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1	Certificate of Head of Institution
2	List of **M.Pharm [Pharmaceutics]** Students under taking Project work/Field work / Internship-HOI
3	List of **M.Pharm [Pharmaceutics]** Students under taking Project work/Field work / Internship.

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1.	TAMILARASU.A. 261121507513	MR.R.SURESH	II	TIZANIDINE-LOADED NANOGEL:FABRICATION, CHARACTERIZATION,AND POTENTIAL BIOMEDICAL APPLICATION OOF A SYNTHETIC POLYMER-BASED DELIVERY SYSTEM	-	-
2.	DHIVAGAR.R. 261121507505	MRS.S.SANGEETHA	II	FORMULATION AND EVALUATION OF TENOXICAM EMULGEL FOR TOPICAL APPLICATION BY USING SYNTHETIC POLYMER	-	-
3.	DEEPTHI.K.C. 261121507504	MRS.S.KAVIBHARATHI	II	FORMULATION AND IN VITRO EVALUATION OF MUCOADHESIVE BUCCAL TEBLETS OF LOSARTANPOTASSIUM USING NATURAL POLYMER	-	-
4.	MOHAMED SHIHAB.K.E 261121507507	MRS.S.KAVI BHARATHI	II	FORMULATION AND EVALUATION OF ETODOLAC NANOSPONGES BY USING B-CYCLODEXTRIN AS A POLYMER FOR TOPICAL	-	-

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				DRUG DELIVERY		
5.	J.NAVANANDHINI 261121507509	MR.R.SURESH	II	SOLID DISPERSIOIN STRATEGIES FOR IMPROVED AMLODIPINE BESYLATE PERFORMANCE:PREPARATION AND ASSESSMENT	-	-
6.	PAVITHARA.B. 261121507510	DR.S.CHANDRA	II	FORMUATION AND EVALUATION OF SUSTAINED RELEAE MATRIX TANLETS CONTAING AMBROXOL HYDROCHLORIDE	-	-
7.	VENKATESH.S. 261121507514	MRS.S.SANGEETHA	II	FORMULATION AND EVALUATION OF BACLOFEN NANOGEL BY USING SYNTHETIC POLYMER	-	-
8.	JAFERI SANDOSH.A. 261121507506	MR.R.SURESH	II	MCC UTILIZATIOIN IN DEVELOPING LOSATRAN POTASSIUM AND HYDROCHLOROTHIAZIDE TABLES DESIGNS	-	-
9.	ASHIK.P.M. 261121507502	MRS.S.KAVIBHARATHI	II	FORMULATION AND DEVELOPING OF NANOSUSPENSION OF BROMHEXINE HYDROCHLORIDE	-	-
10.	AMRITHA.J. 261121507501	DR.S.CHANDRA	II	FORMULATIN AND EVALUATION OF LEVOFLOXACIN FLOATING TABLETS CONTAINING FOR SELECTED ANTIBIOTIC	-	-
11.	MOHAMMED	MRS.S.SANGEETHA	II	FORMULATION AND EVALUATION OF ORAL	-	-

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	YASEEN.M. 261121507508			MOUTH DISSOLVING FLIM OF PITAVASTATIN CALCIUM		
12.	SOUNDARA PANDIYAN.G. 261121507512	DR.S.CHANDRA	II	DESIGN AND EVALUATION OF SUSTAINED RELEAE TABLET OF HYDROPHILIC MATRIX SYSTEM DRUG USED ACECLOFENAC	-	-

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FORMULATION AND EVALUATION OF ORAL MOUTH DISSOLVING FILM OF PITAVASTATIN CALCIUM

Dissertation submitted to

THE TAMILNADU Dr.M.G.R. MEDICAL UNIVERSITY,

CHENNAI – 32

In partial fulfillment of the requirements for the award of the degree of

MASTER OF PHARMACY

IN

PHARMACEUTICS

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11. SUMMARY AND CONCLUSION

SUMMARY

Pitavastatin calcium is an Anti-hyperlipidaemic drug used for the treatment of high cholesterol level, prevention of cardiovascular disease and for cardiovascular risk reduction. But major disadvantage associated with Pitavastatin calcium is poor solubility and bioavailability. Hence enhancing the solubility of Pitavastatin calcium is inevitable to get an improved bioavailability.

Mouth Dissolving Film (MDF) have better patient acceptance and compliance, may offer improved bioavailability of poorly soluble drug like Pitavastatin Calcium and improves efficacy compared with conventional dosage form. As the MDF dissolves in saliva, it may pass through enterohepatic circulation and thus prevents first pass metabolism, as it is absorbed in mouth.

In the present work, analytical method was developed for Pitavastatin Calcium using UV-spectrophotometer at λ max 245 nm. It obeys the lamberts law between 2 to 10 µg/ml. FTIR study for API, placebo and blend was performed and the result confirms that the drug is compatible with other excipients.

The solubility of Anti-hyperlipidaemic drug Pitavastatin Calcium has been increased or enhanced by preparing 1:1 ratio of PEG inclusion complex and solid dispersion using water soluble carrier. Among the inclusion complex and solid dispersion, Pitavastatin Calcium with PEG inclusion complex showed increased solubility and rapid dissolution.

To select a suitable polymer and concentration, placebo films were prepared with HPMC (3cps&15cps) and PVA in three different concentrations (150 mg, 200 mg and 250 mg per petridish). Among the trials taken, 150 mg of HPMC 15cps showed least *in- vitro* dispersion time. Hence it was selected for further formulation of MDF with selected Drug-PEG inclusion complex.

The prepared MDF were evaluated for physicochemical characteristics like uniformity of weight, thickness, folding endurance, surface pH, drug content, disintegration time, *invitro* dispersion time, *invitro* dissolution time.

The Pitavastatin Calcium showed excellent weight uniformity and thickness. MDF showed neutral surface pH. The disintegration time of MDF's were below 9 sec which fulfils the FDAs disintegrating time of 30 sec for ODT.

Since marketed MDF is not available, *in-vitro* dissolution study in simulated salivary fluid and 0.1 N Hcl were compared with marketed IR tablet (Pivasta 4 mg). The result indicated that dissolution rate of MDF was superior than IR tablet.

CONCLUSION

The formulation of Mouth dissolving Film of Pitavastatin Calcium complies all the requirements of mouth dissolving Film as per USP standards. It was successfully formulated.

The molecular inclusion complex of Pitavastatin Calcium prepared in this study was found to have higher dissolution rates compared to commercially available immediate release tablets of Pitavastatin Calcium

Solubility enhancement, faster disintegration of Pitavastatin calcium MDF and pregastric absorption may enhance the bioavailability. On commercialization of this patient-friendly dosage form after required clinical studies, may result in a great patient compliance and a more effective treatment.

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DESIGN AND EVALUATION OF SUSTAINED RELEASE TABLET OF HYDROPHILIC MATRIX SYSTEM DRUG USED ACECLOFENAC

Dissertation submitted to

THE TAMILNADU Dr.M.G.R. MEDICAL UNIVERSITY, CHENNAI – 32

In partial fulfillment of the requirements for the award of the degree of

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IN
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8. CONCLUSION

The study was undertaken with the aim to Formulation and evaluation of Aceclofenac sustained release tablet using HPMC grade of polymer as retarding agent. Preformulation studies were done initially and result directed for further course of formulation. Based on the pre formulation studies different batches of Aceclofenac are prepared using selected excipients and the granules were evaluated for tests of Loss on drying,angle of repose,bulk density,tapped density,compressibility index,Hauser ratio,sieve analysis before being punched as tablets which were found within the limits. Tablets were tested for weight variation, hardness, thickness, friability and in vitro drug release as per pharmacopoeial procedure, which are within the limits.

Kinetic studies were observed as zero order and release mechanism of drug through polymeric membrane was found through diffusion and rate of diffusion is controlled by swelling of polymer.

Infrared spectra of the tablet revels, that there is no significant interaction between drug and polymer.

The dissolution studies formulations of F2, F5, F8 were good release and F6 formulation was excellent.

From the above results and discussion, it is concluded that the formulation of sustained release tablet of Aceclofenac containing HPMC K100 , mannitol and lactose which are taken as ideal or optimized formulation of sustained release tablet for 24 hours release as it fulfills all the requirement of sustained release tablet and study encourages further clinical trials and long term stability study on this formulation.

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SUMMARY AND CONCLUSION

Nanogel based materials have high drug loading capacity, biocompatibility and biodegradability which are key points to design the drug delivery system effectively. Drug molecules loaded into the nanogel need to be retained and not to be transported out or leak prematurely while circulating in order to provide maximum therapeutic effects and minimum toxicity or side effect.

Main objective of this study was to formulate Baclofen hydrochloride using polymer is an effective as vesicular system and can efficiently deliver the drugs through transdermal route to treat spasms, cramping and tightness of muscles.

The present work aimed at formulating Baclofen hydrochloride nanogel with hydrophobic polymer using emulsion solvent diffusion method. This method was simple and cost effective.

Pre-formulation studies were carried out to find out the solubility of Baclofen hydrochloride. Solubility test gave an idea that Baclofen hydrochloride is water soluble and soluble in solvents.

FTIR and UV spectral studies authenticate the spectra obtained with the sample drug matched with standard pure drug. UV spectra gave the maximum absorption peak at 228nm

Formulation was carried out by emulsion solvent diffusion method. Trial batches indicated that hydrophilic polymers are not suitable for the Baclofen hydrochloride nanogel. The hydrophobic polymers produced good formulation. Eudragit were selected for further studies.

MCC UTILIZATION IN DEVELOPING LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE TABLETS DESIGNS

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This is to certify that the dissertation work entitled **" MCC UTILIZATION IN DEVELOPING LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE TABLETS DESIGNS"** is the bonafide work carried out by.,**Mr. JAFERI SANDOSH A Reg. No: 261121507506**, under the guidance and supervision of **Mr.R. SURESH, M.Pharm.,** Associate Professor, Department of Pharmaceutics.

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CONCLUSION

Extra granular materials sifting:

Sifting:

Sieve Losartan potassium, lactose monohydrate, microcrystalline cellulose separately throughASTM mesh #30.

Dry mixing:

Sifted materials are loaded to rapid mixer granulator and dry mixing was carried out up to 15minutes with impeller at slow speed, 6 point unit dose samples collected in duplicate after 5,10, 15 minutes of mixing intervals and submitted for analysis in the first trail for optimisationOptimum time for dry mixing is determined to be 10 minutes based on the RSD values. From the second trail drymixing is done for 10 minutes.

Granulation:

The granulating fluid was added over a period of 4 to 5 minutes with impeller fast speed and chopper off. Kneading was done with impeller and chopper at slow speed for 30 seconds, followed by impeller and chopper at slow speed for 30 seconds for the first trail, by incresing the kneading time to 1 minute sticking problem is solved in the second batch.

Drying:

Drying was carried out at an inlet temperature of 60^0 C ± 5^0 C in fluidised bed dryer till theloss on drying of granules is 2.0-3.5 % w/w.

Sifting and milling:

Dried granules are sifted through #18 mesh and retentions milled through multi mill using 1.0mm screen at slow speed, knives forward direction. Milled granules were sifted through #18 mesh and retentions were milled through 1.5mm screen at medium speed, knives forwarddirection and sifted through #18 mesh.

FORMULATION AND DEVELOPMENT OF NANOSUSPENSION OF BROMHEXINE HYDROCHLORIDE

Dissertation submitted to

THE TAMILNADU Dr.M.G.R. MEDICAL UNIVERSITY,CHENNAI – 32

In partial fulfillment of the requirements for the award of the degreeof

MASTER OF PHARMACY

IN

PHARMACEUTICS

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8.CONCLUSION

From the present study, the following conclusions can be drawn:

1. Nanosuspension of Bromhexine Hydrochloride was good with the in-vitro diffusion study.
2. Infrared spectroscopic and Differential Scanning Calorimetric studies indicated that the drug is compatible with the polymers and excipients.
3. For proper solubility and in vitro release, the polymer and stabilizer must be used in the proper ratio.
4. Formulation F3 shows comparatively good in-vitro drug release profilr, drug
5. content, optimum particle size, good stability than the other formulations.
6. The prepared nanosuspension have a good solubility and drug releasing time thereby enhancing properties leading to its increased bioavailability.
7. Administration of the nanosuspension of Bromhexine Hydrochloride has been reported that its diffusion almost ceases because of the low solubility. The oral bioavailability of Bromhexine hydrochloride is 20%. Advantages of nanosuspension of Bromhexine Hydrochloride will surely enhance the patient compliance and improve bioavailability.

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FORMULATION AND EVALUATION OF SUSTAINED RELEASE MATRIX TABLETS CONTAINING *AMBROXOL HYDROCHLORIDE*

dissertation submitted to

THE TAMILNADU Dr.M.G.R.MEDICAL UNIVERSITY,

CHENNAI – 32.

In partial fulfillment of the requirements for the award of the degree of

MASTER OF PHARMACY

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SUMMARY AND CONCLUSION

- In this project work, an attempt has been made to design sustained release matrix tablets of Ambroxol Hydrochloride, by using hydrophilic polymers HPMC K100M and HPMC 5CPS employed for mucolytic activiy in various pulmonary disorders. The matrix tablets were prepared by wet granulation technique.
- Based on studies of the API organoleptic properties were complied with the BP specification. Physical properties such as bulk density and tapped density, angle of repose, carrs index, hausners ratio were within the in house tentative specification in case of granules ready for compression than that of Ambroxol raw powder. Sieve analysis and melting point determination were given the information about particle size distribution and purity of the drug powder respectively. Loss on drying was within the B.P limit.
- Solution properties i.e pH of the solution and solubility were evaluated, results were complied with the pharmacopoeial specification. Assay of Ambroxol Hydrochloride was carried out by HPLC method and was found to be 99.90%.
- The physical compatibility evaluation was performed in visual basic and FT-IR. The study implies that the drug, polymer and other excipients were physically compatible with each other as there was no change of physical description. Infra Red spectrum of Ambroxol HCl matches with the standard spectrum as well as there was not any additional peak formation with the excipients.

SOLID DISPERSION STRATEGIES FOR IMPROVED AMLODIPINE BESYLATE PERFORMANCE: PREPARATION AND ASSESSMENT

dissertation submitted to

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In partial fulfillment of the requirements for the award of the degree of

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6. SUMMARY AND CONCLUSION

SUMMARY

Solid dispersion of Amlodipine Besylate with PEG 6000 (F1, F2, F3)by solvent evaporation method, (F7, F8, F9) by physical mixture methodand Solid dispersion of Amlodipine Besylate with HPMC (F4, F5, F6) bysolvent evaporation method, (F10, F11, F12) by physical mixture methodwere prepared successfully.

In case of drug content determination, formulations F3 (AmlodipineBesylate PEG 6000 (1:3) Solid Dispersion by Solvent Evaporation Method)showed higher drug content of 99.84%. By increasing PEG 6000concentration the drug content concentration also increases. Whereas,formulations F6 and F12 showed decrease in drug content (93.05% and93.37%) by increasing HPMC concentration.

The FTIR spectrum of solid dispersion of Amlodipine Besylate withboth polymers, i.e PEG 6000 and HPMC showed peak similar to that ofpure Amlodipine Besylate. It revealed that there is no interaction betweendrug and polymer.

The *in-vitro* release profile of formulation F3 (Amlodipine BesylatePEG 6000 (1:3) Solid Dispersion by Solvent Evaporation Method) and F9(Amlodipine Besylate PEG 6000 (1:3) Solid Dispersion by Physical MixtureTechnique) showed higher drug release of 89.50% and 89.29%respectively at the end of 60 mins. When compared to that of formulationF6 (Amlodipine Besylate HPMC (1:3) Solid Dispersion by SolventEvaporation Method) and F12 (Amlodipine Besylate HPMC (1:3) SolidDispersion by Physical Mixture Method), and pure drug showed only62.39%, 68.20% and 60.11% respectively at the end of 60 mins.

The in-Vitro release data was fitted to various release kinetic modelsnamely, Zero order plot, first order plot, Higuchi plot and Korsmeyer –Peppas plot. The result revealed that Higuchi kinetics show good linearity.In addition, the korsmeyer-peppas model, the value of 'n' showed(Formulation F3) greater than 1 designates a supercase –II transportmechanism of durg release.

CONCLUSION

Amlodipine Besylate is an Antihypertensive; antianginal drug usedin treatment of Hypertension. The solubility and dissolution profile ofAmlodipine Besylate, a poorly water soluble drug, was significantlyimproved by preparing solid dispersion with water soluble carriers likePEG 6000 and HPMC by solvent evaporation technique and Physicalmixture method.

Among all the formulations the, Formulation Code F3 of AmlodipineBesylate Solid dispersion prepared by Solvent evaporation method usingPEG 6000 at 1:3 drug : carrier ratio has shown highest improvement in thedissolution profile of Amlodipine Besylate.

Hence it may be concluded that PEG may be used as the carrier ofchoice for the preparation of Solid Dispersions. The techniques exploredare relatively easy, simple, quick, inexpensive, and reproducible suggestingthat solid dispersion is a trustworthy alternative for solubilityenhancement of poorly water soluble drug.

FORMULATION AND IN VITRO EVALUATION OF MUCOADHESIVE BUCCAL TABLETS OF LOSARTANPOTASSIUM USING NATURAL POLYMER

Dissertation submitted to

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10. CONCLUSION AND SUMMARY

In conclusion, the aim of the present study was to develop mucoadhesive drug delivery system for Losartan potassium with a prolonged effect and to avoid first pass metabolism. These mucoadhesive formulations of Losartan potassium, in form of mucoadhesive buccal tablets were developed to a satisfactory level in terms of drug release, mucoadhesive time, physicochemical properties and surface pH.

Losartan potassium buccal tablet could be formulated using Drug and and natural polymers, Sodium alginate and xanthan gum in ratio 1:1. increase in results of % Drug release, mucoadhesive strength and *in vitro* residence time.

In case of natural polymers sodium alginate as a primary polymer and xanthan gum gives more drug release and mucoadhesive strength than guar gum at same concentration.

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FORMULATION AND EVALUATION OF ETODOLAC NANOSPONGES BY USING β-CYCLODEXTRIN AS A POLYMER FOR TOPICAL DRUG DELIVERY

Dissertation submitted to

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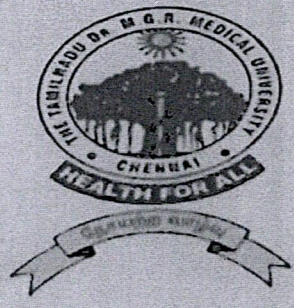

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CERTIFICATE

This is to certify that the dissertation work entitled **"FORMULATION AND EVALUATION OF ETODOLAC NANOSPONGES BY USING β-CYCLODEXTRIN AS A POLYMER FOR TOPICAL DRUG DELIVERY"** is the bonafide work carried out by, **Mr. MOHAMED SHIHAB K E . Reg. No : 261121507507** under the guidance and supervision of **Mrs.S.KAVIBHARATHI, M.Pharm., Assistant Professor,** Department of Pharmaceutics.

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7.SUMMARY AND CONCLUSION

Etodolac is an NSAID (Non-steroidal anti-inflammatory drug) used in the treatment of rheumatoid arthritis, osteoarthritis, and other inflammatory conditions. ETO belongs to the Class II of the Biopharmaceutical Classification System (BCS), that is; it shows poor bioavailability and low water solubility in this study, an attempt was made to develop ETOloaded Cyclodextrin nanosponges in order to enhance its oral bioavailability by improving solubility and permeability. Etodolac's anti- inflammatory effects, like those of other NSAIDs, are caused by suppression of the enzyme cyclooxygenase (COX). This inhibits the development of periphery prostaglandins, which are essential in the regulationof inflammation. Etodolac attaches to the upper portion of the active site of the COX enzyme, preventing arachidonic acid, the enzyme's substrate, from entering the active site.Etodolac, previously assumed to be a non-selective COX inhibitor, is now known for being5–50 times more selective for COX-2 than COX-1β Cyclodextrin based nanosponges were prepared and loaded with ETO using Diphenyl carbonate (DC) as a crosslinker. Five NS formulations loaded with the same amount of ETO, but varying cross-linker concentrations with β CD and were prepared using the melting method. Evaluations like entrapment efficiency, Saturation solubility studies, *in vitro* drug release studies, etc were conducted in order to select a favorable formulation.

In vitro release studies of pure ETO, ETO-loaded Nanosponges were performed in phosphate buffer pH 7.4. After comparing the 5 formulations, F2 was chosen to proceed with further studies.

The drug-excipient compatibility study of the physical mixture and formulation F2 was carried out by FTIR spectroscopy. All the major peaks present in the spectrum of pure drug were observed in the spectrum of physical mixture of drug and excipients as well as in the spectrum of the formulation F2 with only negligible change in the position suggesting that there was no pronounced interaction present. The particle size and zeta potential were found to be 505 nm and –24.9 respectively. The morphological analysis was done for F2 by scanning electron microscopy and revealed the porous structure with a size ranging around 500 nm.

Etodolac Nanosponge gel was formulated for topical therapy. *In vitro* drug release data of the formulation F2 gel 82% CDR compared to other formulation.

TIZANIDINE-LOADED NANOGEL: FABRICATION, CHARACTERIZATION, AND POTENTIAL BIOMEDICAL APPLICATIONS OF A SYNTHETIC POLYMER-BASED DELIVERY SYSTEM

Dissertation submitted to

THE TAMILNADU Dr.M.G.R. MEDICAL UNIVERSITY,
CHENNAI – 32

In partial fulfillment of the requirements for the award of the degree of

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IN
PHARMACEUTICS

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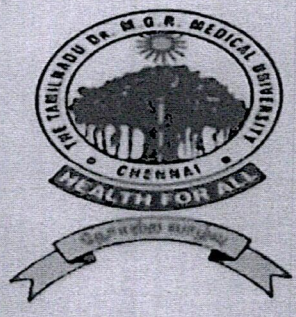

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SUMMARY AND CONCLUSION

Nanogel based materials have high drug loading capacity, biocompatibility and biodegradability which are key points to design the drug delivery system effectively. Drug molecules loaded into the nanogel need to be retained and not to be transported out or leak prematurely while circulating in order to provide maximum therapeutic effects and minimum toxicity or side effect.

Main objective of this study was to formulate Tizanidine hydrochloride using polymer is an effective as vesicular system and can efficiently deliver the drugs through transdermal route to treat spasms, cramping and tightness of muscles.

The present work aimed at formulating Tizanidine hydrochloride nanogel with hydrophobic polymer using emulsion solvent diffusion method. This method was simple and cost effective.

Pre-formulation studies were carried out to find out the solubility of Tizanidine hydrochloride. Solubility test gave an idea that Tizanidine hydrochloride is water soluble and soluble in solvents.

FTIR and UV spectral studies authenticate the spectra obtained with the sample drug matched with standard pure drug. UV spectra gave the maximum absorption peak at 228nm

Formulation was carried out by emulsion solvent diffusion method. Trial batches indicated that hydrophilic polymers are not suitable for the Tizanidine hydrochloride nanogel. The hydrophobic polymers produced good formulation. Eudragit were selected for further studies.

FORMULATION AND EVALUATION OF TENOXICAM EMULGEL FOR TOPICAL APPLICATION BY USING SYNTHETIC POLYMER

Dissertation submitted to

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8. SUMMARY AND CONCLUSION

- In this study, Tenoxicam loaded emulgel was formulated and formulations were quite stable, it may be concluded that the formulation F9 was good showing high percentage of entrapment with desired sustained release of drug.
- The FTIR studies concluded there is no major interaction occurred between the drug and polymer.
- The formulation F9 with Tenoxicam emulgel showed good result. The percentage of drug release was found 91.4%.
- Malvern zeta sizer was used to explore the particle size of Tenoxicam emulgel. The average particle size of emulgel was 98.19 nm.
- Malvern zeta sizer was used to explore the zeta potential of Tenoxicam emulgel. The average particle size of emulgel was 0.0204.
- The presence of stabilizer made the emulgel formulation more stable with high entrapment efficiency 91%.
- The optimized formulation was found to be Higuchi order pattern.
- We can consider the emulgel could be used as a drug carrier for Tenoxicam and also to sustain the effect of drug for a longer duration of action.

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FORMULATION AND EVALUATION OF LEVOFLOXACIN FLOATING TABLETS CONTAINING FOR SELECTED ANTIBIOTIC

Dissertation submitted to

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MASTER OF PHARMACY

IN

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CONCLUSION

- Hydrodynamically balanced tablets of Levofloxacin can be formulated with an approach to increase gastric residence and thereby improve drug bioavailability.
- An attempt to develop floating tablets of Levofloxacin using sodium bicarbonate as gas generating agents and natural gums as polymers by direct compression technique was achieved.
- The formulated tablets showed compliance for various physiochemical parameters viz. tablet dimensions, total floating time, tablet density and drug content.
- The dissolution studies formulations of F2, F5, F8 were good release and F10 formulation was excellent.
- Data obtained from kinetic treatment revealed F2, F5, F8 and F10 formulations follow Huguchi plot model. The 'n' value obtained from 0.521 to 0.633 indicates the non Fickian diffusion.
- The results of stability studies indicated that the most suitable storage temperature for Levofloxacin floating tablets was 2-8°C for a period of 60 days.