

CONTENT

REVIEW ARTICLE

- **Chronotherapy: A New Branch of Therapy**
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ABSTRACT

Human being shows chronological behaviour with time clock. Chronotherapy is designed accordingly to the chronological behaviour of body. It delivers drug at specific time, at specific site and in specific amount to overcome the problem of conventional modified drug delivery system. It is advantageous to treat disease showing chronological behaviour, such as cardiovascular disease, asthma, rheumatoid arthritis and ulcers. These systems are also beneficial for the drugs having chronopharmacological behaviour where night time dosing is required and for the drugs having high first-pass effect and having specific site of absorption in GIT. Various methodologies are employed for developing chronotherapeutic system like time controlled, self regulating and externally modulated system. Chronotherapy based drug delivery system like OROS[®], CODAS[®], DIFFUSCAP[®], CEFORAM[®], PULSINCAP[®] are available in market. Due to such beneficial characteristics chronotherapy should be promising in the future.

KEYWORDS: Chronotherapy, PULSINCAP[®], OROS[®], single/multiple unit.

- **Pellets as Controlled Release Drug Delivery System: A Review**
Sapkal SR, Jaiswal SB, Chandewar AV, Gaikwad SB, and Pathan AM.....179

ABSTRACT

In the recent years, considerable attention has been focused in the development of controlled release drug delivery system. The pellets have since long been used as an important formulation tool. Pelletization is an agglomeration process that converts fine powders or granules of bulk drugs and excipients into small, free flowing, spherical or semispherical units referred to as pellets. Pellets range in size typically, between 500-1500 µm. When pellet containing the active ingredient are administered in vivo in the form of suspension capsule or disintegrating tablets, they offer significant therapeutic advantage over single unit dosage forms. An ideal controlled drug delivery system is the one which delivers the drug at a predetermined rate, locally, or systemically, for a specified period of time. Controlled release pellet formulation can be formulated by many techniques such as extrusion/spheronization, powder layering, solution/suspension layering etc.

Various applications of pellets in controlled drug delivery system formulation, recent developments, polymer and excipients used for formulation of controlled release drug delivery system are discussed in this review.

KEYWORDS:

RESEARCH ARTICLE

- **Optimization of Pellet Coating Techniques**

AP Dhojte, PB Suruse, JG Awari, AK Raut and VV Kale.....184

ABSTRACT

In the present study, pellets were prepared and optimization of pellets coating technique was done. Extrusion-spheronization technique was employed to prepare pellets by optimizing operational variables like spheronization time, spheronization speed and percent of granulating fluid to obtain smooth and spherical pellets. Pellets were coated employing spray coating and powder layered coating techniques in order to obtain sustained release. Hydroxy Propyl Methyl Cellulose (HPMC) K-15M was used as a coating polymer. Diclofenac sodium loaded pellets (20%) were prepared with 76% MCC and PVP K-30 at spheronization speed of 120 RPM for 20 min using 76% granulating fluid. Spray coating was done employing HPMC K-15M solution (1%) in (70: 30) water: ethanol mixture. Powder layering was done using 5% PVP K-30 in (50: 50) ethanol: water mixture as binder solution and powdered HPMC K-15M. Both the processes were continued till 5% coating level was achieved. Powder layered and spray coated pellets were evaluated for physical characteristics like drug content and *in-vitro* drug release. Physical characteristics like angle of repose, bulk density, tapped density, friability, moisture content and percentage drug content were found to be within standard limits. *In-vitro* drug release was found to be 0.5 to 1% in pH 1.2 buffer from both the pellets. In pH 6.8 buffer powder layered pellets showed 25% drug release, while spray coated pellets showed 45% drug release after 7 h. From the above study, it was concluded that powder layered pellets sustain drug release more than spray coated pellets.

KEYWORDS: Pellets, Diclofenac sodium, Spray coating, Powdered layer coating, Extrusion-spheronization technique.

- **Efficacy of Novel Acid Buffering Vaginal Tablet of Metronidazole for Bacterial Vaginosis**

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ABSTRACT

To develop more effective treatment for bacterial vaginosis, metronidazole was formulated in acid buffering bioadhesive tablet formulations that increase the time of contact of drug with the vaginal mucosa. Oral metronidazole is still the drug of choice in the treatment of bacterial vaginosis. Yet, side effects have been reported, and dosage as well as duration of therapy is still controversial. This study presents a possible alternative treatment using a single dose of metronidazole administered in a vaginal bioadhesive table. Double blind, randomized, clinical trials with 24 patients was carried out. The cure rate in acid buffering bioadhesive metronidazole vaginal tablet group was higher (86.66%) than metronidazole vaginal tablet (60%). No side effects were reported. Treatment of bacterial vaginosis with a single application of metronidazole in a bioadhesive vaginal tablet was found to be a valid alternative. These results indicate that a new bioadhesive vaginal tablet formulations might be further developed for safe convenient and effective treatment of bacterial vaginosis.

KEYWORDS: Metronidazole, bioadhesion, inclusion-exclusion criteria, randomized clinical trial, vaginal retention

- **Hydrophilic Matrices Geometry, Swelling and Erosion Investigations to Clarify the Release Mechanism**

Rajendra Kotadiya, Vishnu Patel and Harsha Patel.....191

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Aim of present work is to study the effect of viscosity and geometry of tablets on swelling, erosion and drug release behavior of matrix tablets of theophylline, a model drug, using natural gums viz. Chitosan [F5], Xanthan [F3], Locust bean gum [F4] and Guar gum [F2] and hydroxypropyl methylcellulose [F1]. Matrix tablets were produced by wet granulation method. The physical characteristics of tablets including geometry of tablets, the swelling and erosion behavior of tablets were studied and the results were correlates with the in vitro drug release. Drug release was proportional to surface area/volume ratio and it was similar for similar surface area/volume ratio. The formulation F5 containing chitosan starts erosion immediately when contacted with dissolution medium and eroded within 5 minutes. Based on the degree of swelling, the formulations arranged as F4>F2>F3>F1 and as per the erosion study the formulations were arrange as F1>F3>F2>F4. These may attributes to polymer viscosities because the formulation F2 (240cp) and F4 (250cp) which showed higher degree of swelling and lower rates of erosion compare to formulation F3 (150cp) and F1 (107cp). Thus, the effect of viscosity and geometry on swelling and erosion behavior of matrix tablets was profound and thus they are significant parameters to study out for the formulation of matrix tablets.

KEYWORDS: Natural gum • swelling • erosion • geometry of tablet

• **Evaluation of a New Tablet Binder - *Chlorophytum tuberosum***

Prithviraj Chakraborty, Kumar Suresh, Veera Garg and Anu Goyal.....196

ABSTRACT

A preliminary study was carried out for establishing powdered tubers *Chlorophytum tuberosum* (Roxb.) Baker (Liliaceae) as a tablet binder. The tablets were prepared by wet granulation method using Paracetamol as a drug, Bentonite as a diluent and 3.5% talc as a glidant. A concentration of 0.25% w/w, 0.5% w/w, 0.75% w/w and 1% w/w of the binder were introduced in different formulations. Various physicochemical parameters like thickness, friability, weight variation, hardness, disintegration time, etc. on the tablets prepared with different concentrations of *Chlorophytum tuberosum* were determined. Dissolution study was carried out for different tablets and comparison was done with the prepared tablets using 5% starch paste as standard binder. The tubers of *Chlorophytum tuberosum* (Roxb.) Baker (Liliaceae) showed the presence of carbohydrate in it which helped it to act as a binding agent. Amongst the various formulations, the tablets prepared with 0.5% of the above binder showed excellent physicochemical parameters and better drug release pattern. No significant interaction with binder was found in FTIR study. The aim of this study was to suggest that, the tubers of *Chlorophytum tuberosum* can be used as a tablet binder in a very less concentration and can give an economic means for tablet formulation in Pharmaceutical Industries.

KEYWORDS: *Chlorophytum tuberosum*, musli, binder, Paracetamol

• **Studies on Occlusion Complexes of Aceclofenac with β -Cyclodextrin and Hydroxypropyl- β -Cyclodextrin**

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KEYWORDS: Aceclofenac, β -cyclodextrin, Hydroxypropyl- β -cyclodextrin, Inclusion complex, DSC, FTIR, solubility, Dissolution Enhancement.

- **Optimization of Coating Solution for Preparation of Sustained Release Tablet**
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KEYWORDS: Punch, Coating, Diffusion, Sustained

- **In-Vitro Release Kinetic Study of Mosapride Citrate Dihydrate from Sustained Release Matrix Tablet Containing Two Different Viscosity Grades of HPMC**
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KEYWORDS: Sustained release matrix tablet, HPMC, Mosapride.

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Rifampicin (RMP) and Isoniazid (INH) are highly unstable in liquid dosage form and there is no liquid product available. A novel concept of formulating a suspension of RMP and INH for pediatric and geriatric application has been tried. The reconstitutable dry syrup which can be reconstituted by using a special vehicle has shown very good stability at 2-8⁰C and at 25⁰C for more than 1 month and 14 days respectively using a stability indicating HPLC method. The in vitro dissolution studies have revealed no adverse impact of special vehicle on dissolution. Thus this combination product could prove to be a major boost for the market need for pediatric patients.

KEYWORDS: Rifampicin, Isoniazid, suspension, stability

- **Development and Evaluation of Topical Microemulsion Gels for Protein and Peptide Drug Bacitracin Zinc**

ABSTRACT

The present study deals with the preparation of topical microemulsion gels of bacitracin zinc an antibacterial agent, with an aim to increase its penetration capacity and there by its efficiency. Microemulsions with varying weight ratios of surfactant to cosurfactant were prepared using oleic acid as oil, tween 80 as surfactant, ethylene glycol/propylene glycol as cosurfactants and saline. The area of the microemulsion region increased with increasing ratios of surfactant/cosurfactant. The mean diameter of the microemulsions was carried out using coulter counter. The size of the systems formed were 87 ± 2 and 61 ± 4 nm. For the final study four formulations were chosen out of which two are microemulsions gels and the rest were microemulsion-based gels. The rheological behaviour of prepared systems revealed that gels were pseudoplastic due to the intermolecular interactions between polymeric chains. The *in vitro* drug release was carried out in pH 7.0 phosphate buffer on excised human cadaver skin using Keshary-Chien diffusion cell for 24 hours and was compared with a marketed formulation. The results showed that release of drug from F4 was found to be 89.33% as compared to 58.05% from marketed and microemulsion based gels.

KEYWORDS: Bacitracin zinc, Microemulsions, Oleic acid, Tween 80.

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The objective of present study was to develop gelatin microsphere containing Benzophenone-3 (Benz-3) for topical delivery, evaluating the effect of stirring speed, Effect of polymer concentration and effect of cross linker (sugars) on particle size, surface morphology, microencapsulation efficiency and *in vitro* drug release. Gelatin microspheres were prepared using emulsion cum thermal gelation technique by dropping Benz-3 and cross linker containing solution of gelatin, into preheated Soya oil. The USP paddle method was selected to carry out the dissolution studies carried out in methanol at pH=5.5 (pH was adjusted by using 0.2M NaOH). It was found that the microspheres with fructose and sucrose have smooth surface having particle size $29.6\mu\text{m}$ and $80.63\mu\text{m}$, respectively. But untreated and glucose treated microspheres have wavy surface with particle size 50.32 and $45.02\mu\text{m}$. It was observed that untreated microspheres and microspheres crosslinked with cross linked sucrose showed faster release of drug although microspheres cross linked with fructose and glucose showed delayed release of drug. *In vitro* drug release data showed that the formulation cross linked with fructose was best for sustained release of Benz-3 due to 95% release of drug after 12 hrs with t_{50} and t_{70} of 400min and 560min, respectively. The release of Benz-3 was influenced by the different cross linkers. Drug release kinetic from the fructose cross linked microspheres corresponded best to the first order kinetics.

KEYWORDS: Bez-3, Emulsion cum thermal gelation technique, gelatin, microspheres.

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KEYWORDS: Topical gels, Ketoprofen

- **Optimization of Formulation and Process Parameters and Product Evaluation of Galactomannan-Borate Complex Based Cream**

ABSTRACT

Optimization of formulation and process parameters and product evaluation of galactomannan and galactomannan-borate complex based liquid paraffin cream were performed in the present study. The concentrations of galactomannan and borax were optimized. Process parameters of galactomannan and galactomannan-borate complex based liquid paraffin cream were optimized. The product evaluation of galactomannan and galactomannan-borate complex based liquid paraffin cream was performed. The galactomannan and galactomannan-borate based complex was compared with vanishing cream.

KEYWORDS: Galactomannan, emulsifying agent, borax.

• **Effect of Superdisintegrants on Olanzapine Oro-Dispersible Tablets**

Satish K Mandlik, Mehul M Joshi, Dinesh S Nandare, Pramod S Jagtap and Kishor S Jain.....233

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This study investigated to compare the disintegration efficiency for the 5 classes of superdisintegrants represented by Cros-carmellose Sodium (CCS), Cros-povidone (CP), Polacrillin K (PK), Sodium Starch Glycolate (SSG), and L-Hydroxy Propyl Cellulose (L-HPC). Tablets were prepared by direct compression method. Effect of 5 superdisintegrants on disintegration time, dissolution parameters, and friability has been studied. Among all the superdisintegrants, a PK containing tablets has shown faster disintegration followed by SSG. Tablets containing L-HPC disintegrated after PK and SSG containing tablets.

Where as disintegration time and dissolution parameters increased with increase in the level of Cros-carmellose in tablets. However the disintegration time value did not reflect in dissolution parameter values of cros-povidone tablets and release was dependent on aggregate size in dissolution medium.

KEYWORDS: Orodispersible Tablets, Olanzapine, Superdisintegrants.

• **Formulation and Evaluation of Sustained Release Matrix Tablets of Propranolol Hydrochloride Using Hydroxyethyl Guar as Rate Sustaining Polymer**

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A swelling index study was also carried out. The selected tablets were kept for accelerated stability study. The study indicated that the guar derivative, HEG, could be utilized for formulation of sustained release tablets of Propranolol hydrochloride. All the selected formulations were found to be physically and chemically stable at different storage conditions at the end of the eight week.

KEYWORDS: Hydroxyethyl guar, propranolol hydrochloride, sustained release tablets.

• **Formulation and In Vitro Evaluation of Periodontal Films Containing Metronidazole**

Biswajit Basu, Kevin Garala, Manojkumar Tyagi, G.L. Prabhushankar, P. R. Sathesh Babu.....240

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Local delivery devices are designed to deliver the drug locally into periodontal pocket. Metronidazole is a nitroimidazole used to treat protozoal infections. For local delivery, metronidazole films were prepared by solvent casting technique using ethyl cellulose, hydroxy propyl methylcellulose and

eudragit RL-100 with dibutylphthalate and polyethylene glycol 400 as plasticizers. FTIR and UV spectroscopic methods revealed no interaction between metronidazole and polymers. The films were evaluated for their thickness uniformity, folding endurance, weight uniformity, content uniformity, tensile strength, and surface pH. Data of *in-vitro* release from films were fit to different equations and kinetic models to explain release kinetics. Hixon-Crowell, Higuchi, and Korsmeyer-Peppas models were used to fit the *in-vitro* release data. Formulation F₆ released 94.18% of drug at the end of 120 h, was considered as best formulation. Short-term stability study revealed that drug content decreased in various films was ranging from 1.361 to 2.209%.

KEYWORDS: Metronidazole; periodontal pocket; periodontal films; local delivery; *in-vitro* release.

- **Formulation and Evaluation of Floating Sustained Drug Delivery for Metformin HCl Using Combination of Natural and Synthetic Polymers**

Dhavale Sushant, Jagtap Rajesh, Kotkar Tushar, Bhosale AV and Hardikar SR.....244

ABSTRACT

Metformin hydrochloride is an oral anti-hyperglycemic drug that has long been used in the management of non-insulin-dependent diabetes mellitus. Absorption of metformin hydrochloride is confined to the small intestine. Furthermore, conventional sustained-release dosage forms may be poorly bioavailable since absorption appears to cease or diminish when the dosage forms pass into the large intestine. A conventional oral SR formulation releases most of the drug content at the colon, which requires that drug will be absorbed from the colon while metformin has poor colonic absorption. In the case of insufficient colonic absorption, clinical advantage may be accomplished by a SR-gastroretentive dosage form that is retained in the stomach and produces a constant input of the drug to the sites of absorption at the upper part of the gastrointestinal (GI) tract. In this study attempt was made to formulate floating sustained drug delivery system for Metformin HCl using combination of natural and synthetic polymer as Psyllium Husk and HPMC respectively. Sodium bicarbonate was added as a gas generating agent. FTIR and DSC study for Drug – Excipient compatibility studies showed no interaction between Metformin HCl and polymers used. The granules prepared by wet granulation technique for sustained release layer of drug and polymers was evaluated for Angle of repose, Bulk Density, Tapped Density, Carr's index and Hausner ratio which concluded that these were considerably good to formulate the tablets also the formulated batches showed good *in-vitro* floating ability throughout the study.

KEYWORDS: Metformin hydrochloride, Floating Drug Delivery, Psyllium Husk, Hydroxypropyl methyl cellulose.

- **Physicochemical Characterization of Solid Dispersion of Telmisartan with Alkaliser by Hot Melt Method**

Patil MD, Keny RV, Pimprikar RB, Yashwante SB, Saindane DS, Mandlik SK, Mujawar Tabrej, Kale MK and Firke BM.....250

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KEYWORDS: Telmisartan (TEL), Solid dispersion (SD), Alkalizer, Hot Melt Method

- **Design, Development and in-vitro evaluation of Herbal Matrix tablet**

NM Bhopale, HS Sawarkar, MB Narkhede, NV Thorat, MR Bhise and SS Khadabadi.....254

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KEYWORDS: Ethanolic extract of *Tinospora cordifolia*, HPMC, Ethyl cellulose, Matrix tablet.

- **Oral Sustained Delivery of Rosiglitazone Maleate Floating Matrix Tablets- Formulation and In Vitro Evaluation**

Rahul K Godge, Syed N Lateef, Mahendra A Giri, Pravin D Chaudhari, Abhijeet N Merekar and Prakash N Kendre.....257

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KEYWORDS: Rosiglitazone maleate, Carbapol, HPMC, Floating matrix tablets, swelling index, buoyancy.

- **Minitablet: A Novel Approach For Oral Extended Release**

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KEYWORDS: matrix tablets, chitosan, minitables, Diltiazem hydrochloride.

- **Effect of Different Polyoxyethylene Matrices on Extended Release Formulation of Cephalexin Trihydrate**

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KEYWORDS: Polyoxyethylene, Cephalexin trihydrate, hydrophilic matrix, release kinetics

- **Effect of Formulation Variables on Pharmacotechnical Properties of Carvedilol Self-Emulsifying Drug Delivery System**

Umesh D Shivhare, Pushpraj T Chopkar, Kishore P Bhusari, Vijay B Mathur and Vivek I Ramteke.....275

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In the present work, self-emulsifying drug delivery system was formulated using Oleic acid (oil) and Tween 80 (surfactant). Carvedilol is a poorly water soluble drug and its bioavailability is very low. A new self-emulsifying drug delivery system (SEDDS) has been developed to increase the solubility, dissolution rate, and ultimately oral bioavailability of carvedilol. The solubility of carvedilol was determined in various vehicles. Pseudo ternary phase diagrams were used to evaluate the self-emulsification existence area. The developed SEDDS were evaluated for phase separation, turbidity, particle size, *in vitro* dissolution study. The release rate of carvedilol was investigated. The release rate was accelerated by decreasing droplet size, and was significantly faster as the particle size decreased. The particle size of formulation consisting of oleic acid 10%, Tween 80 90% and carvedilol 12.5 mg was found to be 41.72 nm and released more than 90% of drug within 30 min. The reduced particle size improved the self-emulsification performance of SEDDS in 0.1N hydrochloric acid pH 1.2 and phosphate buffer solution pH 6.8. The developed SEDDS formulation can be used as an alternative to traditional oral formulations of carvedilol to improve its bioavailability.

KEYWORDS: Self-emulsifying, Carvedilol, Ternary phase diagram, Particle size, Dissolution.

- **Formulation, In Vitro Release and Iontophoresis Study of Fluconazole Hydrogel**

Ashok A Hajare, Mahesh N Mali, Arun S Dange, Sushil M Sarvagod, Shweta V Patwardhan and Sachin T Kurane.....280

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Transdermal delivery of an antifungal drug Fluconazole in the form of hydrogels was formulated using polymers Carbopol 934 and Carbopol 940. The hydrogels were evaluated for various physicochemical parameters such as pH, viscosity, drug content, spreadibility and in-vivo skin irritation test. *In-vitro* drug release and permeation was studied using cellophane membrane and hairless rat skin, respectively using Franz Diffusion cell. The optimized formulations were studied for iontophoresis and for short term

stability. Formulations showed drug content, spreadability and pH in the range of 95.32-99.56%, 13.32-15.16 g.cm/s and 7.2 to 7.5, respectively. From the *in-vitro* drug release study of hydrogels it can be concluded that drug:carbopol 934:carbopol 940 in the ratio 1:0.5:0.5 gave maximum release suggesting its usefulness as hydrogel formulation. The optimized hydrogel formulation showed complete absence of irritation and found to be stable for 45 days.

KEYWORDS: Hydrogel, iontophoresis, fluconazole, skin irritation

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