeshkumar Bhavsar, Ravi Soni, Dr. Mukesh R. Patel, Dr. Kanu R. Patel

Shri, B.M.Shah College of Pharmaceutical Education and Research, Modasa, Gujarat.

Abstract

Aim of the study is the preparing biodegradable microcapsules as possible drug delivery for targeting and controlled release of CAPTOPRIL in hypertensive condition. Here biodegradable polymers used were carbopol and sodium alginate for coating of microcapsules as the carriers of drug with a view to increase efficiency of drug delivery and improving release profile. Microcapsules were prepared by orifice ionic gelation method by employing various polymers as described earlier. Seven batches with core: coat (drug: polymer) ratio of 1:1, 1:2, 1:3, 1:4, 1:5, 1:6 and 1:7 were prepared. From which core: coat ratio 1:6 shows spherical free flowing microcapsules. After selection of polymer ratio polymer: co-polymer ratio was defined by evaluating 1:1, 1:2 and

2:1 ratios. For those polymer: co-polymer ratio various process variables like concentration of coating polymer sodium alginate, concentration of calcium chloride, stirring speed of stirrer, reaction time for formation of microcapsule and polymer(carbopol) grades were evaluated. Microcapsules are evaluated by scannining electrone microscope, sieve analysis, entrapment efficiency, swelling study, mucoadhesion study, in vitro release study and stability studies. From which 1:1 polymer: co-polymer ratio showed better Mucoadhesive, swelling and release characteristic properties. It emphasis that microcapsules with Mucoadhesive property shows controlled release of the drug via gastro intestinal tract.

GUJ/Ceutics/09

Formulation of Fast Dissolving Oral Film of Granisetron HCl

M. P. Panchal^{*}, V. M. Patel, M. K. Modasiya, A.K. Patel, APMC College of Pharmaceutical Education and Research, Himatnagar, Gujarat-India.

Abstract

Granisetron HCL is an antiemetic drug and used orally and intravenously, generally to suppress nausea and vomiting induced from cancer chemotherapy. Problems with the conventional forms are very low bioavailability due to first pass metabolism, delayed onset of action. To overcome the disadvantages of conventional forms, for improved compliance and excellent effectiveness fast dissolving oral films of Granisetron HCL will be prepared. The films will be prepared using solvent casting method. Preliminary screening and optimization of film formers and plasticizers will be done. Low viscosity grades HPMC and Polyvinyl pyrrolidone K90 will be screened and optimized to be used as film formers due to their excellent film forming property and water solubility. PEG-400 will be optimized as plasticizers. The films will be evaluated on the basis of disintegration time of films in the salivary fluid. That will be the most important parameter for evaluation. The film forming polymers will be evaluated for mechanical properties like tensile strength, elastic modulus and folding endurance. A convenient and a complete patient friendly dosage form with pleasant mouth feel and quicker onset of action will be available for the treatment of nausea and vomiting.

GUJ/Ceutics/10

Formulation of Fenofibrate Nanosuspension by using Antisolvent Technique.

Mahmadasif M. Shekh, Dr. Vikram M. Pandya, Dr. Praful D. Bharadia

Abstract:

Fenofibrate nanosuspension was prepared by using bottom up technology i.e. antisolvent precipitation technique. Fenofibrate is BCS class II drug and its bioavailability depends upon its dissolution rate in GIT. Nano formulation of the poorly water soluble drugs is the better alternative for improvement of the bioavailability by increasing solubility of nano particles of drugs. The objective of the study was to identify the proper stabilizer for nanoformulation. For that HPMC E 15, poloxamer 188 and poloxamer 407 were used in different concentration. The prepared formulations were evaluated for particle size measurement which shows that formulations containing HPMC E 15 and poloxamer 188 were found particle size in the range of 1 μ m to 7 μ m and the formulation containing poloxamer 407 was found particle size in the range of 36nm to 73nm.

GUJ/Ceutics/11

Formulation of Occular Insitu Geliing System Containing Moxifloxacin HCl Using Gellan Gum and Sodium Alginate

T. N. Parekh^{*}, V.M.Patel, M.K. Modasiya, A.K. Patel, APMC College of Pharmaceutical Education and Research, Himatnagar, Gujarat-India.

Abstract

The field of Ocular drug delivery is one of the interesting and challenging endeavors facing the pharmaceutical scientist. The most frequently used dosage forms i.e. ophthalmic solutions and suspensions are compromised in their effectiveness by several limitations, leading poor ocular bioavailability. In situ hydrogels are instilled as drops into the eye and undergoes a sol to gel transition in the cul-de-sac, improved ocular bioavailability by increasing the duration of contact with corneal tissue, thereby reducing the frequency of administration. The present work describes the formulation and evaluation of an ophthalmic delivery system of an antibacterial agent, moxifloxacin, based on the concept of ionactivated in situ gelation. Gellan gum (Gelrite) was used as the gelling agent in combination with Na-alginate. The rheological behaviors of all formulations were not affected by the incorporation of moxifloxacin. In vitro release studies indicated that the gellan gum/alginate solution retained the drug better than the Gellan gum or alginate solutions alone. These results demonstrate that the gellan gum/alginate mixture can be used as an in situ gelling vehicle to enhance ocular bioavailability and patient compliance.

GUJ/Ceutics/12

Formulation, Development and Review Of Controlled Porosity Osmotic Pump

Jigar Maniar, V. M. Patel, APMC, Himmatnagar

Abstract:

Conventional drug delivery systems have little control over their drug release and almost no control over the effective concentration at the target site. This kind of dosing pattern may result in constantly changing, unpredictable plasma concentrations. Drugs can be delivered in a controlled pattern over a long period of time by the process of osmosis. Osmotic devices are the most promising strategy based systems for controlled drug delivery. They are the most reliable controlled drug delivery systems and could be employed as oral drug delivery systems. The present research is concerned with the study of drug release systems which are tablets coated with walls of controlled porosity. When these systems are exposed to water, low levels of water soluble additive is leached from polymeric material i.e. semi permeable membrane and drug releases in a controlled manner over an extended period of time. Drug delivery from this system is not influenced by the different physiological factors within the gut lumen and the release characteristics can be predicted easily from the known properties of the drug and the dosage form

Recently, osmotic tablets have been developed in which the pores are formed by the incorporation of a leachable component in the coating. Once the tablet comes in contact with the aqueous environment, the water-soluble component dissolves and pore formation occurs. Subsequently, water diffuses into the core through the micro porous membrane, setting up an osmotic gradient and thereby controlling the release of drug. The release rate from these types of systems is dependent on the coating thickness, level of leachable components in the coating, solubility of the drug in the tablet core, and osmotic pressure difference across the membrane, but is independent of the pH and agitation of the release media means the body's physiological factors.

GUJ/Ceutics/13

Intelligent Drug Delivery System

Vishal Brahmbhatt*, M. R. Patel, K. R. Patel Shri B. M. Shah College of Pharmaceutical Education and Research, Modasa

Abstract

Now a days, there are no. of drugs discovered which has a good pharmacological action but due to lack of proper delivery system they fail to reach to patient. The bridge to fill the gap between patient

and drug is **Intelligent drug delivery systems which** are capable of adjusting drug release rates in response to a physiological need. This new class of intelligent drug delivery includes pulsatile drug delivery, responsive delivery systems, systems utilizing enzymes and antibodies that are designed to perform various functions like detection, isolation and/or release of therapeutic agent for the treatment of diseased conditions.

GUJ/Ceutics/14

Preparation and Characterization of Hollow Microspheres of Diltiazem HCl

Utsav C. Rathod, Moin K.Modasiya, Anandkumar K. Patel, Vishnu M. Patel APMC College of Pharmaceutical Education and Research, Himatnagar.

Abstract

This research work was done with the aim to prepare hollow microspheres as gastroretentive drug delivery system of Diltiazem HCl. In the present study, preparation of Diltiazem HCl microspheres, in-vitro evaluation of Gastroretentive Drug Delivery System (GRDDS), prediction of the drug release, and optimization of polymers concentration to match target release profile was investigated. Hollow microspheres were prepared by emulsion solvent evaporation technique using Eudragit RS 100 and Eudragit RL 100 as the rate controlling polymers. Particle size analysis, drug content, drug encapsulation efficiency and release studies were performed. Results showed that the polymer concentration and stirring speed affected the size and incorporation efficiency and drug release of microspheres (> 12 h) and its floating time (> 10 hr). The best results were obtained at the ratio of drug: Eudragit RL 100 (1:3). The mean particle size of prepared floating microspheres increased but the drug release rate from the microspheres decreased as the polymer concentration increased. The developed hollow microspheres of Diltiazem HCl may be used for prolonged drug release in stomach for at least 12 hrs, thereby improving the bioavailability and patient compliance.

GUJ/Ceutics/15

Quality by Design (QbD): Current Paradigm for Development Self-Nanoemulsifying Solid Dosage Form of Lovastatin

Sanjay. S. Patel*, Maulik J. Patel, Mukesh R. Patel, Natvarlal M. Patel Shri B. M. Shah College of Pharmaceutical Education and Research, Modasa 383315, India

Abstract

"Quality by Design" (QbD) concept is that quality should be built into a product with a thorough understanding of the product and process by which it is developed and manufactured along with a knowledge of the risks involved in manufacturing the product and how best to mitigate those risks. In the present study Lovastatin (LOV) Self-Nanoemulsified Solid Dosage Form (SNESDF) was developed and optimized. In modern drug discovery techniques (i.e. advance in *in-vitro* screening methods, the introduction of combinatorial chemistry), there has been consistently increased in the number of poor water soluble drug candidate compounds, and currently more than 40% of new pharmacologically active compound are lipophilic and exhibit low oral bioavailability. Selfnanoemulsified drug delivery systems (SNEDDS) are some of the most recent approaches have been used to overcome poor bioavailability problem of drugs. Different types of RSM designs include 3level factorial design, Central Composite Design (CCD), Box Behnken statistical design and Doptimal design. The independent variables, Ratio of surfactant: co-surfactant (X1), oil: surfactant cosurfactant (X_2) and % Aerosil (X_3) were optimized using Box Behnken Design because it requires fewer runs (15 runs). The formulations were characterized for its dependent variables such as Droplet size (Y_1) , transmittance (Y_3) , percentage of drug released within 5 minutes (Y_3) , percentage drug release within 15 minutes (Y_4) and zeta potential. Droplet size and zeta potential of the optimized batch were found 21.89 nm and -6.4 mV, respectively. 44.32 % and 90.78 % of the drug content were found to be released within 5 min and 15 min, respectively. Hence, by formulating SNESDF, the solubility of Lovastatin was found to be significantly improved.

GUJ/Ceutics/16

Role of Biopharmaceutical Classification System in Formulation Development

Nikul H Modi., Nitin B. Prajapati Rajanikant C Patel Kalol Institute of Pharmacy, Kalol

Abstract

The in-vivo performance of orally administered drugs depends upon their solubility and tissue permeability characteristics. The release rate or solubility of the drug substance will not be a governing parameter if the absorption of the drug is permeation rate limited and in such cases the in-vitro dissolution study can be used to demonstrate the bioavailability (BA) or bioequivalence (BE) of the drug product through in vitro - in vivo correlation (IVIVC). On the other hand if absorption of the drug is dissolution rate limited that means the drug in the gastrointestinal fluid passes freely through thebio-membranes at a rate higher than it dissolves or is released from the dosage form. The specifically designed in-vivo study will be required in such a case, to access the absorption rate, and hence its bioavailability and to demonstrate the bioequivalence ultimately. Such a drug substance is a good candidate for controlled delivery provided they qualify in terms of their pharmacokinetics and pharmacodynamics for controlled release development. Also if a drug itself is having low solubility and a slow dissolution rate, the release will automatically gets lower and the dosage form need not have an inbuilt release retardation mechanism, rather the absorption will now be governed by the gastric emptying rate. Therefore, the dosage form must be able to restrain within the absorption window for a sufficient time so that absorption can take place. In such case, a hydrodynamically balanced (floating) system or a mucoadhesive dosage form will serve the purpose. Hence the BCS can work as a guiding tool for the development of various oral drug delivery technologies.

GUJ/Ceutics/17

Solubility enhancement of Albendazole by various approaches

Dhagash Patel*,

B. S.P atel Pharmacy College, Saffrony Institute of technology, Linch, Mehsana.

Abstract

The aim of objective was to prepare solid dispersions by using PEG 4000, PEG 6000, PVP K-30 and Complexation was done by Cyclodextrine. Different techniques were employed for preparation of Solid dispersion like physical mixture, melt granulation and solvent evaporation. The physical properties of the prepared solid mass of ABZ was characterized by in vitro dissolution studies, UV spectroscopy, Fourior transform infrared spectroscopy, differential scanning calorimetry (DSC). The solid dispersion (S.D.) of Albendazole shows better result than that of pure drug. The Cyclodextrin complexation also shows better result than pure drug. The S.D. of PEG 4000 with ABZ shows the highest solubility as well as dissolution rate in a ratio of 1:2(Drug: Polymer). The S.D. of PEG 6000 with ABZ shows the highest solubility as well as dissolution rate in a ratio of 1:1(Drug: Polymer). The S.D. of PVP K 30 with ABZ shows the highest solubility as well as dissolution rate in a ratio of 1:2(Drug: Polymer). The complexation of Cyclodextrin with ABZ shows the highest solubility as well as dissolution rate in a ratio of 1:4(Drug: Polymer). Both S.D. as well as Cyclodextrin complexation show greater dissolution profile than that of marketed preparation (Zentel). Various grades of PEG, PVP K-30 are having hydrophilic property which leads to increased solubility as well as dissolution.

GUJ/Ceutics/18

Strategies to Target the Formulation in Colon through Various Approaches

Priyanka J Patel., Rajanikant C Patel and Rajesh A. Keraliya Kalol Institute of Pharmacy.

Abstract

Oral administrations of different dosage forms is the most commonly used method due to flexibility in design of dosage form & high patient compliance but gastrointestinal tract presents several formidable barrier to drug delivery. Pharmaceutical invention & research are increasingly focusing on delivery systems which enhance desirable therapeutic objectives while minimizing side effects. In oral colon specific drug delivery system, colon has a large amount of lymphoma tissue (facilitates direct absorption into blood), negligible brush border membrane activity than that of small intestine. Colon targeted drug delivery has gained increased importance not just for delivery of drugs for treatment of local disease associated with colon but also for its potential for delivery of proteins and therapeutic peptides. Lack of digestive enzymes & long transit time, has been provided to design colon specific drug delivery systems & review is aimed at understanding recent advancements made in multiparticulate formulation approaches, matrix multilayer & compression coated tablets to reach colon intact to be investigated by approaches for targeting through pH sensitive system, microbial triggered system i.e., prodrug & polysaccharide based system, timed release system (lag time), programmed pulsatile release system etc. The colon, as a site for drug delivery, is also beneficial for the treatment of disease sensitive to circadian rhythms & delivery of poorly absorbable drugs. It is a challenging area for future research & holds lots of promises for novel & efficient approach for colon targeted drug delivery system.

GUJ/Ceutics/19

Sustain Release Bilayered Buccal Tablets for Propranolol Hydrochloride

V. R. Leuva, K.S. Rawal, A.K. Patel, M.K. Modasiya, V.M. Patel,

APMC College of Pharmaceutical Education and Research, Motipura, Himatnagar-383001, **Abstract:**

The present research contains the development and in vitro evaluation of propranolol hydrochloride loaded buccal drug delivery system (BDDS) for sustained release. The polymer membranes were prepared using xanthan gum (XG) and sodium alginate (SA) by varying the blends compositions viz., 10:0, 8:2, 6:4, 5:5, 4:6, 2:8, and 0:10 (XG/SA, wt/wt, %). The drug loaded tablets were evaluated for thickness, content uniformity, hardness, mucoadhesion, and in vitro drug release studies. Propranolol hydrochloride was found to be compatible with stability study carried out in human saliva. In vitro release studies were carried out in open glass diffusion cell for a period of 9 h and it showed controlled release of drug from the XG/SA matrix. The present study concludes that, the prepared buccal patchs can be used to achieve sustained release of drug and improved bioavailability.

GUJ/Ceutics/20

Top down Production of Telmisartan Nanosuspension

Divyesh M. Thakar, Dr. Vikram Pandya, Dr. Praful D. Bharadia.

Abstract

The objective of this research study was to optimize formulation and process variables affecting characteristic of nanosuspension in bead milling process. In this study, the practically water-insoluble telmisartan was nanoground by using top down method i.e. media milling method. Here the media used is ZnO_2 beads. A variety of surface active agents were tested for their stabilizing effects. Formulation factors evaluated were ratio of polymer to drug, whereas process parameters were milling time and concentration of ZnO_2 beads. Different concentration of stabilizers such as poloxamer 188, poloxamer 407, HPMC E 15, PVP K30 and combination of stabilizers were used for preparation of telmisartan nanosuspension. Responses measured in this study include particle size measurement, particle size distribution and zeta potential. Evaluation results such as, particle size of the prepared formulation was found in the range of 200nm - 600nm; polydispersity index was found in the range of 0.3 - 0.7 and zeta potential was found in the range of -6 mV to 10 mV.

GUJ/Ceutics/21

Proniosome as Master Formulation for Transdermal Drug Delivery System

Binkal B. Patel, Khusbu D. Patel Arihant School of Pharmacy & Bio- Research, Adalaj

Abstract

Transdermal drug delivery at a programmed rate has been recognized as a superior mode of drug delivery not only to bypass the hepatic first-pass elimination but also to maintain a constant, prolonged, and therapeutically effective drug level in the bodyTransdermal medication delivers a steady infusion of a drug over an extended period of time. A variety of encapsulating systems have been evaluated including liposomes, transfersomes, ethosomes and Proniosomes. Proniosomes has attracted a great deal of attention for the delivery of drugs through transdermal route because of the advantages like non-toxicity and penetration enhancing effect of surfactants and effective modify release. Proniosomes are different from liposomes in that they offer certain advantages overliposomes. Liposomes face problems such as they are expensive, their ingredients like phospholipids are chemically unstable because of their predisposition to oxidativedegradation and they require special storage and handling. Proniosomes do not have any of these problems. Also sinceProniosomes are made of uncharged single-chain surfactant molecules as compared tothe liposomes which are made from neutral or charged double chained phospholipids, the structure of Proniosomes is different from that of liposomes. However Proiosomes are similar to liposomes in functionality. Proiosomes also increase the bioavailability of the drug and reduce the clearance like liposomes. The properties of the Proniosomes depend both on the composition of the bilayer, and themethod of production used. Due to the above advantage, it is possible that an equivalent therapeutic effect can be elicited via transdermal drug input with a lower daily dose of the drug. Useful aspects of Proiosomes drug delivery system is their ability to target drugs for Antineoplastic Treatment, Leishmaniasis, Delivery of Peptide Drugs, Studying Immune Response, Carriers for Hemoglobin.

GUJ/Ceutics/22

Hydrotropy- Novel Technology of Solubility Enhancement

Ranjana Sharma*, Ritu mahatama, Unnati Sharma, Deepika Bairagee B. N. Girls College of Pharmacy, Udaipur (Raj.) 313001

Abstract

In recent years due to application of combinational chemistry and high-throughput screening during drug discovery, a majority of new drug candidates exhibits poor aqueous solubility, due to this reason many pharmaceutically potent products are not reaching to market. Such compounds found to be very challenging for formulation of bioavailable dosage forms for such drugs. Over the years, a variety of solubilization techniques have been studied and widely used for such drugs. Various techniques have been employed to enhance the aqueous solubility of poorly water-soluble drugs. These include micronization, chemical modification, pH adjustment, solid dispersion, complexation, co-solvency, micellar solubilization, hydrotropy etc.

Hydrotropic solubilization is one of them. Neuberg in 1916 first introduced the concept of hydrotropy. Hydrotropy may be defined as a phenomenon in which water solubility of poorly water soluble compounds may be increased several folds by use of diverse groups of hydrophilic solutes called hydro tropes. A hydrotrope is a compound that solubilises hydrophobic compounds in aqueous solutions. Typically, hydro tropes consist of a hydrophilic part and a hydrophobic part (like surfactants) but the hydrophobic part is generally too small to cause spontaneous self-aggregation. This approach can be conveniently applied to wide range of water insoluble compounds.

Urea, Sodium benzoate, sodium salicylate, sodium acetate, sodium citrate, nicotinamide and sodium ascorbate are most popular examples of hydrotropic additives. Hydrotropic solublization is new, simple, economic, safe and precise method that can be used in analysis of drug. It is, thus, concluded

that the proposed method is simple, cost-effective, accurate, safe and precise. There is a good scope for poorly water soluble drugs which may be tried to get soubise by suitable hydrotropic agents precluding the use of costlier and unsafe organic solvents that causes toxicity, pollution, and error, in analysis due to volatility. Mixed hydrotropy may find wide use in development of aqueous formulations of poorly water soluble drugs in future.

GUJ/Ceutics/23

In Vitro Absorption Studies of Mucoadhesive Tablet of [9-(2-Hydroxyethoxylmethyl) Guanine]

Jyotsana Gurjar*, Rishka Rawal, Alok Bhargava¹, Mital Nakrani B. N. Girls College of Pharmacy, Udaipur (Raj.) 313001.

Abstract

Mucoadhesive drug delivery systems interact with the mucus layer covering the mucosal epithelial surface, mucin molecules and increase the residence time of the dosage form at the site of absorption. Thus mucoadhesive dosage forms are advantageous in increasing the drug plasma concentrations and also therapeutic activity. Mucoadhesive drug delivery systems prolong the residence time of the dosage form at the site of application or absorption. They facilitate an intimate contact of the dosage form with the underlying absorption surface and thus improve the therapeutic performance of the drug. A 3^2 full factorial design was employed to study the effect of independent variables like Carbopol-934P and hydroxypropyl methylcellulose K100M, which significantly influence characteristics like swelling index, ex-vivo mucoadhesive strength and *in-vitro* drug release. In all the nine formulations studied, the exponent (n) varied between 0.5266 and 0.7110, showing non-fickian release behavior corresponding to coupled diffusion or polymer relaxation, resulting in a controlled and complete drug release up to 12 h. Both these polymers had a significant effect on the mucoadhesive strength of the prepared tablets, measured as the force of detachment against sheep gastric mucosa. The two factors on the various response variables, this study helped in finding the optimized formulation with excellent mucoadhesive strength and controlled drug release. It can be concluded that by formulating mucoadhesive tablets of acyclovir, its complete release can be ensured prior to absorption window and hence the problem of incomplete drug release and erratic absorption could be solved by increasing the retention of drug in GIT for a longer duration.[9-(2hydroxyethoxylmethyl) guanine], a synthetic purine nucleoside analog derived from guanine, is the most widely used antiviral agent. It is effective in the treatment of herpes simplex virus (HSV), mainly HSV-1 and HSV-2 and varicella zoster virus. The bioavailability of acyclovir after oral administration ranges from 10-30%. Approximately 80% of an oral dose is never absorbed and excreted through feces. Also the frequency of administration of acyclovir is high; being 200 mg five times a day up to 400 mg five times a day depending upon the type of infections.

GUJ/Ceutics/24

Design and Development of Diltiazem HCL Floating Tablet

Kapil Maheshwari^{*}, Dr. M. R. Patel, Dr. K. R. Patel, Dr. N. M. Patel, Shri B. M. Shah College of Pharmaceutical Education and Research, Modasa-383315

Abstract

The purpose of the present study was to develop an optimized floating drug delivery system of Diltiazem hydrochloride. Diltiazem floating tablets were formulated with different concentrations of three grades of HPMC polymers (HPMC K4M, HPMC K15M and HPMC K100M) using suitable experimental design and evaluated for the different evaluation parameters such as thickness, diameter, drug content uniformity, friability, floating lag time, *in-vitro* buoyancy, *in-vitro* drug release studies were performed. All the evaluation parameters results were significant. *In-vitro* drug release studies were performed and drug release kinetics evaluated using the linear regression

method was found to follow Korsemeyer and Peppa's equation. The drug release mechanism was found to be anamolous type. The prepared formulation shows better and significant results for all the evaluated parameters. The formulation D5 shows maximum percentage of drug release (99.97%) and prolonged release for time period of about 12 h, thereby improves the bioavailability and patient compliance.

GUJ/Ceutics/25

Formulation and evaluation of fast dispersible tablet of Fexofenadine HCL

Arpit Shah*, Dr. M. R. Patel, Dr. K. R. Patel, Dr. N. M. Patel, Shri B. M. Shah College of Pharmaceutical Education and Research, Modasa-383315

Abstract

The purpose of this research was to formulate tasteless complexes of Fexofenadine Hydrochloride with Kyron-134 and to formulate tasteless complex into fast-Dispersible tablets (FDT) using suitable experimental design and evaluated for the different evaluation parameters such as thickness, diameter, drug content uniformity, friability, disintegration time, wetting time *, in-vitro* drug release studies were performed. Tasteless Drug resin complexes (DRC) were prepared and evaluated for different factor affecting Drug-Resin Complexation, Complexation time, stirring time, soaking time, temperature, and effect of pH on Fexofenadine Hydrochloride loading on Kyron-134 is reported. Fexofenadine Hydrochloride release from FDT is obtained at salivary and gastric pH. Infrared spectroscopy revealed Complexation of –NH (drug) with Kyron-134. Drug release from FDT in salivary pH was insufficient to impart bitter taste. Complete drug release was observed at gastric pH. Kyron-134 is inexpensive, and the simple technique is effective for bitterness masking of Fexofenadine Hydrochloride. The formulation F5 shows maximum percentage of drug release (98.80 %).

GUJ/Ceutics/26

Ethosomes - A Novel Drug Delivery System

Dipal Patel*, Paridhi Bhargava¹, Anju Goyal, Ankita Sharma, Amit Bhargava B. N. Girls College of Pharmacy, Udaipur, 313001.(Raj.)

Abstract

Ethosomes are the ethanolic phospholipid vesicles which are used mainly for transdermal delivery of drugs. Ethosomes are soft, malleable vesicles tailored for enhanced delivery of active agents. Therefore Ethosomal systems are now a days attracting attention of many researchers. Ethosomes have higher penetration rate through the skin as compared to liposomes hence these can be used widely in place of liposomes. The increased permeation of ethosomes is probably due to its ethanolic content. Ethanol increases the cell membrane lipid fluidity which results in increased skin penetrability of the ethosomes. These ethosomes permeates inside the skin and fuse with cell membrane lipids and release the drug. Hot and cold methods are used for formulation of ethosomes. Evaluation parameters include size, shape, drug content, zeta potential etc. Ethosomes have been successfully evaluated for the delivery of many drugs for e.g. Cyclosporine A, insulin, salbutamol trihexyphenidil, etc. Ethosomes provides a number of important benefits including improving the drug's efficacy, enhancing patient compliance and comfort and reducing the total cost of treatment. Ethosomes can be important drug delivery tool in the future.

GUJ/Ceutics/27

Polymeric Vesicles for Drug and Gene Delivery

Kanchan Choudhary*, Heena Agarwal, Alok Bbhargava¹, Anju Goyal B.N. Girls College of Pharmacy, Udaipur 313001, India

Abstract

The goal of drug delivery is to Improve the therapeutic index of medicines. Employing nanosystems that control drug biodistribution is one way of achieving therapeutic improvements, and polymeric bilayer vesicles are one such nanosystem. Polymeric vesicles, with the ability to transport drugs or genes, are prepared in one of two ways: (i) the self-assembly of amphiphilic polymers and (ii) the polymerisation of monomers (polymerised vesicles). There are two types of self-assembling amphiphilic polymers: water-soluble polymers derivatised with hydrophobic pendant groups and amphiphilic block copolymers. Amphiphilic alkenes and alkynes are the main compounds that are used to make polymerised vesicles. Colloid science has given rise to many materials which may be useful in nanotechnology, such as carbon nanotubes and other fullerenes, and various nanoparticles and nanorods. Nanoscale materials can also be used for bulk applications; most present commercial applications of nanotechnology are of this flavor. With the current ground breaking researches as pairing of nanoparticles of gold with protein to form protein gold complex for identification structures and their ability to make cancer cell magnetic to make biopsies more sensitive and efficient has provide more edge to them. This review discusses polymer architecture fundamentals that govern the self-assembly of polymers into vesicles, the fine control on vesicle size that is achievable with polymeric vesicles and the application of the vesicles to drug delivery.

GUJ/Ceutics/28

Formulation and Evaluation of Compress Coated Pulsatile Release Tablet of Lornoxicam

Dharmeshkumar R. Patel^{*}, Dr. M. R. Patel, Dr. K. R. Patel, Dr. N. M. Patel Shri B. M. Shah College of Pharmaceutical Education and Research, Modasa-383315

Abstract

The aim of present investigation was to develop press coated tablet for pulsatile drug delivery of lornoxicam using hydrophilic and hydrophobic polymers. The drug delivery system was designed to deliver the drug at such a time when it could be most needful to patient of rheumatoid arthritis. The press coated tablets containing lornoxicam in the inner core was formulated with an outer shell by different weight ratio of hydrophobic polymer (Ethocel 10cps) and hydrophilic polymers (sodium alginate). Pulsatile tablet were evaluated for FTIR, tensile strength, Bulk density, tapped density, angle of repose and Carr's index, hardness, thickness, weight variation, friability, drug content uniformity and *in-vitro* drug release study. The ratio of Ethocel 10cps and Sodium alginate and coating weight was optimized using 3² full factorial designs. The lag time of the pulsatile release tablets decreased with increasing the ratio of sodium alginate and Ethocel 10cps in the coat and increased with increasing level of coating. It was observed that the response, i.e. lag time was affected by both the factors. These factors were responsible for maintaining desired lag time of pulsatile release tablet. The statistical models were validated and can be successfully used to prepare optimized pulsatile release tablets of lornoxicam.

GUJ/Ceutics/29

Formulation and In-Vitro Evaluation of Mucoadhesive Buccal Tablet of Famotidine

Mr. Jalpeshkumar D. Bhavsar, Dr. Mukesh R. Patel, Dr. Kanu R. Patel, Dr. N. M. Patel Shri, B. M. Shah College of Pharmaceutical Education and Research, Modasa, Gujarat **Abstract**

Famotidine is histamine $-H_2$ receptor antagonist. It has bioavailability of 40 to 45% and it has shorter plasma half life of 2.5 to 3.5 hrs due to first pass metabolism. Buccal delivery gives long residence time for prolong or sustain delivery of drug in body. So it maintains the desired blood level of drug in the body and also increases bioavailability of drug due to highly vascularized area.

Buccal tablet was prepared by using bioadhesive polymers like Sodium CMC and Carbopol934P. The tablet was prepared by direct compression and backing layer of Ethyl cellulose also applied. The formulation was optimized by 3^2 full factorial statistical design by taking Polymer ratio as X1 factor (Sodium CMC: Carbopol 934P – 1:2, 1:1, 2:1) and Polymer concentration as X2 (15%, 20%, 25%). The formulation was evaluated by Hardness test, Friability test, Content uniformity, Drug polymer compatibility study, Surface pH study, Bioadhesive strength test, Swelling index, In vitro release study, Ex-vivo permeation study. The Optimized batch is with ratio of polymer 1:2 of Sodium CMC and Carbopol934P and concentration of polymer is of 15%. This batch shows 102.57% in vitro release in 8 hr., 63.19% swelling index and 14 gm of bioadhesive strength.

GUJ/Ceutics/30

Formulation and Evaluation of Floating In situ gel of Levetiracetam

Miteshkumar J Patel*, Dr. M. R. Patel, Dr. K. R. Patel, Dr. N. M. Patel Shri B. M. Shah College of Pharmaceutical Education & Research, Modasa – 383 315

Abstract

The aim of this study was to develop a new intra-gastric floating in situ gelling system for controlled delivery of levetiracetam for the treatment of partial onset seizures. High dose of levetiracetam (750 to 1000 mg) is difficult to incorporate in floating tablets but can easily be given in liquid dosage form released in stomach. Sodium alginate-based in-situ gelling systems were prepared by dissolving various concentrations of sodium alginate in deionized water, to which varying concentrations of drug and calcium carbonate were added. Fourier transform infrared spectroscopy (FTIR) were used to check the presence of any interaction between the drug and the excipients. A 3^2 full factorial design was used for optimization. The concentrations of sodium alginate (X1) and calcium carbonate (X2) were selected as the independent variables. The amount of the drug released after 1 h (Q1) and 6 h (Q6) and 12 h (Q12) and the viscosity of the solution were selected as the dependent variables. The gels were studied for their viscosity, in-vitro buoyancy and drug release. Other ingredient like HPMC K100M used for strength forming polymer, sodium citrate is used for liquefying solution. The drug release from the in-situ gel follows the Higuchi model and Korsemeyer-peppas model, which indicates a diffusion-controlled release.

GUJ/Ceutics/31

Chronopharmaceutical Drug Delivery of Salbutamol Sulphate for Treatment of Nocturnal Asthma

Ms Priti L. Patel, Dr. K. R. Patel, Dr. M. R. Patel. Dr N. M. Patel Shri B. M. Shah College of, pharmaceutical Education & Research, Modasa, Gujarat.

Abstract

The present study aimed at preparing a novel time dependent pulsed release system containing 'Tablet-in-tablet' for the programmed release of salbutamol sulphate for the treatment of nocturnal asthma. The core tablets of salbutamol sulphate were prepared using direct compression containing a superdisintegrant. Physical characterization of tablet and powder blends used to form the core tablet was under taken using a range of experimental technique. L HPC and M HPC were used as swellable polymers for coating the core tablet. Coating done through compression coating. The ratio of L HPC and M HPC and the coating level was optimized using 3² full factorial designs. Factors studied in design wereratio of L HPC and M HPC and the effect coating level on In-vitro drug release. Dissolution studies carried out in media with different pH (1.2,7.4) showed that drug release in colon could be modulated by optimizing the concentration of L HPC and M HPC . The study showed that, lag time prior to drug release was highly affected by the coating level. The dissolution data reveled that the level of coating and the ratio of polymers are very important to achieve a optimum formulation.

GUJ/Ceutics/32

Design and Development Of Osmotic Drug Delivery Of Verapamil HCl

Ravi Doshi, Dr.M.R.Patel, Dr. K.R.Patel, Dr. N. M. Patel

Shri B. M. Shah College of Pharmaceutical Education & Research, Modasa, Gujarat

Abstract

Experimental Work done: The aim of the current study was to design controlled porosity osmotic pump tablets of Verapamil hydrochloride. Cellulose acetate was used as the semipermeable membrane. The porous osmotic pump contains pore forming water-soluble additive (PEG-400) in the coating membrane which after coming in contact with water, dissolve, resulting in an in-situ formation of microporous structure. The plasma half-life ranges from 5 to 7 hours. Hence, Verapamilhydrochloride was chosen as a model drug with an aim to develop a controlled release system for 24 hours. The effect of different formulation variables, namely, ratio of drug to osmogent, membrane weight gain and concentration of pore former on the in-vitro release was studied using 2³ factorial design. Drug-excipients compatibility was studied by FTIR.

GUJ/Ceutics/33

Development & Characterization of Floating Tablet of Tolperisone Hydrochloride.

Soni Ravi P.*, Dr. Mukesh R. Patel, Dr. Kanu R. Patel, Dr. Natubhai M. Patel. Shri, B. M. Shah College of Pharmaceutical Education and Research, Modasa, Gujarat.

Abstract

Aim of present work was to develop and characterize floating tablet of tolperisone Hydrochloride using different polymer and excipient. Tolperisone, a centrally acting muscle relaxant agent, which has been in therapeutic use for more than three decades, has been widely used as spasmolytics of choice. The influence of various excipients was studied during study. Formulation was optimized using 3^2 full factorial design. Tablets were prepared by using direct compression method.

GUJ/Ceutics/34

Formulation and Evaluation of Fast Dispersible Tablet Of Fexofenadine HCL

Arpit Shah*, Dr. M. R. Patel, Dr. K. R. Patel, Dr. N. M. Patel Shri B. M. Shah College of Pharmaceutical Education and Research, Modasa-383315 **Abstract:**

The purpose of this research was to formulate tasteless complexes of Fexofenadine Hydrochloride with Kyron-134 and to formulate tasteless complex into fast-Dispersible tablets (FDT) using suitable experimental design and evaluated for the different evaluation parameters such as thickness, diameter, drug content uniformity, friability, disintegration time, wetting time *, in-vitro* drug release studies were performed. Tasteless Drug resin complexes (DRC) were prepared and evaluated for different factor affecting Drug-Resin Complexation, Complexation time, stirring time, soaking time, temperature, and effect of pH on Fexofenadine Hydrochloride loading on Kyron-134 is reported. Fexofenadine Hydrochloride release from FDT is obtained at salivary and gastric pH. Infrared spectroscopy revealed Complexation of –NH (drug) with Kyron-134. Drug release from FDT in salivary pH was insufficient to impart bitter taste. Complete drug release was observed at gastric pH. Kyron-134 is inexpensive, and the simple technique is effective for bitterness masking of Fexofenadine Hydrochloride.

GUJ/Ceutics/35

Formulation and In Vitro evaluation of gastric-mucoadhesive Microcapsules of captopril

Ms. Asha A. Patel^{*}, Dr. Mukesh R. Patel, Dr. Kanu R. Patel, Dr. N.M. Patel Shri B. M. Shah College of Pharmaceutical Education and Research, Modasa-383315

Abstract

A new oral drug delivery system for a water soluble angiotensin converting enzyme inhibitor, captopril, was developed utilizing both the concepts of controlled release and mucoadhesiveness, in order to obtain a unique drug delivery system which could remain in stomach and control the drug release for longer period of time. Captopril is routinely used in the management of hypertension. When the drug is administered by oral route it undergoes first pass hepatic metabolism and hence its half-life is less than 2 hours. These limitations of Captopril in conventional dosage from can be overcome by administering Captopril by alter delivery system. An attempt was made to design captopril microcapsules using biodegradable polymers carbopol and sodium alginate as the carrier, with a view to increase the efficiency of drug delivery, improve release profile,15 formulation were prepared using orifice ionic gelation technique among them Batch M16B chosen as best batch due to its encapsulation efficiency 62.32%, Swelling ratio of 10.20, percent adhesion after one hour ranged from 32-78% and In vitro release shows 88% up to 12 Hrs.

GUJ/Ceutics/36

Design and Development Of Extended Release Tablet Of Nicotinic Acid

Brijesh Chaudhari*, Dr. M. R. Patel, Dr. K. R. Patel , Dr. N. M. Patel Shri B. M. Shah College of Pharmaceutical Education & Research, Modasa, Gujarat

Abstract

Nicotinic acid (NA) is a lipid lowering agent drug has not become a first-line treatment due to the strong side effect called flushing occurs when given in Immediate release (IR)dosage form. In the present research, an attempt has been made to formulate extended release(ER) matrix tablet using suitable experimental design. The tablets were prepared by wet granulation method and the prepared tablets of NA will remain intact up to 2 hrs even in pH 1.2 due to eudragit L100-55 coat and its release is not only initiated but tact fully retarded up to 12 hrs and were found to be superior in physical properties and dissolution characteristics. The in vitro NA release data justified the release mechanism to be Case-III and Dissolution control transport was found to be a mixed pattern of zero order and Korsmeyer-Peppas release models. The formulation N8 shows maximum percentage of drug release for time period of about 12hrs, thereby improve the bioavailability and patient compliance.

Abstract of the Poster Presentation Gujcost/Q. A. /01 - Gujcost/ Q. A. /30

GUJ/Quality Assurance/01

Simultaneous spectrophotometric determination of rosuvastatin calcium and fenofibrate in tablets using Q - absorbance ratio method

Dave Jay; Parmar Rajesh; Dr.Dushyant Shah.,

APMC College of Pharmaceutical Education & Research, Himmatnagar, Gujarat, India.

Abstract

The present manuscript describe simple, sensitive, rapid, accurate, precise and economical Qabsorbance ratio method for the simultaneous determination of Rosuvastatin calcium & Fenofibrate in combined tablet dosage form. Absorbance ratio method uses the ratio of absorbances at two selected wavelengths, one which is an isoabsorptive point and other being the λ -max of one of the two components. Rosuvastatin calcium and Fenofibrate show an isoabsorptive point at 251.5 nm in methanol& Distill water combine solvent. The second wavelength used is 241 nm, which is the λ max of Rosuvastatin calcium. The linearity was obtained in the concentration range of 2-17 µg/ml for Rosuvastatin calcium and 2-22 µg/ml Fenofibrate. The concentrations of the drugs were determined by using ratio of absorbance at isoabsorptive point and at the λ -max of Rosuvastatin Calcium. The method was successfully applied to pharmaceutical dosage form because no interference from the tablet excipients was found. The results of analysis have been validated statistically and by recovery studies.

GUJ/Quality Assurance/02

Absorption Correction Method for Simultaneous Estimation of Metoprolol Succinate and Olmesartan Medoxomil in Combined Tablet Dosage Form

Bindi Vora

APMC Pharmacy college, Himmatnagar

Abstract

A new, simple, precise, accurate and sensitive UV - spectrophotometric absorption correction method has been developed for simultaneous determination of Metoprolol Succinate and Olmesartan Medoxomil in combined tablet dosage form. *Material and Methods* : Methanol was used as solvent. Absorbance correction method was based on the property of additivity of absorbance. The two wavelengths on Olmesartan medoxomil curve were found out where it showed same absorbance, which were 233 and 244 nm. At 244 nm, Olmesartan Medoxomil showed some absorbance while Metoprolol succinate showed zero absorbance. Both the drugs gave absorbance at 233 nm. The method involved solving of an equation based on measurement of absorbance at two wavelengths 233 and 244 nm. The determinations were made at 233 nm for Metoprolol Succinate and Olmesartan Medoxomil and 244 nm for Olmesartan Medoxomil over the concentration range of 5-25 µg/ml for Metoprolol and 4-20 µg/ml for Olmesartan medoxomil with mean recovery of 99.81 \pm 0.45 and 99.45 \pm 0.406 % for Metoprolol Succinate and Olmesartan Medoxomil, respectively by absorbance correction method. Result and *Conclusion*: This method was found to be simple, sensitive, accurate, precise, reproducible, and economical and can be applicable for the simultaneous determination of Metovolol and Olmedipine besylate in combined dosage form.

GUJ/Quality Assurance/03

Analytical method development and validation of piracetam in pharmaceutical dosage form.

Mr. Sunil R. Patel APMC College of Pharmacy, Himmatnagar

Abstract

Two simple, precise and economical UV methods have been developed for the estimation of Piracetam in pharmaceutical formulations. piracetam in distilled water and 0.1 M NaOH shows the maximum absorbance at 220 nm (Method A). Method B utilises area under curve (AUC) in the wavelength range from 215-225.0 nm for analysis of Piracetam. The drug was found to obey Beer-Lambert's law in the concentration range of 100-500 μ g/mL for all three proposed methods. Results of the analysis were validated statistically and recovery studies were found to be satisfactory.

GUJ/Quality Assurance/04

Design, Synthesis and Biological Evaluation of Novel 2-Amino Pyrimidine Derivatives as Direct Thrombin Inhibitors

JIGNASA K.SHUKLA, DR. L.J. PATEL

Dept. of Pharm. Chemistry, S. K. Patel College of Pharm. Edu & Research., Kherva.

Abstract

A Novel series of 2-Amino pyrimidine derivatives has been designed, synthesized and evaluated as direct thrombin inhibitors. Synthesized 2-Amino pyrimidine moiety as P1 pocket which is basic and hydrophilic (Log P -0.19) in nature and bind to thrombin catalytic site and prevent thrombus formation. It is act as univalent DTIs and give potent activity. It is very useful in ischemic Stroke (cardiovascular diseases). A series of 2-amino pyrimidine derivatives synthesized from sulfacetamide and chloroacetylchloride. After introduced various aniline substitution as P3 pocket which is lipophilic in nature. Cyclization of pyrimidine ring by using guanidine.HCl and prepared chalcone. Synthesized target compound characterized by IR, MASS, NMR. In *vitro* Pharmacological evaluation performed by determination of clotting time. Thrombin enzyme inhibition activity will be taken by using chromogenic substrate and thrombin enzyme.

GUJ/Quality Assurance/05

Determination of Impurities in APIs and Formulation by Hyphenated Techniques in Chromatography.

Shurshti Mehta & Alka Sadhu

Abstract

Unwanted chemicals produce impurities during synthesis or storage of APIs. Impurities can also come/from in drug during formulating them. Impurities affect the safety and efficiency of dosage forms. Some regulation are there to control the impurities level into drug, such as ICH,USFDA,health agency etc.Qualification and Quantification of an impurities is required to assure the quality of APIs /drug. Some characterization like process related impurities and degradation of product are done by conventional method like NMR,MS,TLC,HPLC,HPTLC etc.United state pharmacopoeia(USP) has identified method for organic volatile oil impurities (OVIs) in APIs by Gas Chromatography(GC) method. The approaches of hyphenated technique having revolutionized for more accuracy , quickness, safety . By hyphenated technique we can detect structure identification of organic, inorganic and residual impurities. Current write up gives idea about hyphenated technique like LC-MS-MS, LC-NMR-MS, GS-MS, LC-MS.

GUJ/Quality Assurance/06

Development and Validation of Difference Spectroscopic Method for the Estimation of Tolperisone HCL in Bulk And Pharmaceutical Dosage Form

Kirtansinh N. Gohil, Piyush M. Patel, N. M. Patel Shri B.M.Shah College of Pharmaceutical Edu. and Research, Modasa.

Abstract

A simple, precise and accurate difference spectroscopic method has been developed for the estimation of Tolperisone HCl in bulk and in pharmaceutical dosage form. The proposed method is

based on the principle that Tolperisone HCl can exhibit two different chemical forms in basic and acidic medium that differ in the absorption spectra in basic and acidic medium. Since the drug was freely soluble in distilled water, a stock solution (1 mg/mL) was prepared with distilled water. Further dilution was made by using 0.1 M sodium hydroxide and 0.1 M hydrochloric acid separately. The maxima and minima in the difference spectra of Tolperisone HCl were at 231 nm and 263 nm, respectively. Difference in absorbance between these maxima and minima was calculated to find out the amplitude. This amplitude was plotted against concentration. Beer's law is valid in the concentration range of 10-50 µg/mL. The results of analysis have been validated statistically and by recovery studies.

GUJ/Quality Assurance/07

Development and Validation of Simultaneous UV Spectrophotometric Method for Estimation of Paracetamol and Tolperisone Hydrochloride in Tablet Dosage Form

Miss. Shrushti Mehta Arihant School of Pharmacy & Bio- research, Adalaj

Abstract:

A simple, rapid, accurate, precise and economical UV spectrophotometric method for the simultaneous determination of Paracetamol and Tolperisone Hydrochloride in combined tablet dosage form using simultaneous equation method has been developed. *Materials and methods*: The method is based on the simultaneous equations for analysis of both the drugs using distilled water as solvent. Paracetamol has absorbance maxima at 242.5 nm and Tolperisone Hydrochloride has absorbance maxima at 260 nm in distilled water. *Results*: linearity was obtained in the concentration range of 4-12 μ g/ml and 2-18 μ g/ml for Paracetamol and Tolperisone Hydrochloride respectively. The concentrations of the drugs were determined by using simultaneous equations method. The mean recovery was 102.03 ± 3.79and 98.93 ± 0.90 for Paracetamol and Tolperisone Hydrochloride respectively. *Conclusion:* The method was found to be simple, accurate and precise and was applicable for the simultaneous determination of Paracetamol and Tolperisone Hydrochloride in pharmaceutical tablet dosage form. The results of analysis have been validated statistically and by recovery studies.

GUJ/Quality Assurance/08

Development and Validation of Spectrophotometric Method for Simultaneous Estimation of Rosuvastatin Calcium and Aspirin in Bulk and Pharmaceutical Dosage Form

Bhoomi B. Patel, Piyush M Patel., N.M Patel. Shri B. M. Shah College of Pharmaceutical Education and Research, Modasa.

Abstract

A simple, sensitive, rapid and precise spectrophotometric method has been developed and validated for simultaneous estimation of Rosuvastatin calcium and Aspirin from bulk and its pharmaceutical dosage form. These drugs were estimated in formulation by Q-absorption method in which wavelengths selected were 257nm as iso-absorptive point and 244nm as λ_{max} of Rosuvastatin calcium. Linearity was observed in the concentration range of 10-50 µg/ml and 40-120 µg/ml for Rosuvastatin calcium and Aspirin respectively. Validation study revealed that the method is specific, accurate, precise, reproducible and economic and can be used for routine quantitative analysis of Rosuvastatin calcium and Aspirin in pure and combined dosage form.

GUJ/Quality Assurance/09

Dual Wavelength Method for Simultaneous Estimation of Moxifloxacin Hydrochloride and Bromfenac Sodium in Eye Drops

Alpa N. Parmar

APMC College of Pharmaceutical Education and Research, College Campus, Himatnagar

Abstract

A simple, accurate, precise, sensitive and a highly selective spectrophotometric method was developed for the simultaneous estimation of moxifloxacin hydrochloride (MOXI) and bromfenac sodium (BROM).*Material and Methods*: The estimation of moxifloxacin hydrochloride was carried out by dual wavelength method at 275.0 nm and 260.5 nm where BROM shows similar absorbance while bromfenac sodium was estimated at 291.2 nm and 285.2 nm where MOXI shows similar absorbance. Distilled water taken as a solvent. The method was found to be linear in the range of 2-10 μ g/ml for MOXI and 4-20 ug/ml for BROM *.Results and Conclusion*: Mean recovery of 99.8 % and 99.6 % for MOXI and BROM respectively. The developed method was validated according to ICH guidelines and it found to be accurate and precise. Thus the proposed method can be successfully applied for simultaneous determination of MOXI and BROM in routine analysis work.

GUJ/Quality Assurance/10

Inductively coupled plasma atomic emission spectrometric detection in supercritical fluid chromatography

Bushra M. Malik

Arihant School of Pharmacy & Bio- research, Adalaj

Abstract

Supercritical fluid chromatography (SFC) is rapidly growing technique as an alternative to gas chromatography (GC) and high performance liquid chromatography (HPLC).Because supercritical fluids have properties intermediate between those of gases and liquids, the selectivity of SFC is resemble to that of GC or HPLC depending on the volatility and solubility of the compounds to be separated and also the operational temperature and pressure of the supercritical fluid. Plasma based detectors are promising because they have low detection limits, high precision and/or accuracy, wide dynamic ranges, and capabilities for simultaneous multi-element analysis. Complete chromatographic resolution is not required because of their elemental selectivity. Microwave induced plasmas (MIP) is a powerful and informative detector in capillary SFC for organo-chlorine and sulphur containing compounds. Inductively coupled plasma (ICP) provides an alternative mode for chromatographic detection in SFC. The SFC-ICP has been proved as a highly informative hyphenated technique in SFC.

GUJ/Quality Assurance/11

Multidimensional Supercritical Fluid Extraction and Supercritical Fluid Chromatography Patel Jagdish M.

Abstract

In the realm of analytical chemistry, the sample preparation step is often the most error prone step requiring arduous and sometimes lengthy procedures before the actual sample can be analyzed. SFE directly addresses sample preparation methodologies and provides analysts with the option to directly couple the sample preparation procedure to gas chromatography (GC) or supercritical fluid chromatography (SFC) to effectively achieve the analytical objectives. The flexibility exists whereby the analyst can use SFE in an off-line collection mode as well as on-line. In most cases, SFE as a sample preparation tool should be used in both the on-line and off-line modes. Off-line SFE gives the analyst the most capability for method development and analytical characterizations since the extraction effluent can be collected and then taken to any analytical instrument (i.e. GC, LC, SFC, MS, NMR, IR, etc.). After the initial method development for a sample type where initial characterizations have been performed, online SFE can be utilized to simplify the analytical tasks and reduce the methods to practice.

GUJ/Quality Assurance/12

Regulatory Affairs – New Drug Approval

Bhaumik A. Sharma, Priyanka V. Patel,

Shri B. M. Shah College of Pharmaceutical Education and Research, Modasa-383315

Abstract

Regulatory affairs is Comparatively New Profession which has Developed from Desire of Government to Protect Public Health by Controlling Safety,Efficasy of Product in Areas Including Pharmaceutical, Veterinary Medicine, Medical Devices, Pesticides, Agrochemicals, complementary Medicine. In today's competitive Environment, Reduction of time taken to reach Market is Critical to a Product &hence thus company success. The Proper Conduct of Product R.A activities is therefore of considerable Economic importance for Company. the R.A Department will Take part in the development of product Marketing concept require to approve Packaging & Advertising before it is use commercially .R.A Department must aware of R.A requirement in all companies, export market. The aim of this review is to discuss the present status of R.A for Pharmaceutical, The regional Variation for R.A & roll of R.A in new drug development. This help to improve the accuracy of R.A & help to conserve resources in the process of drug discovery & development.

GUJ/Quality Assurance/13

RP-HPLC method for simultaneous estimation of Epalrestate and Metformin hydrochloride

Kandarp M. Patel, Paresh U. Patel, Deepa R. Patel S. K. Patel College of Pharmaceutical Education & Research, Kherva

Abstract

Epalrestate(EPL), 3-Thiazolidineacetic acid, 5-(2-methyl-3-phenyl-2-propenylidene)-4-oxo-2thioxo-,(E,E)-5-((1Z,2E)-2-Methyl-3-phenylpropenylidene)-4-oxo-2-thioxo-3-thiazolidineacetic acid, is an aldose reductase inhibitor while Metformin hydrochloride(MET), N,Ndimethylimidodicarbonimidic diamide, is an oral antidiabetic drug belong to the class of biguanides. In the present study attempts were made to develop a rapid, economical, precise and accurate method for the simultaneous determination of the EPL and MET. A RP-HPLC method has developed for simultaneous estimation of epalrestate and metformin hydrochloride. Chromatography was carried out on Varian C₁₈ column using mixture of acetonitrile and 10mM ammonium acetate in the ratio of 70:30, v/v as a mobile phase at a flow rate of 1ml/min and detection at 240nm. The retention time for epalrestate and metformin hydrochloride was 2.10 and 5.61 min respectively. The calibration curve for EPL & MET was found to be linear over the range of 5-30µg/ml and 10-60µg/ml respectively. The limit of detection for epalrestate and metformin hydrochloride was 0.273μ g/ml and 0.267μ g/ml respectively. The limit of quantification for epalrestate and metformin hydrochloride was 0.911µg/ml and 0.893µg/ml respectively. The method was validated for accuracy, precision, robustness and system suitability. The proposed method was fast, accurate and precise so it can be used for regular quality control of the bulk drug and laboratory mixture.

GUJ/Quality Assurance/14

Simultaneous Estimation and Validation of Method for Amlodipine Besylate and Indapamide in Pharmaceutical Dosage Form by Absorption Correction Method

Ghanshyam R. Shah*, Rajesh R. Parmar, Dr. Dushyant A. Shah APMC College of Pharmaceutical Education and Research, College Campus, Himatnagar

Abstract

A Versatile, accurate, precise and economic method for simultaneous determination of Amlodipine besylate (AML) and Indapamide (IND) in fixed dose combination products was developed. Wavelengths selected for AML was 343 nm as IND shows zero absorbance. So absorbance of IND was found by subtracting absorbance of AML. Absorbance corrected for IND was measured at 263.5 nm. This method obeyed Beer's law in the concentration range of mixture of 14–38 μ g/ml for AML and 4-12 μ g/ml for IND. The results of analysIs have been validated for linearity, accuracy and precision, LOD and LOQ of the proposed method.

GUJ/Quality Assurance/15

Simultaneous Estimation of Atorvastatin Calcium and Aspirin in Pharmaceutical Dosage Form by UV Spectrophotometric Method

Chintan P. Patel*, Rajesh R. Parmar, Dr. Dushyant A. Shah APMC College of Pharmaceutical Education and Research, College campus, Himatnagar

Abstract

A simple, precise, accurate, rapid and economical spectrophotometric method have been developed for simultaneous estimation of Atorvastatin calcium and Aspirin in pure and in combined capsule dosage form. Simultaneous equations by using 240nm and 230nm as absorbance maxima (λ max)for Atorvastatin calcium and Aspirin respectively. A 0.1N NaOH was used as Solvent. Linearity was observed in the concentration range of 2-26 µg/ml for Atorvastatin calcium and 5-25 µg/ml for Aspirin respectively. The method was validated statistically and recovery study was performed to confirm the accuracy of the method.

GUJ/Quality Assurance/16

Simultaneous Estimation of Montelukast Sodium and Theophylline in Pharmaceutical Dosage Form by UV Spectrophotometric Method

Rakesh B. Patel*, Rajesh R. Parmar, Visnu M. Patel, Dushyant A. Shah APMC College of Pharmaceutical Education and Research, College campus, Himatnagar

Abstract

A simple, precise, accurate, rapid and economical spectrophotometric method have been developed for simultaneous estimation of Montelukast sodium and Theophylline in pure and in combined tablet dosage form. Simultaneous equations by using 287nm and 271nm as absorbance maxima (λ max)for Montelukast sodium and Theophylline respectively. Water was used as Solvent. Linearity was observed in the concentration range of 4-24 µg/ml for Montelukast sodium and 2-17 µg/ml for Theophylline respectively. The method was validated statistically and recovery study was performed to confirm the accuracy of the method.

GUJ/Quality Assurance/17

Simultaneous Estimation of Tartrazine and Sunset Yellow in Synthetic Mixture by Q-Analysis Method

S M Rathod, V A Shah, D S Patel, A B Gadhvi, C P Patel, R R Parmar, D A Shah APMC College of Pharmaceutical Education and Research, Himmatnagar, India.

Abstract

This work deals with the simultaneous estimation of Tartrazine & Sunset yellow in synthetic mixture by Q-Analysis Method. The Absorption Maxima at 426.0 nm & 482.0 nm were used for the estimation of Tartrazine & Sunset yellow, respectively and 449.0 nm was used as the iso-absorptive point. Both the colorants & their mixtures obey Lambert-Beer's law at selected wavelength at given concentration range. The result has been validated

statistically. The tartrazine will show the linearity in the range $4-32\mu$ g/ml and Sunset yellow in the range 2-16 μ g/ml.The proposed procedure is simple, rapid & can be used for routine analysis of both colorants.

GUJ/Quality Assurance/18

Simultaneous Estimation of Telmisartan and Indapamide in Pharmaceutical Dosage Form by Simultaneous Equation Method

Purvesh K Patel*, Rajesh R. Parmar, Vaishali N Shah, Dushyant A. Shah APMC College of Pharmaceutical Education and Research, College campus, Himatnagar

Abstract

A Versatile, accurate, precise and economic method for simultaneous determination of Telmisartan and indapamide in fixed dose combination products was developed. The absorbance values at 295.0 nm and 239.0 nm were used for the estimation of Telmisartan and indapamide , respectively without mutual interference. This method obeyed Beer's law in the concentration range of $2-10 \mu g$ /ml for Telmisartan and 2-14 μg /ml for indapamide. The results of analysIs have been validated statistically for linearity, accuracy and precision, LOD and LOQ of the proposed method.

GUJ/Quality Assurance/19

Simultaneous Estimation of Telmisartan and Metoprolol Succinate in Pharmaceutical Dosage Form by Simultaneous Equation Method.

Amit B Gadhavi*, Rajesh R. Parmar, Dr. Vaishali Shah , Dr. Dushyant A. Shah APMC College of Pharmaceutical Education and Research, College campus, Himatnagar

Abstract

A Versatile, accurate, precise and economic method for simultaneous determination of Telmisartan and Metoprolol succinate in fixed dose combination products was developed. The absorbance values at 295.0 nm and 222.0 nm were used for the estimation of Telmisartan and Metoprolol succinate, respectively without mutual interference. This method obeyed Beer's law in the concentration range of $3-15 \mu g$ /ml for Telmisartan and 5-45 μg /ml for Metoprolol succinate. The results of analysis have been validated statistically for linearity, accuracy and precision, LOD and LOQ of the proposed method.

GUJ/Quality Assurance/20

Simultaneous Spectrophotometric determination of Cefpodoxime Proxetil And Ofloxacin in Tablet

Dhaval R Chaudhary, Ashok Mahajan, Dr. Dushyant shah

A.P.M.C college of pharmaceutical education & Research, Himmatnagar, Gujarat, India. **Abstract**

The present manuscript describe simple, sensitive, rapid, accurate, precise and Economical Simultaneous method for the simultaneous determination of cefpodoxime proxetil and ofloxacin in combined tablet dosage form by simultaneous equation method. Ofloxacin and cefpodoxime proxetil shows absorbance maxima at 293 nm and 263 nm in 0.1 M HCL, respectively. The linearity was obtained in the concentration range of 2-10 μ g/ml for both cefpodoxime proxetil and ofloxacin. The method was successfully applied to pharmaceutical dosage form because no interference from the tablet excipients was found. The suitability of these methods for the quantitative determination of ofloxacin and cefpodoxime proxetil was proved by validation. The proposed methods were found to be simple and sensitive for the routine quality control application of ofloxacin and cefpodoxime proxetil tablet dosage form. The results of analysis have been validated statistically and by recovery studies.

GUJ/Quality Assurance/21

Spectrophotometric Determination of Meropenem in Pharmaceutical Dosage Form by First Order Derivative Spectroscopy and Area under The Curve

Vaishali.A.Shah, Sapna.M.Rathod, Rajesh. R. Parmar, Dr. Dushyant. A. Shah A.P.M.C College of Pharmaceutical Education and Research

Abstract

UV spectrophotometric method for the quantitative determination of meropenem, a highly active carbapenem antibiotic, in powder for injection was developed. In the present work, two rapid, economical and accurate methods have been developed for the estimation of meropenem in pharmaceutical dosage form. Method A is first order derivative spectroscopy where derivative amplitudes were calculated by considering minima (320.0nm) and maxima (282.0 nm) of the curve. Method B is area under the curve in which wavelength range 304-299 nm was selected. Linearity was observed in the concentration range 10-50 μ g/ml and 5-45 μ g/ml for first order derivative spectroscopy and area under the curve respectively the methods (r2=0.999 for method A and r2=0.999 for method B). The % assay for the marketed formulation by first order derivative and area under the curve was found to be 98 % and 98% respectively. The method was validated with respect to linearity, precision and accuracy studies. Both the methods were found to be simple, precise and accurate and can be employed for routine quality control analysis of meropenem in pharmaceutical dosage form. The proposed analytical methods were compared using statistical analysis.

GUJ/Quality Assurance/22

UV Spectrophotometric Method Development and Validation for Simultaneous Estimation of Rosuvastatin Calcium and Telmisartan in Bulk Drug and In Combined Dosage Form

Binal B Shah, Piyush M. Patel, N. M. Patel Shri B. M. Shah College of Pharmaceutical Education and Research, Modasa.

Abstract

A sensitive, rapid and specific Simultaneous Equation method has been developed for the simultaneous estimation of Rosuvastatin Calcium and Telmisartan and in bulk drug and in combined dosage form. Rosuvastatin Calcium and Telmisartan showed absorbance maxima at 242.0nm and 295.5nm respectively in 0.1N Sodium Hydroxide solution. Linearity range was observed in the concentration range of 0-60 μ g/ml for Rosuvastatin Calcium and 0-50 μ g/ml for Telmisartan. Concentration of each drug was obtained by using the Absorptivity values calculated for both drugs at two wavelengths 242.0nm and 295.5nm and solving the simultaneous equation. The developed methods are simple, rapid, accurate, precise, reproducible and economic and can be used for routine quantitative analysis of Rosuvastatin Calcium and Telmisartan in pure and tablet dosage form. The method was validated using ICH Guidelines.

GUJ/Quality Assurance/23

Weekly Measurement of Optical Density of Blood Using UV- VIS Spectroscopic Method.

Dr.S.V.Patel, Dr.S.M.Dave, Prof.D.G.Acharya, Dr Jayshree N. Patel Sir P.T.Science College, Modasa.Gujarat (India).

Abstract:

The object of the present work is to measure and study the optical density of blood at various stipulated periods of time using ultraviolet and visible spectroscopic method. SL 108 single beam UV-Vis spectrophotometer was used to record the spectra in the wavelength range between 200 and 700 nm. There are six wave-length maxima exhibited at 215, 280, 346, 418, 544 and 578 nm corresponding to proteins, amino acids, NADH and NADPH, CO-hemoglobin and oxy-hemoglobin respectively in blood. From the study it is observed that optical density of blood constituents decreases with time except CO-hemoglobin which occurs at the wavelength at 418 nm.

GUJ/Quality Assurance/24

High-performance liquid chromatography/NMR spectrometry/Mass spectrometry: A new triple-hyphenated approach for structure elucidation

Patel Krupa

Arihant School of Pharmacy & Bio- research, Adalaj Abstract

Screening analysis that aims at rapidly distinguishing new molecules in the presence of a large number of known compounds becomes increasingly important in the fields of drug metabolite profiling and nature product investigation. In the past decade, online-coupled liquid chromatography-nuclear magnetic resonance spectroscopy-mass spectrometry (LC-NMR-MS) has emerged as a powerful tool for the detection and identification of known and, more important, emerging compounds in complex clinical, pharmaceutical samples and nature product extracts, due to the complementary information provided by the two detectors for unambiguous structure elucidation. Novel method termed as High-performance liquid chromatography/NMR spectrometry/mass spectrometry (HPLC-NMR-MS) was developed by coupling High performance liquid chromatography simultaneously to high field NMR and MS detectors, giving UV, NMR and mass spectra for each component in a mixture, after on-line separation to discover the intrinsic correlation between retention time (R_t) , mass/charge (m/z) and chemical shift (delta) data of the same constituent from mixture.LC/NMR/MS system include studies of combinatorial chemistry libraries, synthetic chemical impurities, characterization of drug mixtures, identification of natural products of possible pharmaceutical interest and identification of xenobiotic metabolites in human, animal and in vitro systems. This powerful new tool for the structure elucidation of components in mixtures without isolation has been successfully applied to the analysis of the metabolites of paracetamol in human urine also.

GUJ/Quality Assurance/25

Development and validation of UV spectrophotometric method for the simultaneous estimation of Rosuvastatin calcium and aspirin in pharmaceutical dosage form by simultaneous equation method

Dhiren S. Patel*, Rajesh R. Parmar, Ashok Mahajan , Dr. Dushyant A. Shah APMC College of Pharmaceutical Education and Research, College campus, Himatnagar

Abstract

Versatile, accurate, precise and economic method for simultaneous determination of Rosuvastatin calcium and Aspirin in fixed dose combination products was developed. The absorbance values at 242.0 nm and 297.0 nm were used for the estimation of Rosuvastatin calcium and Aspirin, respectively without mutual interference. This method obeyed Beer's law in the concentration range of $2-26 \ \mu g$ /ml for Rosuvastatin calcium and 5-25 $\ \mu g$ /ml for Aspirin. The results of analysis have been validated statistically for linearity, accuracy and precision, LOD and LOQ of the proposed method.

GUJ/Quality Assurance/26

Simultaneous Determination of Metformin and Repaglinide in Pharmaceutical Dosage Form by Difference Spectroscopy

Mahipal M Makwana*, Rajesh R. Parmar, Vaishali N Shah, Dushyant A. Shah

APMC College of Pharmaceutical Education and Research, College campus, Himatnagar

Abstract

A simple and rapid difference spectroscopic method was developed for the simultaneous determination of metformin (MET) and repaglinide (REPA) without prior separation. The REPA has 269 nm and 304 nm maxima and minima respectively. The proposed method depends upon measuring the absorbance of MET at 238.5 nm which is the zero crossing point on the difference spectra of REPA in 0.1 N NaOH *vs.* 0.1 N HCl. The absorbance of REPA was measured at 234.5 nm which is λ_{Max} of MET. Beer's law was obeyed in the concentration range of 2-12 and 10-50 µg/mL for MET and REPA, respectively. The results of analysis have been validated statistically for linearity, accuracy and precision, LOD and LOQ of the proposed method.

GUJ/Quality Assurance/27

3d-Qsar Studies On 2- Arylcarbonyl -3-Trifluoromethylquinoxaline 1, 4-Di-N- Oxide Derivatives and their Reduced Analogues Using K-NN MFA Approach

Joohee Pradhan¹, Dr. Rajesh Sharma, Dr. Anju Goyal Abstract

A set of thirty three Quinoxaline derivatives with cytotoxic activities against nine types of tumoral subgroups was subjected to three dimensional quantitative structure activity relationship studies through recently introduced k- nearest neighbor molecular field analysis with step wise, simulated annealing and genetic algorithm as variable selection methods resulting in eight statistically significant models for leukemia, nonsmall lung, colon, CNS, ovarian, prostate and breast cancers. These models gave a value of q^2 as high as 0.9122 for model 1 and value of pred_r² as high as 0.6738 for model 3.The k-NN MFA contour plots provided further understanding of the relationship between the structural features of quinoxaline derivatives and their activities, which should be applicable to design new, potential cytotoxic agents.

GUJ/Quality Assurance/28

Stigmasterol: A Comprehensive Review

Insha zaidi*, R. S. Bhadauria, Dipal Patel¹ Shrinathji Institute of Pharmacy, Nathdwara, (Raj).

Abstract

Extensive research has been carried out from last decades to discover potential constituents from plant sources. Stigmasterol is an important constituent and has been isolated from plants by extracting with solvents which are higher in the ellutropic series i.e., non-polar solvents only. It has been found in the petroleum ether extract of aerial parts of Ageratum convzoides (Asteraceae), Calotropis gigantean, root and aerial part of Desmodium gangeticum, seeds of Terminalia chebula, petroleum ether extract of aerial parts of Byrophyllum pinnatum, petroleum ether extract of woody stem of Abelmoschus manihot, hexane extract of leaves of Pandanus amaryllifolius. Biosynthesis of stigmasterol (phytosterol) from mevalonate and deoxy-xylulose pathway was investigated in the callus culture of *Croton sublyratus* from the leaf explants. It was found that biosynthesis was active during the linear phase of the culture and both pathways contribute equally. It is involved in the synthesis of many hormones like progesterone, androgens, estrogens, corticoids and in the synthesis of vitamin D3. In addition to stigmasterol many of its derivatives like spinasterol, fucosterol, cvasterone. stigmasterol glucoside, fucosterol-epoxide, Foetidin. 6-chlorostigmasterol. Dehydrooogoniol, stigma-4en-3one, 29- fluorostigmasterol etc. have been isolated and their pharmacological aspects has been assessed. This comprehensive account provides information about stigmasterol and its derivatives. Stigmasterol has been investigated for its pharmacological prospects such as antiosteoarthritic, antihypercholestrolemic, cytotoxicity, antitumor(inhibition of DNA repair synthesis), Anti feeding, Antidiabetic, Female activating hormone, Insecticide, Neurotoxic, hypoglycaemic, antimutagenic, antioxidant, anti-inflammatory and CNS effects.

GUJ/Quality Assurance/29

Green Chemistry in Pollution Prevention

Krishna Soni, Kanchan Choudhary, Deepika Bairagi B. N. Girls College of Pharmacy, Udaipur 313001, India

Abstract

Green chemistry defines the efforts of chemists to develop processes and products that prevent pollution and are inherently safe for human and environment. The green chemistry program supports the invention of more environmentally friendly chemical processes which reduce or even eliminate the generation of hazardous substances. Implementing green chemistry will improve the quality of the environment for present and future generations. For technology development, green chemistry requires an interdisciplinary approach including chemists, biochemists, statisticians, and health care professionals. Achieving the goals of green chemistry requires cooperation among numerous stakeholders. Green chemistry incorporates pollution prevention in the manufacturing of chemicals, and promotes pollution prevention and industrial ecology. Manufacturing a chemical product require a synthetic pathway as well as a safe and efficient chemical manufacturing strategy. The greening of a chemical product or process may be accomplished through a number of means, including improved synthetic procedures, better catalysts, novel process design, use of renewable raw material, discovery of less toxic products, use of environmentally benign solvents, or design of recyclable materials. Thus the concept of green chemistry can be invoked in any aspect of fundamental or applied chemistry as well as toxicology and risk assessment alongside fundamental scientific data in all efforts to make greener chemical products and processes.

GUJ/Quality Assurance/30

Qualitative and Quantitative analysis of human friend Flavonoids:

Rishika Rawal*, Noopur Sharma, Ankita Sharma, Amit Bhargava B.N.Girls College of Pharmacy, Udaipur

Absract

Flavonoids are to know for their flavour properties, they have several beneficial effects on diseases, including allergy, asthma, atopic dermatitis cataract diabetes gout haemorrhagic conditions, macular degeneration migraine stomach ulcer varicose veins. Flavonoids have two classes Open bridges close bridges further they have following sub classes Open bridges further classify in to chalcones and dihydro chalcones. Close bridge in to flavones, flavonols isoflavones flavonones flavanals aurones biflvonoides anthocyanin. Because of their wide spectrum effects they sometimes refer as human friend. There are some methods which are use for determination of qualitative and quantitative contains of flavonoids including thin layer chromatography, Ultra violet spectroscopy, HPLC. Thin layer chromatography separation of compound is based on the competition of the solute and mobile phase for binding on the stationary phase Thin layer chromatography monitor their progress of the flavonoids contains solution. Identify complex of flavonoids present in given mixture and determine the purity of flavonoids. Ultra violet and visible spectroscopy is routinely used in analytical chemistry for the quantitative determination of different flavonoids. It follows beerlambert law. The beer lambert law has implicit assumption that must be met experimentally for it to apply.High performance liquid chromatography (HPLC) technique use to separate mixture of flavanoids these sample to be analysed is introduced in small volumes in to the stream of mobile phase. The solution moved through the column is slowed by specific chemical or physical interaction with the stationary phase present with in the column. Recent work been carried on strawberry tree and on Ficaria verna huds.

Abstract of the Poster Presentation Gujcost/Cognosy/01 - Gujcost/ Cognosy /16

GUJ/COGNOSY/01

Anti diabetic effect of ethanolic extract of *Euphorbia Neriifolia* Linn. in Alloxan induced diabetic rats

Mushir I Mansuri ,Vishnu M. Patel Research scholar, JJT University, Jhunjhnu, Rajasthan)

Abstract

Euphorbia Neriifolia Linn. (Ephorbiaceae) is traditionally used to treat diabetes mellitus. The extract of Euphorbia Neriifolia Linn. are having potential in the development of drug for diabetes due to their antidiabetic activity. Purpose of the study was to evaluate the antidiabetic activity of ethanolic extracts of leaves of Euphorbia Neriifolia Linn. (Ephorbiaceae) in alloxan induced diabetic rats. Ethanolic extracts (200 and 400 mg/kg body weight), were administered orally to Wistar albino rats of either sex. Alloxan monohydrate120mg/kg was used to induce diabetes mellitus. Glibenclamide 2.5mg/kg,p.o was used as standard drug. The parameters studied included oral glucose tolerance test, fasting blood glucose, serum lipid profile, and changes in body weights. In oral glucose tolerance test, reduction of fasting blood glucose levels took place from 60 min of extract administration. The extracts produced a dose-dependent fall in fasting blood glucose (FBG). After 15 days of treatment with extracts the maximum reduction in FBG was observed in diabetic rats treated with ethanolic extract 400 mg/kg dose. Serum lipid levels were reversed towards near normal and a control in the loss of body weight was observed in treated rats as compared to diabetic control. The results demonstrate that Euphorbia Neriifolia Linn. (Ephorbiaceae) possesses significant antidiabetic activity in diabetic rats. The results suggest that Euphorbia Neriifolia Linn.has antidiabetic activity.

GUJ/COGNOSY/02

Antidiabetic Activity of Actinodaphne Hookeri Meissn Leaves

Dewanshi Mehta*, Dharmeshkumar Prajapati, N.M.Patel, BMCPER, Modasa

Abstract

Leaves of *Actinodaphne hookeri* Meissn (Family Lauraceae; Pisa) has been in use traditionally for the treatment of diabetes and disorders of the urinary tract which are more common in Chattisgarh and eastern part of India. In the present study, leaves of *Actinodaphne hookeri* were subjected to phytochemical investigation and evaluated for anti-diabetic activity. Ethanol extract, successive petroleum ether extract, chloroform extract, methanol extracts of the leaves of *Actinodaphne hookeri* as well as glibenclamide were evaluated for anti-diabetic activity in alloxan-induced diabetic model in rats. The extracts were also subjected to phytochemical investigation. The ethanol- and the chloroform extract were found to have significant (p<0.01) blood glucose lowering effect. The extracts also significantly (p<0.01) lowered the increased serum cholesterol and low density lipoprotein (LDL) levels. Preliminary phytochemical investigation revealed the presence of alkaloids, flavonoids, triterpenoids and glycosides as the major constituents in the ethanol extract. The chloroform extract also showed significant (p<0.01) antihyperglycemic activity and contained alkaloids and triterpenes. It is concluded that the antidiabetic activity of *A. hookeri* may be due to the presence of alkaloids and triterpenes, and might be. Promising for the development of phytomedicine for diabetes mellitus along with its associated complications.

GUJ/COGNOSY/03

Current status & Future prospective of Pharmacognosy & Phytochemistry worldwide

Suchita Patel, Pooja Patel, Dharti Patel, Gaudani Rashmi, Bhavesh Nayak

Abstract

Phytochemical studies have experienced a great deal of change during the last century. This change has mainly been related to two key points: the methodologies used in phytochemical studies and the important of secondary metabolites appeared in plants. This transformation in the field has led to new concerning such different subjects as evolution, paleobotany, biochemistry, plant physiology and ethnography. The main issue is to clarify the role that secondary metabolites play in the plant (and other organisms) and whether the resources invested in their production (C and N allocation, genes encoding their biogenetic pathways, specific enzymes, energy-rich molecules such as ATP and NADPH) have or lack a reasonable reward in terms of advantages for survival. In this review there are two main aim like to describe briefly the influence that the development of the methodologies needed for compound isolation and structure elucidation have had on the field of phytochemistry & to be covered concerns the new theories addressing the role of secondary metabolites from an ecological point of view: co-evolution of plants and their potential enemies (phytophagous insects, microbes, herbivores and other plants), chemical plant defence, adaptative strategies of phytophagues to plant toxins.(among them sequestration will be briefly mentioned), and models and theories for carbon and nitrogen allocation. Some final remarks are made to summarize our opinion about the immediate future of phytochemical ecology and phytochemical studies. This review attempts to provide both an overview of the current state of the art and a perspective of the major challenges that remain.

GUJ/COGNOSY/04

Halal Certification - An Essential Need for Herbal / Food Industry

Divyang Patel, Niyati Acharya, Sanjeev Acharya, Vimal Kumar, Institute of Pharmacy, Nirma University, S.G Highway, Ahmedabad-382 481, Gujarat

Abstract

Halal is an Arabic term meaning 'permitted, allowed or lawful'. *Halal* when used in relation to food and other consumer goods, means "permissible for consumption and use by Muslims.*Halal* covers the aspects of slaughtering, storage, display, preparation, hygiene and sanitation. It covers food products, dairy products, herbal products, etc. Given the speed of trade globalization, the advancement in science and technology, and the on-going initiatives to simplify manufacturing processes, it is essential that the *halal* concept be fully understood by marketers of herbal / food products. Halal certification process involves mainly two steps : (1) Pre audit requirements & (2) Plant audit. After complete plant audit, if all the requirements are according to halal concept, halal certification is given to the industry , which is valid for one year & required to be renewed. This certification grantes the companies the use of *halal* logo for printing on their products' packaging or for the display at the company's premise.

GUJ/COGNOSY/05

Isolation, Characterization and Estimation of Karanjin from Seeds and Market Formulation of *Pongamia Glabra Using* HPTLC Method

Arti Pansuriya*, Pankti Patel, Shailja Khachar, Dr. Sindhu Ezhava, Ishwarsinh Rathod, Dr. B N Suhagiya

Abstract

Karanja (*Pongamia glabra*, family- Fabaceae) seed contains 'Karanjin' a bioactive molecule with important biological attributes, which include anti-fungal, insecticidal and anti-bacterial activity. Pure Karanjin was isolated from the methanolic extract of seed oil and characterized by melting point and spectrophotometric methods (U.V. spectra, I.R. spectra and mass spectra). A simple, accurate and specific HPTLC method was developed for the determination of Karanjin in seed powder and market preparation of *Pongamia glabra*. The mobile phase Toluene: Ethyl-Acetate (90: 20 %, v/v) with pre-saturation time of 30 min. provided good resolution for Karanjin with the Rf value of 0.48 \pm 0.03 at 260 nm. The linearity of Karanjin was found to be within range of 200-1400ng/spot (r = 0.9992). Recovery of the karanjin was found to be 102.39%. LOD and LOQ of the

mehod were found to be 20 ng/spot and 200 ng/spot respectively. Intraday and Interday precision were found to be 0.93-2.3 and 1.37-3.41 respectively. The amount of Karanjin in karanja seed and seed oil as estimated by the developed validated HPTLC method were $1.50 \pm 0.08\%$ w/w and $2.61 \pm 0.06\%$ w/v respectively.

GUJ/COGNOSY/06

Mechanism of action of diuresis and pharmacological activity of "Protate capsule" using Lipschitz model on Wistar rats.

Avani B. Patel*, Chelli P. Israni, N.M.Patel, A.A.Patel, BMCPER, MODASA

Abstract

Protate capsule is a product of Shri Nimbark Ayurvedic pharmacy, Mehsana. It is mainly used as diuretic. Protate Capsule consists of five ingredients viz., extract of *Boerhaavia diffusa, Tinospora cordifolia, Tribulus terrestris, Curcuma longa, Crataeva nurvala*.and It used as diuretic, antioxidant, antimicrobial and in Kidney stone. Wister albino rats weighing between 150-200gm were used for this experiment. Animals were divided into 4 groups, 6 animals in each group. They were kept in a metabolic cages so as to separate urine and faeces. After oral administration of test drug, the urinary output of each group was recorded at different time intervals from the graduated urine chamber in metabolic cage. Urine samples were analyzed for Na+ and K+ concentration by flame photometric method. The Cl⁻ ion concentration was found by titration of samples with 0.02 N AgNO₃ using 5% potassium chromate solutions as indicator. Protate capsule at 500mg/kg shows significant diuretic activity. So, It is concluded that Protate capsule may be formulated as diuretic.

GUJ/COGNOSY/07

Medicinal Uses of Some Selected Plants of Mimosaceae Family of Modasa Taluka, Dist. Sabarkantha (Gujarat) India

M. S. JANGID, Department of Biology Sir P. T. Science College, Modasa-383315, INDIA

Abstract

In this present work, some selected plants of Mimosaceae family are considered, which are normally used by local and tribal people of Modasa taluka. These plants are used to treat their ailments by using fresh plant materials only. The plants were collected from the various villages and forests area including hill and hillocks of the Modasa taluka. In the enumeration, the collected plants have been arranged alphabetically, the botanical name, floristic characters, flowering and fruiting time, vernacular name and medicinal uses are given.

GUJ/COGNOSY/08

Pharmacognostical and Phytochemical Profiling of Ipomoea reniformis Chois

Mehul K Bhatt Ajay K. Saluja, Dholwani Kishor K. Shivam Pharmaceutical studies and Research centre, Valasan, Anand.

Abstract

Ipomoea reniformis (Convolvulaceae) commonly used in name of "Underkani" in Gujarat. Ethnic people use this herb in inflammation, headache, bronchitis, paralysis, epilepsy and also as diuretic. Review of the literature did not reveal much work on this herb, but ethno medically whole herb is said to be having good ant-inflammatory properties^{1, 2}. Hence it was thought worth to study the whole herb. Objective: The objective of the current study was to develop distinct phytochemical and microscopy protocol and standards that can be used in quality control of the crude drug of *Ipomoea reniformis*. Method: The present investigation deals with macroscopic, microscopicstudy including powder characteristics & phytochemical analysis of the *Ipomoea reniformis*.

GUJ/COGNOSY/09

Pharmacognostical Evaluation Of Withania Somnifera Leaf

Sunita Panchawat

B. N. Girls' College Of Pharmacy, Udaipur (Rajasthan), India

Abstract

Withania somnifera Linn. (Solanaceae) is an erect, evergreen and perennial shrub. Traditionally it has been used in treatment of rheumatism, gout, hypertension, nervine and skin diseases. It has been widely used as sex stimulant and rejuvenator and is considered as vigor and strength promoting drug. The main constituents of ashwagandha are alkaloids and steroidal lactones. Among the various alkaloids, withanine is the main constituent. The leaves contain steroidal lactones, which are commonly called as "withanolides".Pharmacognostical and Phytochemical studies of *W. somnifera* Linn. leaves were carried out in present study. Morphology and microscopy of plant, total ash, acid insoluble and water insoluble ash were determined. The extractive values i.e. alcohol soluble and water soluble were determined. The total glucose content and bitterness value of hydro-alcoholic extracts were also determined. Thin layer chromatography of *Withania somnifera* (leaf) extracts were performed for preliminary identification of constituents.

GUJ/COGNOSY/10

Pharmacognosy in 21st century

Hannah Christian, Kruti Dhanani, Dharati Kotadiya,Gaudani Rashmi, Bhavesh Nayak Shree Swaminarayan Shankar pharmacy college, Zundal

Abstract

The term Pharmacognosy as a constituent scientific discipline of pharmacy has been in use for nearly 200 years, and it refers to studies on natural product drugs. During the last half of the 20th century, Pharmacognosy evolved from being a descriptive botanical subject to one having a more chemical and biological focus. At the beginning of the 21st century, Pharmacognosy teaching in academic pharmacy institutions has been given new relevance, as a result of the explosive growth in the use of herbal remedies (phytomedicines) in modern pharmacy practice, particularly in Western Europe and North America. In turn, pharmacognosy research areas are continuing to expand, and now it include cell and molecular biology in relation to natural products, ethno botany and phytotherapy, and phytochemistry. The systematic study of herbal remedies offers pharmacognosy groups an attractive new area of research, ranging from investigating the biologically active principles of phytomedicines. Today, it plays an integral role in the field of Pharmaceutical Sciences through the discovery, identification, and evolution of bioactive compounds from natural sources. Studies of plants used in European, North American, African, and Asian traditional medicine are conducted with the goals of identifying bioactive constituents and discovering new lead compounds.

GUJ/COGNOSY/11

Phytochemical and Antimicrobial Evaluation of Ajuga Bracteosa Wall

Rachana V. Patel, N.M. Patel, A. A. Patel, Dipti M. Pokal.Shri B. M. Shah College of Pharmaceutical Education & Research, Modasa.

Abstract

Ajuga bracteosa Wall. ex Benth. herb belongs to family Labiatae; commonly known as *Neelkanthi*; is distributed in subtropical and temperate regions from Kashmir to Bhutan, Pakistan, Afghanistan, China and Malaysia. Traditionaly the herb having various biological activity such as anti-microbial, antitumor, anti-inflammatory, hepatoprotective, immunomodulatory, cytotoxic, antisecticidal and insect-antifeedant properties. Extraction of *A. bracteosa* Wall. ex Benth. herb in different solvents like petroleum ether, benzene, chloroform, acetone, ethanol and water. All the extracts were tested to know the different constituents present in them by the standard procedures. Total phenolic,

flavonoid content in the ethanol and aqueous extracts and antimicrobial activity carried out. Results indicated that *Ajuga bracteosa* Wall. Ex Benth. herb having significant antimicrobial activity due to presence of different phytoconstituents.

GUJ/COGNOSY/12

Qualitative Parameter of Pepgard Syrup - A Poly Herbal Formulation

Shraddha R. Patel, Dr. N.M.PATEL, Dr. A.A.PATEL, Sejal P. Patel Shri B.M.Shah College of Pharmaceutical Education & Research, Modasa

Abstract

The most important challenges faced by herbal formulations arise because of their lack of complete evaluation. Evaluation is necessary to ensure quality and purity of the herbal product. For evaluation of syrup containing single herb various parameters were tested. These parameters for raw material include Organoleptic, Physicochemical, Phytochemical and Physical etc. and assay of active constituent. Quality control parameters like description, pH, viscosity, specific gravity, surface tension, total sugar, and total solid content, heavy metal analysis and microbial analysis of Pepgard Syrup were carried out as a part of evaluation. Pepgard Syrup consists of nine ingredients eg. aqueous extract of *De Glycyrrhizinated Glycerrhiza glabra* Linn. (D.G.L), *Asparagus racemosus* Willd., *Centella asiatica* Linn., *Embellica officinale* Gaertn., *Ipomoea turpethum* Linn., *Syzgium aromaticum* Linn., *Fumaria officinalis* Linn., cold macerated extract of fresh herb *Coriandrum sativum* Linn. and powder of Sajjkhar (*Astoneman indicum*). Results point out that raw material of 'Pepgard syrup' has passed through all Organoleptic, Physicochemical, Physical and Phytochemical parameters. All three batches of 'Pepgard Syrup' were uniform description, pH, viscosity, specific gravity, surface tension, total sugar, and total solid content etc. Heavy metal and microbial contamination was below the detection limit.

GUJ/COGNOSY/13

Qualitative Evaluation of Abha Capsule

Dipti M. Pokal, N.M. Patel, A. A. Patel, Rachana V. Patel Shri B. M. Shah College of Pharmaceutical Education & Research, Modasa

Abstract

The most important challenges faced by herbal formulations arise because of their lack of complete evaluation. Evaluation is necessary to ensure quality and purity of the herbal product. Abha capsule consists of four ingredients viz., extract of *Cissus quadrangularis* Linn, and powder mixture of Abha guggul, Kishore guggul, and Lakshdi guggul. It is used in Fracture healing, osteoarthritis, painful arthritic condition, relieves pain and inflammation. For evaluation of capsule containing single herb various parameters were tested. Parameters for raw material Physicochemical and phytochemical parameters. Parameters for finished product (capsule) include uniformity of weight, pH, moisture content, disintegration time and dissolution study. 'Results point out that raw material of 'Abha capsule' has passed through all Physicochemical and Phytochemical parameters. All three batches of 'Abha capsule' were uniform in colour, size, weight, dissolution and disintegration time, moisture content, angle of repose, bulk and tap density.

GUJ/COGNOSY/14

Standardization and Laxative Activity of Swadist Virechan Churna A Poly Herbal Formulation

Sejal P. Patel, N.M. Patel, A. A. Patel, Shraddha R. Patel, BMCPER, MODASA

Abstract

Standardization is an essential measurement for ensuring the quality control of the herbal drugs. Swadist Virechan churna consist of *Cassia angustifolia, Foeniculum vulgare, Glycyrrhiza glabra,* Sarkara and Shuddh Gandhak and used in constipation as a laxative. In present study the quality control of Swadist Virechan Churna is carried out by evaluting various parameters like powder fineness, moisture content, angle of repose, bulk density, tapped density, carr's index, hausner's ratio, pH, heavy metal analysis, microbial analysis, evalution of pharmacological activity and parameters for raw material includes organoleptic, physicochemical, phytochemical. Results indicate that Swadist Virechan churna has passed through all organoleptic and physicochemical parameters. Moisture content and pH of all ingredients and finished formulation are within limit so there is less chances of microbial growth and gastric irritation. Heavy metal analysis shows that all heavy metals are within limit. Total ash and water soluble extractive for all ingredients is within limit therefore it can be said free from impurities. Laxative activity of Swadist Virechan Churna on Wistar albino rats had showed significant fecal output after 8 hours as compared to control group. So, it is concluded that Swadist Virechan churna may be formulated as a laxative.

GUJ/COGNOSY/15

Standardization of Arthrum Plus Capsule

Jalpa R. Modh, N.M. Patel, A. A. Patel, Avani B. Patel BMCPER, MODASA

Abstract

The most important challenges faced by herbal formulations arise because of their lack of complete evaluation. Evaluation is necessary to ensure quality and purity of the herbal product. For evaluation of capsule containing single herb various parameters were tested. These parameters for raw material include powder characteristic study, Organoleptic, Physicochemical, Physical, Phytochemical parameters etc., and assay of active constituent. Parameters for finished product (capsule) include uniformity of weight, pH, moisture content, disintegration time and dissolution study. 'Arthrum plus capsule' consists of four ingredients viz., Oleogum resin of aqueous extract of *Boswellia serrata* Roxb, Leaves of aqueous extract of *Pluchea lanceolata* C.B. Clarke, *L*eaves of aqueous extract of *Vitex negundo* Linn and Yograj Guggula powder. It is used in Rheumatoid arthritis, Osteoarthrosis, Gouty arthritis and Spondylitis. Results point out that Raw material of 'Arthrum plus capsule'has passed through all Organoleptic, Physicochemical, Physical, and Phytochemical parameters. All three batches of 'Arthrum plus capsule' were uniform in colour, size, weight, dissolution and disintegration time, moisture content, angle of repose, bulk and tap density etc.

GUJ/COGNOSY/16

Studies on Solubility of Curcumin

M. K. Modasiya¹ and V. M. Patel.

APMC College of Pharmaceutical Education and Research, Gujarat Himatnagar-383001.

Abstract

Curcumin is coming from the *Curcuma longa* which gives golden color and have the biological importance. As per the survey it is water insoluble, the poor solubility and wettability of curcumin leads to poor dissolution and hence shows poor bioavailability. The present study is aimed at increasing solubility of drug using solid dispersion technique. The solid binary systems were prepared using different drug: polymer ratio (1:1, 1:4 and 1:8) with polyethylene glycol 4000 and 6000 by different techniques like physical mixing, melting method and solvent evaporation method. PVP K 30 was also used as a polymer. The formulations were characterized by scanning electron microscopy, thin layer chromatograpy, compatibility study, diffraction study and *in vitro* dissolution rate studies. The solubility of drug increased linearly with the increase in polymer concentration. The solid dispersion of drug prepared by hot melt method demonstrated higher drug dissolution rates in comparison to solid dispersion prepared by physical mixtures, solvent evaporation method and pure curcumin.

Abstract of the Poster Presentation Gujcost/Cology/01 - Gujcost/ Cology /10

GUJ/COLOGY/01

Anti-diabetic and antioxidant activity of Cynodon Dactylon Linn. in rats

Amit¹ Bhargava, A.C. Rana

Rayat Institute of Pharmacy, Railmajra (Punjab)

Abstract

Objectives: The present work is carried out to study the effect of *Cynodon dactylon* Linn. (Poaceae) on blood glucose levels and antioxidant enzymes levels in alloxan induced diabetic rats. *Cynodon dactylon* Linn. (commonly known as Bermuda grass) is used traditionally in the treatment of inflammation. In order to evaluate this information anti-diabetic and antioxidant activity of whole plant of *Cynodon dactylon* Linn. was investigated.Material and methods: Whole plant of *Cynodon dactylon* Linn. was collected and cleaned of extraneous matter and shade dried. This plant matter was macerated for three days in 70%v/v ethanol and dried on water bath. Total yield of the extract was 14.8%. Thirty six white albino rats of either sex weighing between 175-225 g were used for this study. Diabetes was induced by alloxan (70 mg/kg, i.p) alloxan induced diabetic rats were treated with *Cynodon dactylon Linn*. ethanolic extract in two doses 250mg/kg/p.o. and 500mg/kg/p.o. for 20 days. Glucose level was measured in blood and antioxidant enzymes levels viz. super oxide dismutase (SOD) and catalase (CAT) were measured.

GUJ/COLOGY/02

Pathological Changes Involved With Insulin Resistance in Altered Thyroid State

Dipal S. Patel, Kunal B. Kapadia, Dr. I S Anand Shri Sarvajanik Pharmacy College, Mehsana, Gujarat, India

Abstracts

The prevalence of thyroid disease in patients with diabetes is significantly higher than that in the general population. This indicates a possible interplay between thyroid status and insulin sensitivity. Complex interplay between thyroid function and insulin resistance has been implicated in diabetic dyslipidemia. My study objective is to assess the correlation between altered thyroid state and insulin resistance by Preclinical study. To investigate this, in preclinical study induction of hypo and hyperthyroid state was done for one month and after 6 weeks blood glucose levels, insulin levels, thyroid (TSH) levels, total cholesterol, LDL and HDL level, and oral glucose tolerance test (OGTT), insulin tolerance test (ITT) and HOMA-IR was estimated for the development of insulin resistance in mice. There was significant increase in the HOMA-IR in hyperthyroid and hypothyroid group as compared to control group suggesting development of insulin resistance. Also the insulin levels were significantly higher in hyperthyroid as compared to control. Thyroid disorder, including both hypo- and hyper have been associated with insulin resistance due to various mechanism like altered insulin secretion and lipid levels. Thus even subtle increase or decrease in the thyroid levels can lead to insulin resistance leading to glucose related disorder like diabetes.

GUJ/COLOGY/03

Novel Therapeutic Targets for the Treatment of Tubulointerstitial Fibrosis

Pankaj A Leuva,* Hetal H Chaudhari, I. S. Anand, Department of Clinical Pharmacy Shri Sarvajanik Pharmacy College, Mehsana, Gujarat, India

Abstract

Approximately 80% of the kidney is composed of tubular cells which secret and reabsorb substances to and from the urine. Activated tubular cells play a pivotal role in the etiology of renal fibrosis.

During renal injury, these activated tubular cells participate in the initiation of fibrogenic processes which eventually may lead to tubulointerstitial fibrosis and end stage renal disease (ESRD). Current therapies such as angiotensin converting enzyme inhibitors, angiotensin II receptor type-1 antagonists and statins do not suffice for the treatment of renal fibrosis. However, in recent years, better understanding of disease mechanisms led to the development of new drug entities that intervene in the signal transduction pathways involved in the disease pathogenesis. This review discusses possible new drugs directed to intracellular signal transduction pathways such as mitogen–activated protein kinases (p38, ERK and JNK), growth factors receptor tyrosine kinases (TGF- β and PDGF), Rho kinase, and nuclear transcription factors that are activated during disease. In addition to kinase inhibitors, novel approaches such as renal selective drug targeting, recombinant protein antifibrotic agents and gene silencing concepts are discussed.

GUJ/COLOGY/04

Hepatoprotective Activity of Curcuma longa

Ankita Sharma*, Amit Bhargava, Anju Goyal, Kanchan Chodhary B. N. Girls College of Pharmacy, Udaipur (Raj.)313001

Abstract

The liver plays an astonishing array of vital functions in the maintenance and performance of the body. Some of these major functions include carbohydrate, protein, and fat metabolism, detoxification, and secretion of bile. Therefore, the maintenance of a healthy liver is vital to overall health and well being. Unfortunately, the liver is often abused by environmental toxins, poor eating habits, alcohol, and prescription and over-the-counter drug use, which can damage and weaken the liver and eventually *lead to* hepatitis, cirrhosis, and alcoholic liver disease. Conventional medicine is now pursuing the use of natural products such as herbs to provide the support that the liver needs on a daily basis. There has been an increased interest globally to identify hepatoprotective compounds that are pharmacological potent and have less side effect due to hepatotoxic effect of most of medicines, as medicinal plant produce significant amount of hepatoprotective to prevent hepatotoxicity by free radical scavenging and reduce oxidative stress caused by photones and oxygen. Traditional herbal medicines and Ayurveda is the oldest medicine system in the world so considering the growing interest in review of medicinal plants on hepatotoxicity, in this review discussion involves hepatoprotective activity of Curcuma longa, synonym is turmeric zardchob. The biological source consists of dried rhizomes of *Curcuma longa/domestica* belonging to familyzingiberaceae/scitaminaceae. The chemical constituents are curcuminoids-2-6%, curcumin-50-60%, essential oil 3-7%, Sesquiterpine and polysaccharide A B C and vitamin D. Many Ayurvedic herbs, such as andrographis have a long history of traditional use in revitalizing the liver and treating liver dysfunction and disease. Many of these herbs have been evaluated in clinical studies and are currently being investigated phytochemically to better understand their actions. Literature showed that 50% ethanol extract of plant produced hepatoprotective action by antioxidant and free radicals scavenging effect due to cucurminoides.

GUJ/COLOGY/05

Hydrogen Sulphide A Potential Gasotransmitter

Heena Agarwal, Vishnu Kanta, Anju Goyal B. N. Girls College of Pharmacy, Udaipur 313001, India

Abstract

Gasotransmitters are termed as small gaseous molecules such as CO, NO and H_2S which are freely permeable across membrane and do not act via specific membrane receptors but have specific cellular or molecular targets with specific physiological importance. Hydrogen Sulphide is a new emerging gaseous signalling molecule and a third novel gasotransmitter alongside nitric oxide and

carbon monoxide. They have well-defined specific biological responses at physiologically relevant concentrations. Thus, manipulating the endogenous levels of these gases evokes specific physiological changes.H₂S is normally present in humans and can be generated endogenously from 1-Cysteine in a reaction catalyzed by either cystathionine beta-synthetase (CBS) or cystathionine gamma-lyase (CSE). Functioning of H₂S as a neuromodulator is mediated by NMDA receptors (NMDAR) by inducing the production of cyclic-adenosine monophosphate, and act as an inhibitor of peroxynitrite.H₂S plays a major role in physiological and pathological processes such as blood pressure regulation, neurotransmission release, inflammatory processes, etc. and because of their gaseous nature, NO, CO and H₂S are not stored within the cell in the classic presynaptic vesicles before they are released. They are synthesized and released on demand, which distinguishes these gasotransmitters from classic neurotransmitters such as acetylcholine, norepinephrine, and even the peptide neurotransmitters. Due to the wide ranging effects of H_2S , discovery of suitable modulators of its levels in future may open new avenues of treatment options in a variety of diseases like hypertension, Alzheimer's disease, Down's syndrome, inflammatory conditions like inflammatory bowel disease, septic shock and acute pancreatitis, various neoplasms and erectile dysfunction.

GUJ/COLOGY/06

Optogenetics – Combination switch turns neurons on and off

Noopur Sharma, Alok Bhargava¹, Amit Bhargava, Anju Goyal B. N. Girls College of Pharmacy, Udaipur (Raj.)

Abstract

Optogenetics is a new field of research that aims to control cells using light. To this end, scientists avail of light-sensitive proteins that occur naturally in the cell walls of certain algae and bacteria. They introduce genes with the building instructions for these membrane proteins into the DNA of target cells. Depending on which proteins they use, they can fit cells with on and off switches that react to light of different wavelengths. For accurate control, it is important that the cell function can be switched off and on equally well. This was exactly the problem until now: when the genes are introduced separately, the cell produces different numbers of copies of each protein and one type ends up dominating. For the on and off proteins on the same portion of DNA genes have been located, along with an additional gene containing the assembly instructions for a connection piece. This interposed protein links the two switch proteins and anchors them firmly in the cell membrane. "In this way, one can ensure that the on and off switches are built into the cell wall side by side, and always in a ratio of 1:1. This allows to control the cell with great accuracy (Ernst Bamberg et al). The combination light switch conceived by the researchers consists of the membrane proteins channelrhodopsin-2 and halorhodopsin. Channelrhodopsin-2 originally comes from the single-celled green alga Chlamydomonas reinhardtii. It reacts to blue light by making the cell wall permeable to positively charged ions. The resulting influx of ions triggers a nerve impulse that activates the cell. Halorhodopsin, isolated by scientists from the bacterium Natromonas pharaonis, has the opposite effect: when the cell is illuminated with orange light, it allows negatively charged ions in, suppressing nerve impulses. Since channelrhodopsin-2 and halorhodopsin react to light of different wavelengths, together they comprise a useful tool for switching cells on and off at will. The scientists have shown that the method they used to connect the two molecules is also suitable for use with other proteins. (Affirms Bamberg et al).

GUJ/COLOGY/07

Lobular Carcinoma: Prognosis and Diagnosis

Unnati Sharma, Ranjana Sharma, Meetal Nakrani, Anju Goyal B.N. Girls College of Pharmacy, Udaipur 313001

Abstract

As developing countries grow and adopt western culture they also accumulate more diseases that have arisen from western culture along with its habits (fat/alcohol intake, smoking, exposure to oral contraceptives, the changing patterns of childbearing and breastfeeding). However, because of lack of funding and resources, treatment is not always available to those suffering with breast cancer.

The incidence of breast cancer varies greatly around the world. In the twelve world regions, the annual age-standardized incidence rates per 100,000 women are as follows:

- Eastern Asia 18
- South Central Asia- 22
- Sub-Saharan Africa- 22
- South-Eastern Asia 26
- North Africa and Western Asia 28
- South and Central America- 42
- Eastern Europe 49
- Southern Europe 56
- Northern Europe 73
- Oceania 74
- Western Europe 78
- North America 90

Breast cancers are classified by several grading systems as follows:

Histopathology is usually classified primarily by its histological appearance. Most breast cancers are derived from the epithelium lining the ducts or lobules, and these cancers are classified as ductal or lobular carcinoma. Grading compares the appearance of the breast cancer cells to the appearance of normal breast tissue. By using the TNM system the size of the tumor (**T**), whether or not the tumor has spread to the lymph nodes (**N**) in the armpits, and whether the tumor has metastasized (**M**) (i.e. spread to a more distant part of the body). Breast cancer cells have receptors on their surface and in their cytoplasm and nucleus. Chemical messengers such as hormones bind to receptors, and this causes changes in the cell. DNA testing of various types including DNA microarrays has compared normal cells to breast cancer cells. Breast cancer is *usually* treated with surgery and then possibly with chemotherapy or radiation, or both. A multidisciplinary approach is preferable. Hormone positive cancers are treated with long term hormone blocking therapy. Treatments are given with increasing aggressiveness according to the prognosis and risk of recurrence.

GUJ/COLOGY/08

A Novel Protein FKBPL; Prognostic and Predictive biomarker for anticancer therapy

Parag Patel, Dr. I. S. Anand

Shri Sarvajanik Pharmacy College, Mahesana

Abstract

FKBPs (FK506-binding proteins) have long been recognized as key regulators of the response to immunosuppressant drugs and as co-chaperones of steroid receptor complexes. More recently, evidence has emerged suggesting that this diverse protein family may also represent cancer biomarkers owing to their roles in cancer progression and response to treatment. FKBPL (FKBP-like) is a novel FKBP with roles in GR (glucocorticoid receptor), AR (androgen receptor) and ER (oestrogen receptor) signalling. A relatively new and divergent member of this family, FK506-binding protein like (FKBPL), is emerging as a key player in the DNA damage response, steroid receptor signalling and more recently, control of tumour growth where it regulates response to endocrine therapy in addition to acting as a novel antiangiogenic protein. FKBPL binds Hsp90 (heat-shock protein 90) and modulates translocation, transcriptional activation and phosphorylation of these steroid receptors. It has been proposed as a novel prognostic and predictive biomarker, where high levels predict for increased recurrence-free survival in breast cancer patients and enhanced sensitivity to endocrine therapy. Since this protein family has roles in a plethora of

signalling pathways, its members represent novel prognostic markers and therapeutic targets for cancer diagnosis and treatment.

GUJ/COLOGY/09

Medication Error-A Lie Beneath The Truth

Dharmika Patel & Ankita Agrawal

Abstract

A medication error is any preventable event that may lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; According to the National Academy of Sciences, medical errors are : 1)Surgical Errors. 2)Bad Communication 3)Pharmacy Errors 4) Lab Errors.5)Treatment Errors6)Follow-Up -Care7)Don't Wait Until It's Too Late8)Birth Injuries 9)Use of Abbreviations CAUSES~ Errors in the prescribing, transcribing, dispensing, administering, and monitoring of medications;~Wrong drug, strength, dose errors; patient errors;~Wrong route of administration Calculation or preparation errors; ~Misuse of medical equipment .~Drug-Drug Interaction & Drug Food Interaction .~Staff shortage at pharmacy ,too many customers. The medication errors are reported to The National Medication Errors Reporting Program,(ISMP), confidential voluntary program that provides expert analysis of system-based causes of medication errors. Medication errors, preventable adverse drug reactions, close calls, or hazardous conditions mav be reported to the program. Role of pharmacist in prevention:1) Labeling should be performed by a Pharmacist or under his supervision -Labels should be typed -Only 1 prescription should be labeled and dispensed at a time 2) Medication should be placed in standardized compartments.

GUJ/COLOGY/10

Pterocarpus Marsupium: A Potential Perspective for Effective Management of Lifestyle Disorders

Shelat Devang, Shaival Shah, Vimal Kumar, Niyati Acharya, Sanjeev Acharya Institute of Pharmacy, Nirma University, Ahmedabad

Abstract

Pterocarpus marsupium Roxb. (Fabaceae) commonly known as vijaysar / bijasal / kino is the potential source of drugs, used traditionally as antifungal, antioxidant, analgesic, anti inflammatory, hepatoprotective, elephantiasis, erysipelas, erethorrhea and ophthalmology. Many chemical constituents have been identified and isolated such as pterostilbene for antioxidant activity, epicatechin for antidiabetic, marsupinol for antihyperlipidemic activity, liquirtigenin for antidiabetic activity and kino is used widely for diarrhea and dysentery. The concentration of uranium and thorium was quite high in the heartwood of *P. santalinus*. Phytochemicaly, many phenolics like β- sitosterol, lupenol and epicatechin; iso-flavanoids, terpenoids and aurone glycoside. In period of time progress has been made in the identification and development of novel anti-obesity agents. Major efforts continue to be directed towards the development of appetite suppressants. The etiology, metabolic characteristics and treatment of obese patients were reviewed and important recent advances in obesity research were summarized. Monographs summarizing the relationships between obesity and diabetes mellitus including the role of a) adipose cellularity, b) metabolic, neuroendocrine, and nutritional factors, and c) membrane insulin receptors and transport mechanisms have been identified. This will help to explain the information regarding the phytochemistry and pharmacological activity of the plant and lead to a new perspective.