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FORMULATION AND *INVITRO* EVALUATION OF FLOATING TABLETS USING TAPENTADOL HCL AS A MODEL DRUG

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Abstract:

The oral route is the predominant and most preferable route for drug delivery, but drug absorption is unsatisfactory and highly variable in the individuals despite excellent in vitro release patterns. Several approaches are currently utilized in the prolongation of the gastric residence times, including floating drug delivery systems, swelling and expanding systems, polymeric bio adhesive systems, modified-shape systems, high-density systems and other delayed gastric emptying devices. Pain is a disorder that everyone experiences. Analgesics having similar effectiveness with improved compliance in comparison to opioids are valuable additions to the analgesic armamentarium. Polymers used in the drug delivery system are of two types Natural and Synthetic based on their origin. Both types of the polymers have some advantages and disadvantages. This results in prolonged gastric retention time of floating forms which improve bioavailability of drug and also improve clinical situations. FDDS is one amongst the GRDF's used to achieve prolonged gastric residence time. The purpose of writing this review on FDDS was to compile the recent literature with principle mechanism of floatation to achieve gastric retention. The development of FDDS including the physiology and formulation factors affecting gastric retention, classification and formulation, advantages and disadvantages are covered. This also summarizes the in vitro studies to evaluate the performance and application of FDDS.

Keywords: *Delayed gastric emptying devices, Analgesics, opioids, Natural and Synthetic Polymers, FDDS and GRDF.*

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INTRODUCTION:

Oral administration is the most convenient and preferred means of any drug delivery to the systematic circulation. Oral controlled release drug delivery have recently been of increasing interest in pharmaceutical field to achieve improved therapeutic advantages, such as ease of dosing administration, patient compliance and flexibility in formulation. Drugs that are easily absorbed from gastrointestinal tract (GIT) and have short half-lives are eliminated quickly from the systemic circulation. To avoid this limitation, the development of oral sustained-controlled release formulations is an attempt to release the drug slowly into the gastrointestinal tract (GIT) and maintain an effective drug concentration in the systemic circulation for a long time. After oral administration, such a drug delivery would be retained in the stomach and release the drug in a controlled manner, so that the drug could be supplied continuously to its absorption sites in the gastrointestinal tract (GIT) [1] Prolonged gastric retention improves bioavailability, increases the duration of drug release, reduces drug waste, and improves the drug solubility that are less soluble in a high pH environment[2].Sustained release, sustained action, prolonged action, controlled release, extended action, timed release, depot and repository dosage forms are terms used to identify drug delivery systems that are designed to achieve a prolonged therapeutic effects by continuously releasing medication over an extended period of time after administration of a single dose. The term ”controlled release” has become associated with those systems from which therapeutic agents may be automatically delivered at predefined rates over a long period of time. The safety margin of high-potency drugs can be increased, and the incidence of both local and systemic adverse side effects can be reduced in sensitive patients [3].

Gastrointestinal tract physiology

Stomach

The stomach is situated in the left upper part of the abdominal cavity immediately under the diaphragm. Its size varies according to the amount of distension: up to 1500ml following a meal; after food has emptied, a collapsed state is obtained with resting volume of 25–50ml (Waugh & Grant, 2001). The stomach is anatomically divided into three parts: fundus, body, and antrum (or pylorus). The proximal stomach, made up of fundus and body regions, serves as a reservoir for the ingested materials, while the distal region (antrum) is the major site of mixing motions, acting as a pump to accomplish gastric emptying.

Gastrointestinal motility

Two distinct patterns of gastrointestinal motility and secretion exist corresponding to the fasted and fed states. As a result the bioavailability of orally administered drugs will vary depending on the state of feeding. In the fasted state, it is characterized by an inter-digestive series of electrical event and cycle, both through the stomach and small intestine every 2–3h. This activity is called the interdigestive myoelectric cycle or Migrating motor complex (MMC). MMC is often divided into four consecutive phases: basal (Phase I), pre-burst (Phase II), burst (Phase III), and Phase IV intervals.

• Phase I (basal phase) lasts from 40–60min with rare contractions.

• Phase II (pre-burst phase) lasts for 40–60min with intermittent action potential and contractions. As the phase progresses the intensity and frequency also increases gradually.

• Phase III (burst phase) lasts for 4–6min. It includes intense and regular contractions for short periods. Due to this contraction all the undigested material is swept out of the stomach down to the small intestine. This is also known as the housekeeper wave.

• Phase IV lasts for 0–5min and occurs between phases III and I for two consecutive cycles. The motor activity in the fed state is induced 5–10 min after the ingestion of a meal and persists as long as food remains in the stomach. The larger the amount of food ingested, the longer the period of fed activity, with usual time spans of 2–6 h, and more typically 3–4 h, with phasic contractions similar to Phase II of MMC.

Emptying of Dosage form from the Stomach

To achieve gastric retention, the dosage form must resist premature gastric emptying. For this, the dosage form must be able to withstand in the stomach against the force caused by peristaltic waves. Furthermore, once its purpose has been served the dosage form should be removed from the body with ease. Table 1 explains the GIT transit time of various dosage forms [4,7,9].

Factors Affecting Gastric Retention[9]

Gastric residence time of an oral dosage form is affected by several factors. To pass through the pyloric valve into the small intestine the particle size should be in the range of 1 to 2 mm. The pH of the stomach in fasting state is ~1.5 to 2 and in fed state is 2 to 6. A large volume of water administered with an oral dosage form raises the pH of stomach contents to 6 to 9. Stomach doesn’t get time to produce sufficient acid when the liquid emptics the stomach; hence generally basic drugs have a better chance of dissolving in fed state than in a fasting state.

The gastric retention time (ORT) of dosage form is controlled by several factors, that affect their efficacy as a gastroretentive system.

i. *Density:* Density of the dosage form should be less than the gastric contents (1.004gm/ml).

ii. *Size and Shape:* Dosage form unit with a diameter of more than 7.5 mm are reported to have an

increased GRT competed to with those with a diameter of 9.9 mm. The dosage form with a shape tetrahedron and ring shape devises with a flexural modulus of 48 and 22.5 kilopond per square inch (KSI) are reported to have better GIT for 90 to 100 % retention at 24 hours compared with other shapes.

Fed or Unfed State: Under fasting conditions, the GI motility is characterized by periods of strong motor activity or the migrating myoelectric complexes (MMC) that occurs every 1.5 to 2 hours. The MMC sweeps undigested material from the stomach and if the timing of administration of the formulation coincides with that of the MMC, the GRT of the unit can be expected to be very short. However, in the fed state, MMC is delayed and GRT is considerably longer.

Nature of the meal: Feeding of indigestible polymers of fatty acid salts can change the motility pattern of the stomach to a fed state, thus decreasing the gastric emptying rate and prolonging the drug release.

Caloric Content: GRT can be increased between 4 to 10 hours with a meal that is high in proteins and fats.

Frequency of feed: The GRT can increase by over 400 minutes when successive meals are given compared with a single meal due to the low frequency of MMC.

Gender: Mean ambulatory GRT in meals (3.4±0.4 hours) is less compared with their age and race-matched female counterparts (4.6±1.2 hours), regardless of the weight, height and body surface.

Age: Elderly people, especially those over 70 years have a significantly longer GRT.

Posture : GRT can very between supine and upright ambulatory states of the patients

iii. *Concomitant drug administration:* Anticholinergic like atropine and propentheline opiates like codeine and prokinetic agents like metoclopramide and cisapride.

Floating Drug Delivery System

Floating drug delivery systems (FDDS) or hydro dynamically controlled systems are low-density systems that have sufficient buoyancy to float over the gastric contents and remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time. While the system is floating on the gastric contents, the drug is released slowly at the desired rate from the system. After release of drug, the residual system is emptied from the stomach. This results in an increased GRT and a better control of the fluctuations in plasma drug concentration. However, besides a minimal gastric content needed to allow the proper achievement of the buoyancy retention principle, a minimal level of floating force (F) is also required to keep the dosage form reliably buoyant on the surface of the meal . Many buoyant systems have been developed based on granules, powders, capsules, tablets, laminated films and hollow microspheres [5].

The object floats better if F is on the higher positive side. This apparatus helps in optimizing FDDS with respect to stability and durability of floating forces produced in order to prevent the drawbacks of unforeseeable intra-gastric buoyancy capability variations.

F = F buoyancy-F gravity= (Df -Ds) gV

Where,

F= total vertical force, Df = fluid density, Ds = object density, V = volume and g = acceleration due to gravity [2].

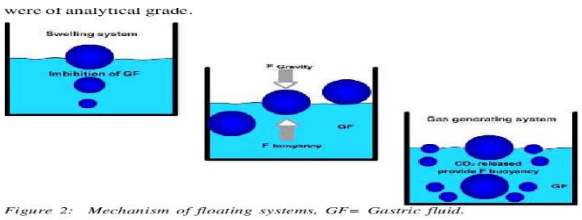

Figure 2: Mechanism of floating systems, GF= Gastric fluid.

Drugs available as Floating Drug Delivery System [7]

S.NO	DOSAGE FORM	DRUGS USED
1	Floating tablets/pills	Acetaminophen, Acetyl salicylic acid, Amoxicillin trihydrate, Ampicillin, Atenolol, Cinnarizine, Captopril, Cinnarizine, Carbamazepine, Chlorpheniramine maleate, Ciprofloxacin
2	Floating Capsules	Diazepam, Furosemide, Nicardipine, L-Dopa, Pep-statin, Misoprostol, Chlordiazepoxide HCl
3	Floating microspheres/Floating beads	Amoxicillin, Aspirin, Griseofulvin, Ibuprofen, Piroxicam, Cholestyramine, Dipyridamole, p-nitroaniline
4	Floating Granules	Diclofenac Sodium, Indomethacin, Meloxicam, Nicardipine, Riboflavin
5	Powders	Several basic drugs
6	Films	Albendazole, Cinnarizine

Classification of Floating Drug Delivery System [2]

1. Single Unit Floating Dosage Systems
a) Effervescent Systems (Gas-generating Systems)
b) Non-effervescent Systems
2. Multiple Unit Floating Dosage Systems
a) Non-effervescent Systems
b) Effervescent Systems (Gas-generating Systems)
c) Hollow Microspheres
d) Raft Forming Systems.

Floating Mechanism

A) Effervescent

Effervescent floating system prepared with help of swellable polymers such as methyl cellulose, chitosan and various effervescent compounds eg: Sodium bi-carbonate, Tartaric acid and citric acid. After oral administration this dosage in contact with the gastric content CO2 liberate and gas entrapped in swollen hydrocolloids which provide buoyancy to the dosage form. Gas Generating agent push the tablet towards surface of gastric fluid, time required for this process is called log time. Then drug releases at surface of gastric fluid in controlled manner. Controlled release approximately6-8 hrs in targeted regions [6].

These buoyant systems utilize matrices prepared with swellable polymers like methocel, polysaccharides like chitosan, effervescent components like sodium bicarbonate, citric acid and tartaric acid, or chambers containing a liquid that gasifies at body temperature. The common approach for preparing these systems involves resin beads loaded with bicarbonate and coated with ethylcellulose. The coating, which is insoluble but permeable, allows permeation of water. Thus, carbon dioxide is released, causing the beads to float in the stomach. Strubing et al. (2008a) investigated the mechanism of floating and drug release behaviour of poly(vinyl acetate)-based floating tablets with membrane controlled drug delivery. Benchtop MRI studies of selected samples were performed and the results suggested that the drug release was delayed efficiently within a time interval of 24h by showing linear drug release characteristics. Patel et al. (2007a) used hydroxypropyl methylcellulose, ethyl cellulose, and sodium bicarbonate to prepare floating tablets and optimization was done using a simplex lattice design. All the tablet formulations remained buoyant for more than 12h and the release profile of the optimized batch fitted best to the zero order model. Shishu et al. (2007a) developed a FDDS using gasforming agents, like sodium bicarbonate, citric acid, and hydrocolloids, like hydroxypropyl methylcellulose (HPMC) and Carbopol 934P. The results of the in vitro release studies showed that the optimized formulation could sustain drug release for 24h and remain buoyant for 16 h. Atyabi et al. (1996) prepared ion exchange resin beads loaded with bicarbonate and coated with a semipermeable membrane. These prepared beads exhibit prolonged gastric residence due to the release of carbon dioxide which is trapped inside the coating of the beads [4].

These effervescent systems further classified into two types:

1) Gas generating systems.
2) Volatile liquid or Vacuum containing systems [7].

Drug Candidates suitable for floating Drug Delivery

1. Drugs which shows site-specific absorption in the stomach or upper parts of the small intestine. For example: furosemide, riboflavine-5-phosphate.
2. The drugs which are unstable in the lower part of GIT. For example: captopril.
3. Drugs required to exert local therapeutic action in the stomach .For example: antacids, anti-H. pylori agents, misoprostol.

4. Drugs with variable bioavailability. For example: satolol HCl.
5. Drugs which are insoluble in intestinal fluids. For example: quinidine, diazepam

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Advantages of FDDS [5, 10]

a. The Floating systems are advantageous for drugs meant for local action in the stomach. E.g. antacids.
b. Acidic substances like aspirin cause irritation on the stomach wall when come in contact with it. Hence FDDS may be useful for the

administration of aspirin and other similar drugs.

c. The Floating systems are advantageous for drugs absorbed through the stomach. E.g. Ferrous salts, antacids.
d. Administration of prolongs release floating dosage forms, tablet or capsules, will result in dissolution of the drug in the gastric fluid. They dissolve in the gastric fluid would be available for absorption in the small intestine after emptying of the stomach contents.
e. It is therefore expected that a drug will be fully absorbed from floating dosage forms if it remains in the solution form even at the alkaline pH of the intestine.
f. As sustained release systems, floating dosage forms offer various potential advantages. Drugs that have poor bioavailability because their absorption is limited to upper GI tract can be delivered efficiently thereby maximizing their absorption and improving their absolute bioavailability.

Limitations of FDDS

a. Floating system is not feasible for those drugs that have solubility or stability problem in G.I. tract.
b. These systems require a high level of fluid in the stomach for drug delivery to float and work efficiently coat, water.
c. The drugs that are significantly absorbed through out gastrointestinal tract, which undergo significant first pass metabolism, are only desirable candidate.
d. The dosage form should be administered with a full glass of water (200-250 ml).
e. These systems do not offer significant advantages over the conventional dosage forms for drugs, which are absorbed throughout the gastrointestinal tract.
f. The drug substances that are unstable in the acidic environment of the stomach are not suitable candidates to be incorporated in the systems.

Disease State

Pain is a disorder that everyone experiences and is often difficult to treat. Current drug treatment options for management of pain include opioids, nonsteroidal anti-inflammatory drugs (NSAIDs), and paracetamol. Analgesics having similar effectiveness with improved compliance in comparison to opioids are valuable additions to the analgesic armamentarium [11]. The particular modality or modalities utilized for a particular patient will depend on the risk-benefit profile and patient preferences. Ideally, analgesic options should be incorporated into a multimodal approach to facilitate patient recovery after surgery [12]. Until the 1960s, pain was considered an inevitable sensory response to tissue damage. There was little room for the affective dimension of this ubiquitous experience, and none whatsoever for the effects of genetic differences, past experience, anxiety, or expectation. In recent years, great advances have been made in our understanding of the mechanisms that underlie pain and in the treatment of people who complain of pain [15]. The practice and theoretical basis of pain measurement is reviewed and critically examined in the areas of animal research, human subjects laboratory investigation and clinical study [16].

Methodology

A drug used to treat moderate to severe pain. it binds to opioid receptors and molecules in central nervous system. Tapentadol hydrochloride is a type of opioid and a type of analgesic agents also called "NUCYNTA".

Materials

Tapentadol hydrochloride form -A (DRUG), HPMC (polymer), Dextrose, Sodium carbonate, citric acid, PVP K30.

Method of Preparation

Preparation of Tapentadol Hydrochloride Tablets

Four different formulations were prepared using various concentrations of the sodium bicarbonate and HPMC (polymer). The concentration of polymers for the factorial design was finalized based on the evaluation of trials. In preliminary study, sodium bicarbonate was used in concentration as floating agent. citric acid is used in combination with sodium bicarbonate in all batches. HPMC (polymer)is a traditional pharmaceutical excipient with favorable safety profile. Used as a raw material for coatings with moderate strength, moderate moisture and oxygen barrier properties , elasticity . And it is also used as a tablet binder and as a tablet matrix for extended release. PVP K30 it has multiple uses including as a binder for tablets and capsules , a and film former for ophthalmic solution .

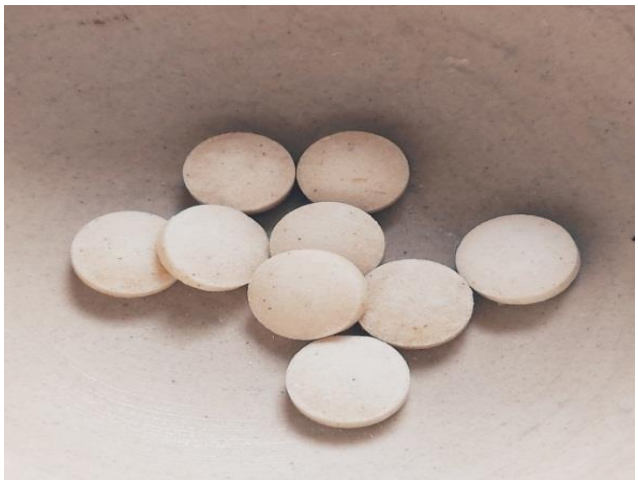
The tablet of trial batches were prepared by direct punching method .The tablet is been punched under tablet punching machine.

General Procedure for the Preparation

- Weigh the following drug and the materials mentioned below, according to their quantities.
- By using motor and pestle Tapentadol Hydrochloride (drug) and the excipients are grinding into fine powder .
- The powder is sieved to separate the particles of different sizes.
- The powder which obtained is of fine particles .
- According to the given quantity's tablets are weighed and punched by 4 different formulations which vary in there polymer and binders

Formulation

S.NO:	MATERIALS	F1	F2	F3	F4
01.	Tapentadol Hydrochloride form A (DRUG)	100 mg	100mg	100mg	100mg
02.	HPMC (Polymer)	200mg	100mg	150mg	175mg
03.	Dextrose	66mg	216mg	116mg	141mg
04.	Na2co3	70mg	70mg	70mg	70mg
05,	Citric acid	10mg	10mg	10mg	10mg
06.	PVP K30	4mg	4mg	4mg	4mg



F1

F2

F3

F4

Evaluation Test

All the formulations were evaluated for various parameters such as Shape and size, Hardness, friability, Dissolution test, Drug content.

Shape and Size

Shape is the form of an object or its external boundary ,outline, or external surface, as opposed to other properties such as color ,texture or material type .

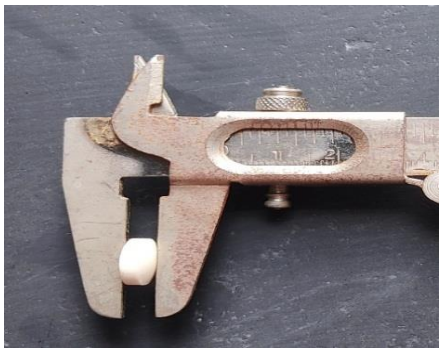
Whereas, size is the measurement of other end ,is the magnitude or dimensions of a thing. size can be measured as length ,width ,height ,diameter, perimeter, area, volume or mass .

Thickness of all tablets was measured using a vernier calliper.

FORMULATIONS	F1	F2	F3	F4
SHAPE	5	5	5	5

FORMULATIONS:	F1	F2	F3	F4
SIZE	Circular/Biconvex	Circular/Biconvex	Circular/Biconvex	Circular/Biconvex

Hardness



A Hardness is a method employed to measure the hardness of a material .Hardness refers to materials resistance to permanent indentation.

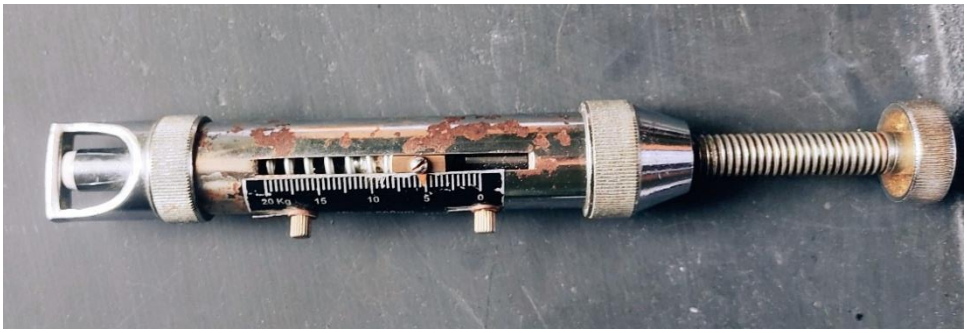
Hardness of the tablet was determined by using "**Monsanto**" hardness tester.

***P*rocedure**

Here ,tablet is put between moving jaw and fixed jaw. Moving jaw is moved and pressure is applied on tablet by means of screw knob .The point where tablet get break down, it is recorded by means of scale .

The hardness is measured in kg/cm2.

FORMULATIONS:	F1	F2	F3	F4
Hardness	7	2.5	3	3



Friability

Friability testing is used to treat the durability of tablets during packing processes and transit. This involves repeatedly dropping a sample of tablets over a fixed time, using a rotating drum with a baffle.

In simple words, friability test tells how much mechanical stress tablets are able to withstand during their manufacturing , distribution and handling by the customer.

Procedure

Friability is defined as the % of weight loss by tablets due to mechanical action during the test.

Tablets are weighing before and after testing and friability is expressed as a percentage loss on pre test tablet weight.

Friability refers the ability of the compressed tablet to avoid fracture and breaking during transport.

Dissolution Test

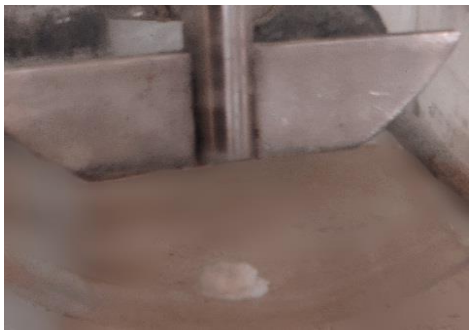
Dissolution is the process by which solid substance enters into a liquid known as dissolution medium or solvent to form a solution.

Dissolution is a test which is used for a pharmaceutical product to evaluate the rate of release of a drug substance from the dosage form.

Procedure

The release rate of tapentadol hcl from floating tablets was determined using united states pharmacopeia (usp)dissolution testing apparatus .The dissolution test was performed using 900ml ,of 0.1N HCL ,at 37 ±0.5ºC and 75 rpm .A sample (5ml) of the solution was withdrawn from the dissolution apparatus hourly for 2hours ,and the

sample were replaced with fresh dissolution medium .The samples were filtered through a 0.45µ membrane filter and diluted to a suitable concentration with 0.1N HCL .Absorbance of these solution was measured at 272nm using double beam UV spectroscopy.



RESULTS AND DISCUSSION:

It was observed that formulations containing 150 mg and 180 mg of Locust bean gum alone showed immediate floating but formulations dissolved within 2 hours, while formulations containing 90 mg and 120 mg of Xanthan gum alone showed floating within 5 min and retardation of drug release for more than 8 hours. Hence combination of these two polymers was used to get optimum floating ability and drug release. Formulation containing Locust bean gum (70 mg) and Xanthan gum (50 mg) in combination showed optimum floating and release pattern

Evaluation of Tablets

Hardness of the formulations F1–F9 was observed within the range of 6.9–8.8 kg/cm^2 as shown in Table 1. Friability of the tablets was observed below 0.30% for all batches which was in the acceptable limit. The thickness of all the tablets was found within the range of 5 ± 2 mm.

Table 1.Evaluation results of formulations F1–F9.

Formulation no.	% Drug release within 8 hrs.	% Drug content	Swelling index	Buoyancy lag time (sec.)	Hardness (kg/cm^2)
F1	95.8	98.60	286.7	69	7.8
F2	98.01	99.24	291.1	48	8.1
F3	96.48	97.89	302.7	75	8.6
F4	98.04	99.09	277.9	62	8.0
F5	102.05	101.80	292.2	58	6.9
F6	97.57	98.93	305.4	91	7.3
F7	95.96	100.56	290.4	53	8.6
F8	100.14	102.37	283.7	58	8.1
F9	97.22	101.46	307.9	85	8.8

The weight of all the tablets was found within the range of 250 mg ± 5 mg. The range of % drug content of the formulations F1–F9 was found between 97.25 and 102.67. The *in vitro* buoyancy study showed the good floating ability of the tablets as shown in the Table 1. Buoyancy lag time indicates the time required for the formulation to float in the medium. From Table 1, it was observed that formulations F6 and F9 show comparatively more floating time as compared to other formulations. It was further observed that formulation F2 shows less floating time than others. This indicates that higher concentration of $NaHCO_3$ affects the release pattern of drug from formulation whereas lower concentration (less than 20%) alone fails to float within a minute.

From evaluation of formulations F1–F9, it was observed that there is linear relationship between swelling index and concentration of polymers. Maximum swelling index was observed with F9 containing maximum concentration of both the polymers. From the swelling index study of all the batches, it was observed that the increase in the concentration of polymers increases the swelling property of the tablets as shown in Table1. Further the formulation containing optimized swelling index was obtained. From the formulation batches, it was observed that the formulations F9 showed maximum swelling index.

In vitro Dissolution Studies

Locust bean gum has low gelling and matrix forming property than Xanthan gum. Hence Locust bean gum alone cannot be used as matrix polymer in the formulation of Matrix tablet. Xanthan gum alone as well as in combination with other gums is good matrix polymer to formulate controlled-release tablets. Locust bean gum (50–60%) alone fails to retard drug release. Xanthan gum (30–40%) alone gives good retardation of drug release for extended period of time. The drug release patterns from all the formulations are shown in Table 1. The percent drug release after 8 hours is as shown in Figure 1.

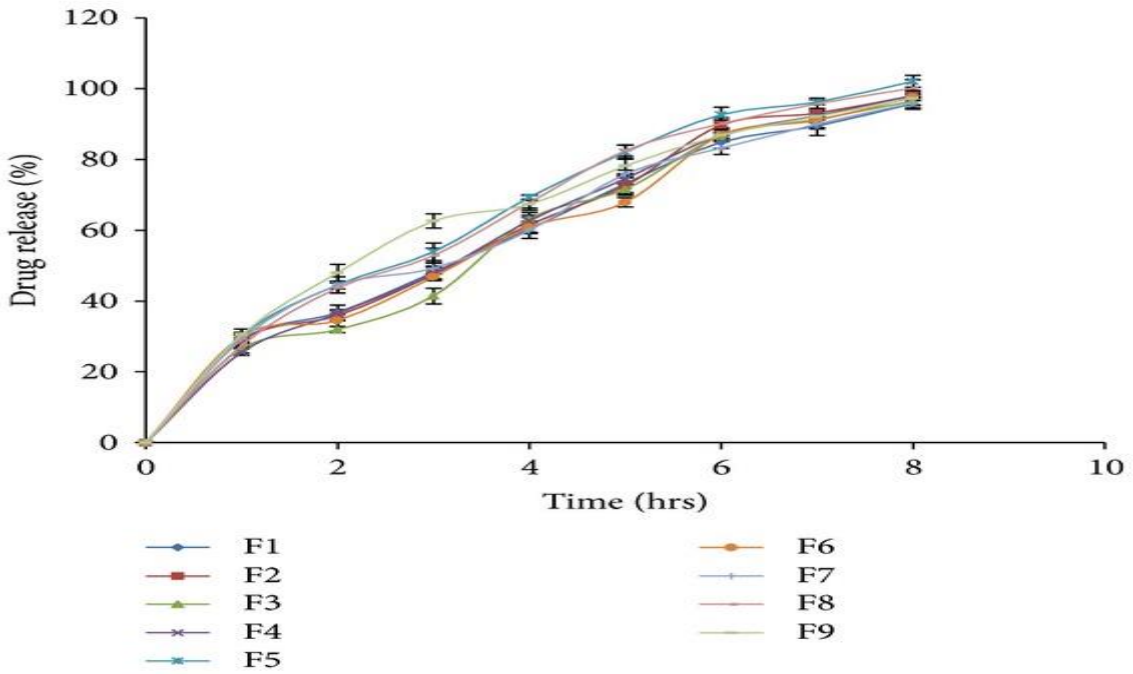


Figure 1% Drug release profile of drug from formulations containing PVP K30

The drug release profile of formulations F1–F9 indicates that as the concentration of polymers increases, the drug release decreases. From the comparison of release profiles of all the batches, it was observed that the formulations containing combination of polymers show retardation of drug release to a greater extent than formulations containing single polymer. The batches F5, F8, and F9 compliy with standards for drug release as mentioned for Modified-release tablet in USP29

From the *in vitro* dissolution studies and the response surface curves, it was observed that the drug release pattern was influenced by the variation in the concentration of polymers. Batches F5, F8, and F9 show optimum drug release profiles but batch F9 fails to float within 1 min. As compared with batch F8, batch F5 has higher swelling index as well as optimum FLT and drug release. The infrared studies show that there is no interaction between the excipient and drug that can affect the efficacy of drug.

CONCLUSION:

The formulation of immediate release tablets of tapentadol hydrochloride were prepared by direct compression method by using different ratios of superdisintegrant explotab, solutab and PVP K30. Among all the formulations, the formulation F2 exhibits highest dissolution using explotab, faster drug release 95.48 % over the period of 45 min while disintegration time of the tablet was showed 12 sec. Therefore the prepared formulation of tapentadol hydrochloride is best formulation and could be used for industrial application.

REFERENCES:

1.Streubel A, Siepmann J, Bodmeier R. Gastroretentive drug delivery system. Expert Opin Drug Deliv 2006; 3(2):217-33.

2.Zubedi SS, Mohammed S, Floating tablets and its polymers,Journal of Drug Delivery and Therapeutics. 2018; 8(5-s):16-24.

3.Lachman L, Lieberman HA, The theory and practice of industrial pharmacy, CBS publishers and distributors, special Indian edition, New Delhi. 2009 p. 300,301,317.

4.Vivek K. Pawar, Shaswat Kansal, Garima Garg, Rajendra Awasthi,Deepak Singodia & Giriraj T. Kulkarni (2011) Gastroretentive dosage forms: A review with special emphasis on floating drug delivery systems, Drug Delivery, 18:2, 97-110.

5.S.Gopalakrishnan, A. Chenthilnathan, Floating Drug Delivery Systems: A Review Journal of

Pharmaceutical Science and Technology Vol. 3 (2), 2011,548-554
6.Suresh karudumpala, Madhusudhana Chetty, Gnanaprakash K, Venkatesh B, Sankar P, A review on bilayer floating tablets, (2013) Int. J. Res. Pharma. Sci., 4(2),354-360.
7.Palavi Pal, Vijaya Sharma, Lalit Singh, A review on floating type gastroretentive drug delivery system et al. IRJP2012,3(4).
8.Shalini Sharma, Mukesh Prashar, Ram Kumar Sahu, Floating Drug Delivery System: Incredible Revolution, Pharmacologyonline 3: 1039-1054(2011).
9.Nikita Dixit, Floating drug delivery system, journal of current pharmaceutical research 2011;7 (1);6-20.
10.Chaturvedi Shashank, Kumari Prabha, Singh Sunil, Agrawal Vipin Kumar, Approaches to increase the gastric residence time: Floating drug delivery systems-A review, Asian journal of pharmaceutical and clinical research, vol 6, issue 3, 2013, 0974-2441.
11.Dewan Roshan Singh, Kusha Nag, Akshaya N. Shetti, and N. Krishnaveni, Tapentadol hydrochloride: A novel analgesic, Saudi J Anaesth. 2013 Jul-Sep; 7(3): 322–326.
12.K Brown MD (Chief Resident)Paul J Christo MD(Assistant Professor)Christopher L Wu MD(Associate Professor), Strategies for postoperative pain management, Elsevier, Volume 18, Issue 4, December 2004, Pages 703-717.
13.W. Jacqueline K wong PharmD PhD1, IpekÖzer-StillmanMS2, Jeffrey D. Miller MS2, Noah A. HaberBA2, Mason W. RussellMAPE2, ShaneKavanaghMSc3, Cost-effectiveness analysis of tapentadol immediate release for the treatment of acute pain, Elsevier, Volume 32, Issue 10, September 2010, Pages 1768-1781
14.William E. Wade, William J. Spruill, Tapentadol hydrochloride: A centrally acting oral analgesic, Elsevier, Clinical Therapeutics,Volume 31, Issue 12, December 2009, Pages 2804-2818
15.John D Loeser MD Ronald Melzack, Pain: an overview, The Lancet, Volume 353, Issue 9164, 8 May 1999, Pages 1607-1609
16.K.L.Casey, R.Dubner, K.M.Foley, R.H.Gracely, A.E.Reading, Pain measurement: an overview, Elsevier, Volume 22, Issue 1, May 1985, Pages 1-31
17.Mr. Y. Shiva Kumar, M. Rasagna, Dr.T.Mangilal, Preparation and Evaluation of Tapentadol Hydrochloride Solid Lipid Nanoparticles, Journal of Drug Delivery & Therapeutics. 2019; 9(4-A):618-624.
18.W. Schröder, T. M. Tzschentke, R. Terlinden, J. De Vry, U. Jahnel, T. Christoph and R. J. Tallarida, Synergistic Interaction between the Two Mechanisms of Action of Tapentadol in Analgesia,Journal of Pharmacology and Experimental Therapeutics April 2011, 337 (1) 312-320.