S. N.	Title	Authors	Name of the Journal	Year of Publication	Volume and Page No.	IF
1	Formulation of mucoadhesive gastric retentive drug delivery using thiolated xyloglucan.	Mangesh R. Bhalekar, Rajesh V. Bargaje, Sanjay J. Kshirsagar.	Carbohydrate polymers	2016	136/537-542	9.381
2	Design and development of liposomes for colon targeted drug delivery	S. Kshirsagar	Journal of Drug Targeting	2013	21/15	5.121
3	Design and Development of pH sensitive budesonide-chitosan mucoadhesive beads for ileo-ceacal targeting	S. Kshirsagar	Asian journal of pharmaceutical science	2011	6/10	6.598
4	Gastroretentive drug delivery system of hydrochlorothiazide:formulation, optimization and in vivo evaluation	S. Kshirsagar	Asian journal of pharmaceutical science	2011	6/10	6.598
5	Development of enzyme-controlled colonic drug delivery using amylose and hydroxypropyl methyl cellulose: Optimization by factorial design	S. Kshirsagar	Drug Delivery	2011	18/385	6.419
6	In Vitro Drug Release and In Vivo Human X-Ray Studies of Ileo-Cecal Targeting Budesonide Fast Disintegrating Tablet	S. Kshirsagar	Drug Development Industrial Pharmacy	2008	35/788	3.225
7	Application of factorial design approach In development and evaluation of self-emulsifying drug delivery system (SMEDDS) of mebendazole.	D.R. Parakh, M.P. Patil, S.S. Sonawane, S.J.Kshirsagar	Journal of Pharmaceutical Investigation	2017	47/507-519	5.24
8	Development of self microemulsifying drug delivery system of mebendazole by spray drying technology: characterization, in-vitro and in-vivo evaluation	D. Parakh, M. Patil, N. Dashputre and S. Kshirsagar	Drying Technology	2016	34/1023-42	4.452
9	Formulation of nanoparticles loaded in situ gel for treatment of dry eye disease: In vitro, ex vivo and in vivo evidences.	S. Kshirsagar	Journal of Drug Delivery Science and Technology	2021	61/1-11	3.891
10	Formulation of PPAR-gamma agonist as surface modified PLGA nanoparticles for non-invasive treatment of diabetic retinopathy: in vitro and in vivo evidence.	S. Kshirsagar	CellPress-Heliyon	2020	6/1-10	2.85

Description of research work

Dr. Sanjay Kshirsagar started his journey in research from 2001 and published more than 160 research articles in National and International peer reviewed journals. His total citation is 744 with cumulative impact factor above 70 till date. His research profile further decorated with patents and awards.
Colon drug delivery systems, Ocular drug delivery systems and novel drug delivery systems are the most significant thrust areas of the Dr. Kshirsagar.

1. Colon Drug Delivery Systems:

Crohn's disease is a type of inflammatory bowel disease that frequently affects the ileo-cecal region of the gastrointestinal tract. For effective treatment of this disease, a site-targeting drug in the ileo-cecal region is essential. Conventional drug delivery systems are unable to deliver therapeutic amount of drug at targeted site and hence fails to produce required action. By considering the limitations of available treatment, Dr. Kshirsagar has developed novel colon targeted drug delivery systems which was further supported with pre-clinical and clinical trials. This work has been published in International (SCI/SCOPUS/WEB of SCIENCE indexed) Journals viz. Pharmaceutical technology, Drug Delivery, Drug targeting, Drug development and industrial Pharmacy etc.

Title of Paper	Formulation of mucoadhesive gastric retentive drug delivery using thiolated xyloglucan.
Publication Details	Carbohydrate Polymer, 2016.
Citation	23
Summary of work	Tamarind seed xyloglucan is a polymer reported to possess mucoadhesive property. In the present work, role of cysteine derivative of tamarind seed polysaccharide (thiomer) to enhance the mucoadhesion and its influence on drug permeation has been studied. The xyloglucan was first chemically modified to carboxymethyl derivative which was further converted to thiomer by conjugation with cysteine in presence of a coupling agent, EDAC. The matrix tablets of simvastatin prepared using thiomer demonstrated drug release retardation, increased mucoadhesion force and increased ex vivo permeation, the same were proportional to the increase in the amount of thiomer. The in vivo residence of thiomer placebo was more than 7 h in rabbit. Pharmacokinetic evaluation in rabbits indicated higher AUC for the formulation with highest content of thiomer and level 'A' correlation could be established from the generated dissolution and bioavailability data.

Title of Paper	In Vitro Drug Release and In Vivo Human X-Ray Studies of Ileo-Cecal Targeting Budesonide Fast Disintegrating Tablet
Publication Details	Drug Delivery, 2011
Citation	7
Summary of work	This study is an attempt to develop the dosage form of a Budesonide (BD) to achieve targeted drug release in the ileo-cecal region. The BD tablets are coated with Eudragit FS 30 D, which is a polymer that specifically dissolves at and above pH 6.8. The in vitro drug release and in vivo tablet disintegration (using X-ray radiography) were carried out. The coating process was optimized successfully. The in vitro performance of the tablet with coating thickness showed that the tablet did not disintegrate till 4.5 hours, which represents the transit time to the ileo-cecal region. In vivo studies also established that the tablet lasted

	till 4.5 hours. The tablet containing 0.5% superdisintegrant and 10% coating thickness was able to deliver BD effectively to the ileo-cecal region, thus making it a promising drug delivery system for the treatment of Crohn's disease.

Title of Paper	Design and development of liposomes for colon targeted drug delivery.
Publication Details	Journal of Drug Targeting, 2013
Citation	53
Summary of work	Present research reveals the potential of liposomes in colon drug delivery systems. Liposomes were prepared using thin film hydration method. Statistical design was used for optimization. Colitis was induced using acetic acid. Inverted sac method was used as ex vivo model for IBD. Myeloperoxidase (MPO) activity and histopathology comparative study was carried out. Liposomes were formulated in enteric coated capsules to deliver the liposome specifically in initial segment of colon. Particle size and entrapment efficiency were between 200 and 300 nm and 40 and 60%, respectively. In vivo and ex vivo study indicates higher accumulation of liposomes in colonic region as compared to pure drug. Enteric coated capsules delivered the drug after 5 h lag time. Low particle size is attributed to low lipid content and stabilization due to surfactant. At higher cholesterol level, vesicles cannot reshuffle into smaller vesicles due to rigidization. Study shows higher accumulation of liposomes due to its lipoidal nature as compared to pure drug due to membrane transfer mechanism of drug thus MPO significantly lowers as compared to standard group ($p < 0.05$).

Title of Paper	Design and Development of pH sensitive budesonide-chitosan mucoadhesive beads for ileo-ceacal targeting.
Publication Details	Asian journal of pharmaceutical science, 2011
Citation	5
Summary of work	The present study is an attempt to design and develop Ileo-cecal targeted multiparticulate mucoadhesive drug delivery system that releases specifically and slowly in ileo-cecal region without being released in the upper gastro-intestinal tract (GIT) for extended period of time (12 h after lag time of 4–5 h). Budesonide (BD) is synthetic, non halogenated glucocorticoid. BD was microencapsulated into chitosan beads by ionotrophic crosslinking method using Sodium tripolyphosphate (TPP) as a cross-linking agent. The beads were filled in HPMC capsule and then enteric coated with Eudragit S100 polymer. The in vitro drug release by changing pH method and in vivo study using X-ray radiography was carried out to ascertain position of capsule in gastrointestinal tract after specific time interval.

Title of Paper	Gastroretentive drug delivery system of hydrochlorothiazide: formulation, optimization and in vivo evaluation
Publication Details	Asian journal of pharmaceutical science, 2011
Citation	10
Summary of work	This research was carried out to develop and optimize floating-bioadhesive gastroretentive drug delivery system (GRDDS) exhibiting a unique combination of floatation and bioadhesion to prolong residence in the stomach, using hydrochlorothiazide (HCTZ) as a model drug by the optimization technique. A 3^2 factorial design was employed for optimization with amount of HPMC K15M and amount of Carbopol 974P as independent variables. Two dependent variables evaluated were: percentage of HCTZ release at 8 h and time require to release 80% of drug (T80%). The main effect and interaction terms were quantitatively evaluated using a mathematical model. The gastro retentive ability of the tablets was studied by X-ray studies in healthy human volunteer. Regression analysis and numerical optimization was performed to identify the best formulation.

	Anomalous release transport was confirmed as the release mechanism from the optimized formulation, which releases the drug for 24 h in sustained manner. The predicted values agreed well with the experimental values and the results demonstrate the feasibility of the model in the development of GRDDS. The tablet was buoyant for up to 16 h in the human stomach. This system would be useful to improve the bioavailability of HCTZ, by retaining the dosage form in stomach for 24 h.

Title of Paper	Development of enzyme-controlled colonic drug delivery using amylose and hydroxypropyl methyl cellulose: Optimization by factorial design.
Publication Details	Drug Development Industrial Pharmacy, 2008
Citation	5
Summary of work	The aim of the study was to develop colon-targeted drug delivery systems for diclofenac sodium which release the drug specifically and instantly at target site using amylose as a carrier. Coating formulations were designed based on the full factorial design. The evaluated responses were lag time prior to drug release and T90. Compression-coated tablets of diclofenac sodium containing various proportions of amylose and HPMC were prepared. In vitro drug release studies were done by changing pH method with enzyme. In vivo studies were done to confirm the potential of formulation to release the drug at target site. The dissolution data revealed that the ratio of polymers is very important to achieve optimum formulation. Results showed that the tablet prepared according to the above formulation released drug instantly at pH 6.8 (simulating colonic pH). An in vivo study shows that optimized formulation disintegrated in the target region. The results of this study revealed that factorial design is a suitable tool for optimization of coating formulations to achieve colon delivery. It was shown that coating formulation consisting of amylose 285 mg and HPMC 150 mg coating has the potential for colonic delivery of diclofenac sodium irrespective of change in pH in a patient with IBD.

2. Self-micro-emulsifying drug delivery systems (SMEDDS):

Oral site is the most preferable route of drug administration as it is associated with better patient compliance. However; majority of recently developed drugs possesses poor solubility (BCS-Class-II or IV) which make administration of drug through oral site as challenging task. By considering these limitations Dr. Kshirsagar have developed Self micro-emulsifying drug delivery systems (SMEDDS) which facilitates the drug delivery of drug possesses dissolution as the rate limiting step. This work is published in journals like Journal of Pharmaceutical Investigation and Drying technology.

Title of Paper	Application of factorial design approach In development and evaluation of self-emulsifying drug delivery system (SMEDDS) of mebendazole.
Publication Details	Journal of Pharmaceutical Investigation, 2017.
Citation	7
Summary of work	This research involves preparation of SMEDDS of mebendazole. Labrafil M2125 CS (an oil), Tween 20 (a surfactant), and Maisine 35-1 (a cosurfactant) were used to formulate SMEDDS. Effect of concentrations of oil and surfactant on emulsification process and in vitro drug release (percent cumulative drug release) was studied using 32 factorial design. Multiple regression analysis data and response surfaces obtained showed that viscosity increased significantly with increasing amount of co-surfactant. Whereas, decrease in emulsification time, it may decreases average droplet size of resultant microemulsion and rapid drug release. The drug release from the formulation increased with increasing amount of surfactant

	concentration increases solubility of drug in system. Prepared SMEDDS produced acceptable properties of immediate-release dosage forms. The L5 formulation was found to be optimized on basis of high percent cumulative drug release. And it is evaluated by globule size and zeta potential indicates globule size is in micrometer range and good stable formulation.

Title of Paper	Development of self microemulsifying drug delivery system of mebendazole by spray drying technology: characterization, in-vitro and in-vivo evaluation.
Publication Details	Drying Technology, 2016.
Citation	7
Summary of work	In this study, a novel liquid self-microemulsifying drug delivery system (SMEDDS) containing mebendazole was formulated and further developed into a solid form by a spray drying method using Aerosil 200 as the solid carrier. The optimum liquid SMEDDS consisted of Labrafil 2125 CS, Tween 20, and Maisine 35-1 as the oil phase, the surfactant, and the cosurfactant, respectively. The formulated SMEDDS was completely emulsified or dispersed within a minute. All formulations were dissolved within 1 h using 0.1 N HCl as dissolution medium, whereas pure drug was less significantly dissolved in this time period. The droplet size was found to be within 250 nm for solid forms of SMEDDS. Solid state characterization was performed by scanning electron micrograph, differential scanning calorimetry, and X-ray powder diffraction. After oral administration to Wistar rats, mebendazole in the solid SMEDDS resulted in the significant improvement in bioavailability compared with that of pure drug analyzed by RP-HPLC. The optimized formulation showed 24.87 folds increase in bioavailability as compared to pure drug and 8.39 folds increase in bioavailability in comparison to marketed tablet of mebendazole. The optimized batch has found to be 3.1726 years of shelf life. In conclusion, the solid SMEDDS is a promising solid dosage form for poorly water-soluble and low bioavailability drugs.

3. Ocular drug delivery systems:

From last four years Dr. Kshirsagar is working on PPAR-gamma receptors for targeting various complications of eyes to overcome limitations conventional treatment. He has targeted major ocular complications like diabetic retinopathy, dry eye disease and glaucoma. This work is published in International Journals like Heliyon-CellPress Journal, Journal of Drug Delivery Science and Technology, Journal of Critical Reviews etc. He has also filed two patents and those are now under examination.

Title of Paper	Formulation of nanoparticles loaded in situ gel for treatment of dry eye disease: In vitro, ex vivo and in vivo evidences.
Publication Details	Journal of Drug Delivery Science and Technology, 2021
Citation	4
Summary of work	This research involves the development of nanoparticles of Peroxisome proliferator-activated receptor-γ agonist for dry eye disease. Nanoparticles of Pioglitazone were prepared by using Poly (D, L-lactide-co-glycolide) which were then suspended in temperature sensitive in situ gel prepared by combination of Poloxamer 407 and HPMC K4M those also contribute in treatment as lubricant. Nanoparticle system and in situ formulation was optimised by 32 factorial design. Optimized nanoparticle system was evaluated for particle size, PDI, % entrapment efficiency, XRD, DSC and then suspended in polymeric in situ gel. In situ gel was characterized by viscosity, %drug release, gelation temperature, gelling strength, sterility test, preservative efficacy

	test. Ocular irritation potential was confirmed by histology study on goat eye cornea. Formulation retained the normal structure of cornea and found non-irritant. Effectiveness of optimised formulation in comparison to existing marketed formulation was estimated by Schirmer's test on mice. Prepared formulation showed induced tear production and further stabilised tear film for long period in comparison to marketed formulation. It can be concluded that prepared formulation can be consider as alternative for existing treatment.

Title of Paper	Formulation of PPAR-gamma agonist as surface modified PLGA nanoparticles for non-invasive treatment of diabetic retinopathy: in vitro and in vivo evidence.
Publication Details	Heliyon-CellPress, 2020
Citation	01
Summary of work	In this study surface modified poly (D, L-lactide-co-glycolide) i.e. PLGA nanoparticles for delivery of pioglitazone-a peroxisome proliferator-activated receptor-gamma agonist were prepared to target posterior segment of the eye by topical administration. The present study investigated two grades of PLGA viz. 75:25 and 50:50. Surface modification was performed using polysorbate 80. Nanoparticles were prepared by single emulsion solvent evaporation method and optimized by using 3-factor 3-level Box-Behnken statistical design. Mean particle size, PDI and entrapment efficiency for optimized batch of PLGA 75:25 was found to be 163.23 nm, 0.286 and 91%, whereas; for PLGA 50:50 it was 171.7 nm, 0.280 and 93% respectively. DSC confirms the molecular dispersion of drug in polymer. In vitro release study showed biphasic drug release pattern with 58.48 ± 1.38% and 74.17 ± 1.38% cumulative drug release by PLGA 75:25 and 50:50 nanoparticles at the end of 10h. The release profile of pioglitazone from nanoparticles appeared to fit best with Higuchi model. In vivo study on rat showed dose dependent reduction in vascular endothelial growth factor concentration in vitreous fluid. The study reveals significance of peroxisome proliferator-activated receptor-gamma in management of diabetic retinopathy.