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Review Paper

An Advance Drug Delivery Approach: Osmotic Pump

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ABSTRACT

The past few decades were challenging for the pharmaceutical industry to bring the new active pharmaceutical ingredients APIs in market. Due to the multiple challenges the novel drug delivery approach were increased. From the numerous novel drug delivery systems one of the definitive approach is Osmotic drug delivery system. Osmotic drug delivery system is a type of controlled drug release and brings relief from local gastrointestinal or systemic toxicity. The active drug molecule is present in the core compartment of the osmotic pump. Osmotic pump utilized in oral administration and implantation procedures. It is much easier to develop a novel drug delivery system in comparison to bring a new chemical entity in world. Novel drug delivery approach can increase market value of an old chemical entity by allowing it to increase its lifespan in market and conflicting to other chemical entity.

INTRODUCTION

For several past year's treatment of an acute illness or chronic disease has been mostly done by the delivery of drugs to patients using different pharmaceutical dosage forms. Consistently, the oral drug delivery has been approved as the most widely utilized route of administration in all the routes that have been known for the systemic delivery of drugs. Positively, Traditional oral drug delivery provides the rapid release of drug substance; but one can't control release of the drug, also can't keep an efficacious dug concentration for long at site of target [1]. The conventional oral drug delivery system comes with a lot of influencing factors like physico-chemical properties, different physiological aspects like pH of Gastro intestinal tract, presence or absence of food in stomach, motility of Gastrointestinal. To get better of this challenge the oral route were replaced by the parenteral route of administration. Parenteral route offers many advantages over oral route such as dose reduction, site targeting, bypass

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of hepatic route as well as stability of GI. In comparison to the conventional drug delivery system the controlled release drug delivery shows enhanced performance. The controlled drug delivery offers maintained drug concentration in bloodstream for extended period of time, this will give a prolonged therapeutic effect. The controlled release of a drug molecule can minimise the side effect as one can modulate the level of plasma concentration. On other hand, targeted drug delivery are also present which can offer specific site drug delivery by decreasing the systemic display of drug [2]. Controlled release pharmaceuticals offer constant therapeutic plasma concentration for a long period of time; and also keep concentration within the therapeutic range. Osmotic pump works by, the osmotic pressure is a driving force to create a controlled release of active molecule. The active molecule is surrounded by a semi-permeable membrane as well as osmogen mixture. Throughout the Gastro intestinal tract, the active molecule gets releases at a constant rate and it is not affected by pH factor.

Nowadays, the novel drug delivery system is becoming the predominant in the pharmaceutical research field because of its cost efficiency and less time consuming compared to the find a new drug molecule. The assignment of drug development is make an enhanced product which can show effective therapeutic property as well as supplementary benefits like:

- Sustained and constant blood levels in therapeutic window.
- Increased bioavailability.
- Decreased interpatient variability.
- Tailored delivery profiles.
- Reduced dose frequency.
- Enhanced patient comfort.
- Decreased side effects.

HISTORY

There, are several patent products present in the market nowadays, which works on osmotic delivery principle; but the first osmotic drug delivery was came in 1955, by an Australian Pharmacologist Rose and Nelson. They developed two osmotic pump which are implantable. These implantable further used by different Pharmacologists. In the days of 1970, a sequence of different of Rose-Nelson pump were came, which are developed by Higuchi and Leeper. This is was time, further number of moderations have made which gave rise to the controlled delivery for most drug molecule [4]. In 1971, Stolzenberg came with another osmotic system but this was close in action to Rose and Nelson's model. But, the con of both systems was they were utilised only in laboratory scale research. There are restrictions on practical use in large scale production.

In 1972, Theuwes invented the osmotic pump, and these designs was an elementary model. Alza Corporation (USA) become the first developer of oral osmotic pump and till today. In the field of osmotic pump drug delivery system Alza corp. become leader, they came with a technology called OROS. In the era of 1980s and 1990s, Alza Corp. made a group of osmotic pump capsule (e.g. OROS®). This controlled drugs delivery was made to release the drug in gastro intestinal tract, and in 1974 made first of patent. Alza Corp. made evolution in various oral osmotic drug delivery as well as implantable (DUROS®) osmotic drug delivery. Felix Theeuwes, Liang Dong, Guohua Chen, Zhongli Ding and Lothar Kleiner contributed a lot to bring this osmotic delivery system in market. Alza Corp. developed the first elementary osmotic pump design which was OROS® as well as number of drugs were commercialized. The Osmosin® was the first product of it, containing indomethacin. The Osmosin® was call backed after a year because side effects like Gastro Intestinal irritation as well as intestinal wall perforation were noticed. To decrease this kind of side effects the controlled-porosity named concept were emerged. This

concept was for oral drug delivery system and given by Zentner *et al* (1985-1991). Zentner and Rork (1990), Zentner and Appel (1991) as well as Mc Celland *et al* (1991) worked for it [6]. The osmotically oral drug delivery system carried with two new design, controlled-porosity osmotic pump (CPOP) as well as push-pull osmotic pump (PPOP). The first objective of CPOP was to reduce the severe localised drug induced irritation, as observed in Osmosin® drug. The poorly soluble drug molecule was utilised by PPOP. Thus, the Procardia XL® (contains nifedipine) in the last century became successful along with other PPOP, making a revival factor for osmotically oral drug delivery system.

Osmosis

Osmosis is defined as the movement of solvent substances from low concentration to high concentration through a semi permeable membrane. Due to osmosis property the controlled drug delivery is still alive. In the osmotic pump, osmotic pressure is created by absorbing the external fluid content inside the dosage form which helps to regulate drug delivery. Rate of drug delivery in osmotic pump is directly proportional to the osmotic pressure which is developed by absorption of fluid. Osmotic pressure is one of the colligative property of solution which means it depends on concentration of solute, creating osmotic pressure.

Principle of Osmosis

In 1748, the first one who reported the osmotic effect was Abbe Nollet; but in 1877, the Pfeffer conducted the first quantitative measurements. In his experiment, he was extracting the sugar solution from pure water with the help of a semi-permeable membrane. The membrane was soluble to water but non-permeable to sugar. Pfeffer was able to show, the osmotic pressure of sugar solution is directly proportional to concentration of solution as well as absolute temperature. Years later Vant Hoff was able to put this all parameters in one equation which is expressed as

$$\pi = \phi nRT$$

Where, π is osmotic pressure, ϕ is osmotic coefficient of solution, n is number of moles of solute, R is gas constant and T is absolute temperature. Osmotic pressure is defined as the pressure greater than that above pure solvent, which is applied to solution to avoid passage of solvent through a semi-permeable membrane.

Solutions of different concentrations having same solute and solvent system shows an osmotic pressure which is directly proportional to their concentration.

COMPOSITION

a. Drug Molecule

The prolong action causing medications are not suitable for osmotic delivery system. Those drugs having biological half-life greater than 12 hours as well as drugs which have less than 1-hour half-life are not suitable for osmotic controlled release system. Those drug molecules have half-life in range of 1-6 hours as well as prescribed to cure disease for prolong period as best suitable drug choice for osmotic system. E.g. Carbamazepine, Diltiazem HCl, Metoprolol, Nifedipine.

Drugs showing following characteristics are suitable for osmotic delivery system-

1. Drug should neither be very high soluble nor very low soluble.
2. Drug should have potent nature.
3. Drug should have prolong release.
4. Drug should show short half-life.

b. Osmotic Agent

Osmotic agents are also known as osmogens or osmogents. The osmogens are the factors which creates the osmotic pressure in the osmotic delivery system. If the active drug has low solubility it shows zero order release at a slow rate. To increase this release rate the osmogens are utilised in the formulations. These agents are able to create a high gradient of osmotic pressure in the

osmotic system, so drug release rate gets enhanced. There are some single and combination of compounds enlisted with their osmotic pressure (Table 1 & 2).

Table no.1 Single Compound

Sr. No.	Compound	Osmotic Pressure (atm)
1.	Sodium Chloride	356
2.	Fructose	355
3.	Sucrose	150
4.	Dextrose	82
5.	Fumaric Acid	10
6.	Adipic Acid	8

Table no.2 Combination of Compound

Sr. No.	Mixtured Compound	Osmotic Pressure (atm)
1.	Mannitol + Sucrose	170
2.	Dextrose + Fructose	450
3.	Sucrose + Fructose	430
4.	Dextrose + Sucrose	190
5.	Mannitol + Fructose	415

c. Semi Permeable Membrane

One of the crucial part of the osmotic system is semi permeable membrane, the membrane allows a polymer which is permeable to water but impermeable to solute. In most of the cases, the cellulose acetate as a semi permeable membrane is preferred because it was obtainable in various acetyl content grades. In that various grades the 32% and 38% are mostly utilized. Acetyl content was determined by the degree of substitution i.e. average number of hydroxyl groups replaced by substituting groups. Some of the polymers like cellulose acetate, cellulose diacetate, cellulose propionate and cellulose ethers like ethyl cellulose are present. The material should have adequate wet strength to keep the integrity of its dimensions, which is advantageous for the device. To maintain the flux rate of water in adequate range then capability of material to allow water permeation must be adequate.

d. Wicking Agent

This substance helps to enhance the contact surface area of drug molecule with incoming aqueous fluid. They have ability to undergo physiosorption with water. Basic function of wicking agent is to carry water inside the core of formulation either by creating channels or increasing surface area. They are of two types swellable and non-swellable. Some of wicking agents are alumina, colloidal silicon dioxide, kaolin, PVP, sodium lauryl sulphate, titanium dioxide, etc.

e. Pore forming Agent

This agent helps to create the micro sized pore in the membrane. During the system operation, the micro channels get formed by leaching the semipermeable walls with helps of this agent. Then dissolution fluid get allowed to enter in osmotic system and drug get released. This are water soluble component. This agent are available in organic as well as inorganic form. Alkaline metal salts like sodium chloride, potassium chloride, potassium phosphate, etc. Alkaline earth metals like calcium nitrate and calcium chloride. Carbohydrates like fructose, glucose, lactose, sucrose, sorbitol and mannitol. Polyethylene glycol and polyvinyl pyrrolidone also used as pore forming agent.

f. Coating Solvents

The outer wall of osmotic device is made by using the polymer solution. The primary function of it is to get dissolved or dispersed the polymer as well as other additive, convey all compounds to substrate surface. Inert organic or inorganic solvents are utilized to make these polymer. Coating solvent include methanol, isopropyl alcohol, ethyl acetate, acetone, carbon tetrachloride, butyl alcohol, water, etc. Mixture of solvent like methylene chloride-methanol (79:21), acetone-methanol (80:20), etc.

g. Plasticizers

Plasticizers are the substances which used in the formation of coating membrane. It decreases the temperature in the second order phase transition. It is able to change the visco-elastic nature of polymers. Due to the visco-elastic nature the change in permeability is also seen. Examples of it are polyethylene glycol, ethylene glycol monoacetate, triethyl citrate, acetate, propionate, etc.

Classification of Osmotic Drug Delivery System

A. Implantable
1. The Rose-Nelson Pump
2. Higuchi-Leeper Pump
3. Higuchi-Theeuwes Pump
4. Mini Osmotic Pump

B. Oral Osmotic Pump

i. Single Chamber Osmotic Pump

- Elementary osmotic pump

ii. Multi Chamber Osmotic Pump

- Push-Pull Osmotic Pump
- Osmotic pump with non-expanding second chamber

C. Special Types
1. Controlled Porosity Osmotic Pump
2. Osmotic Bursting Osmotic Pump
3. Liquid OROS
4. Delayed Delivery Osmotic Pump
5. OROS-CT
6. Osmotic Pump for Insoluble Drugs
7. Monolithic Osmotic System and OSMAT

A. Implantable Pump

1. The Rose-Nelson Pump-

In 1955, the first osmotic pump was reported by two Australian Physiologist. They were working on the drug delivery to the gut of sheep and cattle. The pump was consists of three compartment one contained drug molecule with orifice, second had salt with elastic diaphragm which contains excess solid salt and third had water chamber (Fig.1). The semipermeable membrane were separates the dug and water compartments. The difference which was created by osmotic pressure, shifts the water to salt chamber. The volume of salt compartment gets increased due to this water flow, which further expands of latex diaphragm, results expulsion of drug from device.

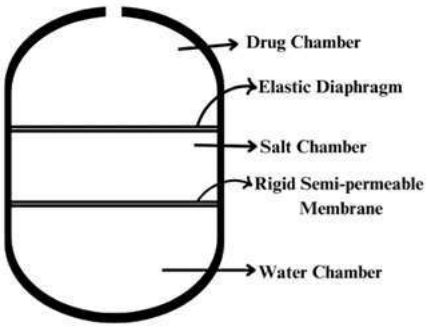

Fig 1. The Rose-Nelson Pump

2. Higuchi-Leeper Pump-

This pump is widely implanted or swallowed in animal body for antibiotic delivery or growth hormones. This pump consists of rigid housing and semi-permeable membrane. A layer of low melting waxy solid, like microcrystalline paraffin

wax was incorporated in between drug and osmotic compartment to separate (Fig. 2). Higuchi-Leeper pump works with pulsatile drug delivery. The pulsatile delivery was created by constructing critical pressure resulting in opening of delivery orifice and drug get released. To achieve the pulsatile drug release drill an orifice in elastic material with can be stretched under osmotic pressure. After attaining critical pressure the orifice get opened results in drug release. Reduced pressure causes closing of orifice. The opening should be small enough to close if threshold osmotic pressure was absent.

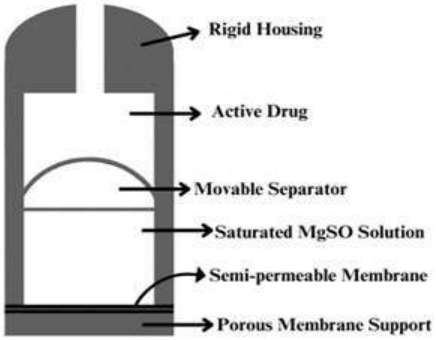

Fig 2. Higuchi-Leeper Pump

3. Higuchi-Theeuwes Pump-

In 1970s, the simple pump design was made by Higuchi and Theeuwes than the Rose and Nelson design. In Higuchi-Theeuwes pump, the outer casing was made by rigid semi-permeable membrane. The outer membrane was a tough enough to hold the developed pump pressure in the pump. Prior to use of pump the specified amount drug is loaded (Fig. 3). When the pump comes in contact with aqueous, drug release mechanism starts following the specific time period set by the used salt material in salt chamber and outer membrane casing permeability.

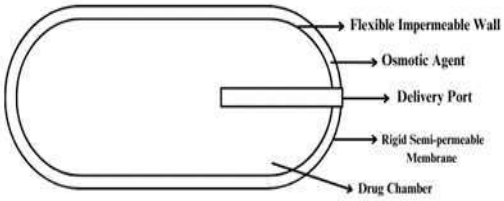

Fig 3. Higuchi-Theeuwes Pump

4. Mini Osmotic Pump-

This mini osmotic pump was early developed by Alza Corp. to study on animal models. This pump consists of three chamber, drug chamber, osmotic sleeves and semi-permeable membrane (to control rate). Flow moderator named component was added to control flow. The drug is kept in the inner chamber surrounded by osmotic sleeves, a chamber containing high concentration of osmotic agent. With the help of semi-permeable membrane, the osmotic sleeves was covered (Fig. 4). When the pump comes in contact with aqueous medium, water enters in osmotic sleeve flowing through semi-permeable membrane, compressing the drug chamber resulting in drug release from flow moderator.

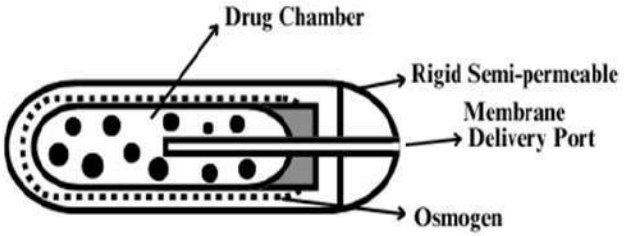

Fig 4. Mini Osmotic Pump

B. Oral Osmotic Pump

i. Single Chamber Osmotic Pump

- **Elementary Osmotic Pump**

In 1974, Theeuwes invented the elementary osmotic pump and consists of active agent which has appropriate osmotic pressure. It is manufactured as tablet, core containing active drug with or without osmogen and coated with semi-permeable membrane. A tiny orifice is made in the membrane coating (Fig. 5). Exposure of tablet to aqueous environment results, tablet soaks the aqueous solution and forms saturated aqueous solution with the active drug inside the device. This formed saturated solution increases the volume in the device. The membrane is non-stretchable, increased volume leads to flow of saturated aqueous solution out of device through the orifice.

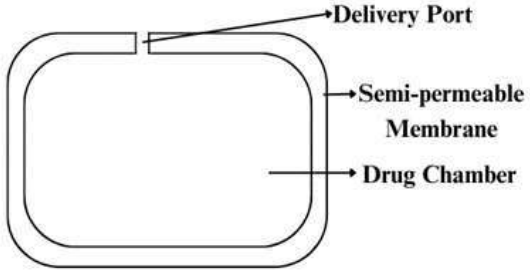

Fig 5. Elementary Osmotic Pump

ii. Multi Chamber Osmotic Pump

- **Push Pull Osmotic Pump**

It is a modified version of elementary osmotic pump. The device is made in two chambers, upper chamber contains active drug, osmotic agents and other excipients. Further, the osmotic agent forms the suspension in situ. The lower chamber contains polymeric osmotic agents. This layer are bonded with tablet compression to make a single bilayer core. The tablet is coated with semi-permeable membrane (Fig. 6). When the device comes in contact with aqueous media, the osmotic attraction pulls aqueous media in the chamber, both chambers soaks the aqueous media. But the lower chamber lack of any orifice it get expanded and pushes the diaphragm to upper drug chamber. The release of drug from orifice in upper chamber takes place. With the help of this device delivery of highly water-soluble drugs and practically water insoluble drugs takes place.

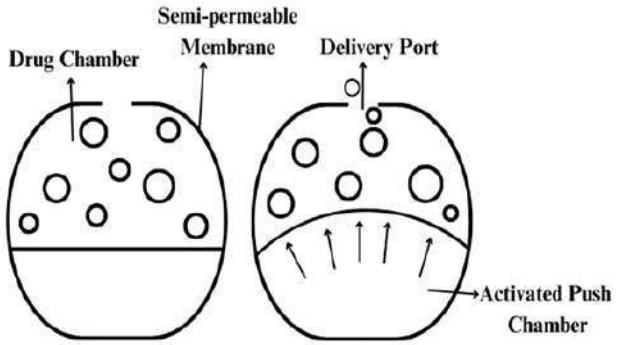

Fig 6. Push Pull Osmotic Pump

- **Osmotic Pump with Non-Expanding second Chamber**

It is a type of multi-chamber device and it consists of non-expanding compartments. This type also contains two sub types depending on second chamber function. One type of devices, second chamber will dilute the drug solution while exiting the device. In this device mechanism, drug must went from second chamber. Aqueous media is drawn osmotically within the chamber either because of drug solution osmotic pressure or second chamber comprises of water soluble diluents (like NaCl). Two rigid chamber form this device, first chamber is comprises of inert osmotic agent (such as sugar or simple salt) and second chamber contains active drug molecule (Fig. 7). Osmotic agent solution made in first chamber goes to drug chamber (second chamber) via connecting hole where it combines together and releases from micro-porous surrounding wall of chamber. Second type of device is for simultaneous delivery of two drugs. Second chamber consists of second active molecule.

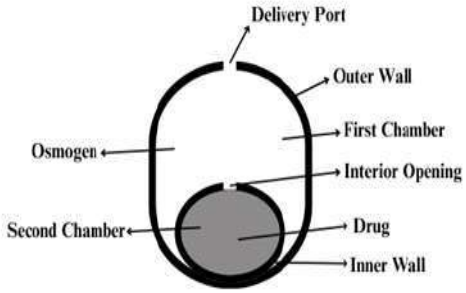

Fig 7. Non-Expanding Second Chamber Osmotic Pump

C. Specific Types

1. Controlled Porosity Osmotic Pump (CPOP)

This type of pump are made either single or multi-chamber dosage form, the drug delivery system consists of active drug molecule in core surrounded by asymmetric structured membrane. This outer membrane is permeable to water whereas impermeable to solute. The wall structure composed of insensitive pore forming excipient (Fig. 8). When this pump is in contact with aqueous media, the coating contains water-soluble excipients resulting in formation of micro-porous membrane (sponge like structure forms). The drug gets out of this micro-porous membrane.

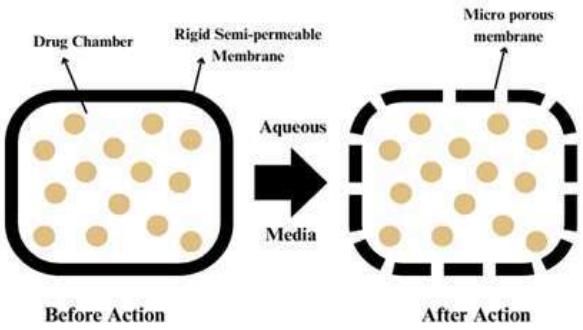

Fig 8. Controlled Porosity Osmotic Pump

2. Osmotic Bursting Osmotic Pump

This device lacks the drug release orifice as well as the size is also smaller. When it comes in contact with aqueous media, water imbibe in and a pressure was created. The formed pressure breaks the device wall and active drug get released to surrounding (Fig. 9).

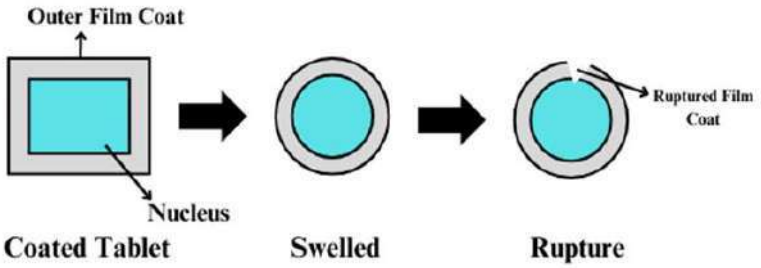

Fig 9. Osmotic Bursting Osmotic Pump

3. Liquid OROS

This device are meant to deliver the liquid dose formulations with extended release as well as high bio-availability benefits. There are three sub-types- a) L OROS Hard Cap, b) L OROS Soft Cap and c) Delayed Liquid Bolus Delivery System. Sub-type a) and b) are produced in order to provide the continuous drug delivery; and "L OROS Delayed Liquid Bolus Delivery system" where prepared to deliver pulse of the liquid drug substance. The c) type contains three layers: A placebo delay layer, a liquid drug layer and an osmotic system. All this three layers are covered with rate controlling semi-permeable membrane (Fig. 10). The orifice for drug release is present at the end of placebo layer. After expansion of osmotic system, firstly the placebo get released and it delays the drug layer release. It can be delayed upto 1 to 10hours, depends on permeability of rate controlling outer semi-permeable membrane as well as placebo layer thickness.

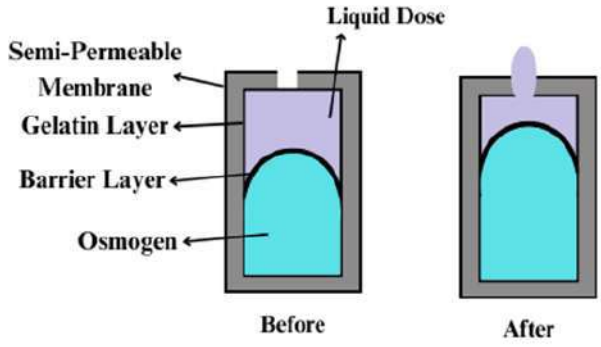

Fig 10. Liquid OROS

4. Delayed Delivery Osmotic Pump

This osmotic system comprises of two compartment, first compartment is loaded with the active drug molecule with orifice for drug release and second compartment have the osmotic system. Both compartments are separated by a wax like material layer. This bilayer tablet, osmotic system is kept in closed end of capsule facing towards closed end as well as barrier is also kept in closed end part but facing towards cap opening. The drug vessel is kept in open end cap. This two parts are compressed to fit together. As it comes in contact with fluid, the osmotic system expands and creates pressure on connected slidable and then on wall parts (Fig. 11). During this delayed time the volume of drug reservoir is kept constant. So, minimal pressure gradient is created. Resulting in delaying the drug release and no drug get released for that particular time period.

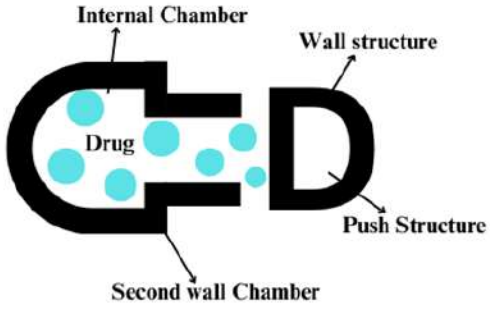

Fig 11. Delayed Delivery Osmotic Pump

5. OROS-CT

OROS-CT (Alza Corp.) made either in single unit osmotic device or in composition of five to six push-pull osmotic units in a hard gelatin capsule. After interaction with gastric fluid the outer covering dissolves but the entry of fluid is prevented by enteric coating. When the capsule reaches small intestine the enteric coating dissolves and the water gets inside the osmotic devise resulting in swelling of push chamber (Fig. 12). At that time, push chamber pushes the active drug to outside of device via orifice at a specified rate. This is controlled system depending on rate of water transport across semi-permeable membrane. This osmotic medication is used as once or twice a day for the colon.

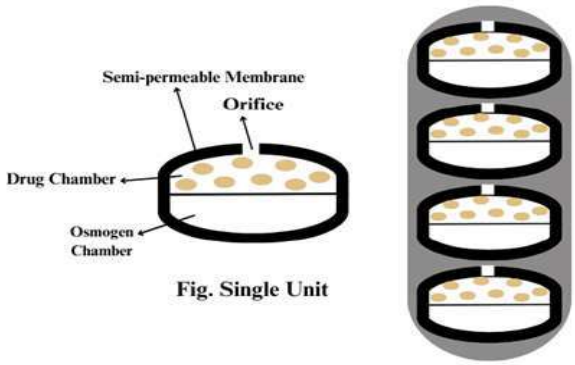

Fig 12. OROS-CT

6. Osmotic Pump for Insoluble Drugs

Those active drugs having poor solubility in water media are dispensed by this osmotic device method. The nucleus of this osmotic device contains the active drug molecule in therapeutic amount. A suitable amount of lipid carrier (water insoluble) are used to suspend the active drug. This lipid carrier should be liquid at room temperature

as well as ensures drug get released from pump. The water-insoluble wall is micro-porous as well as wetted by lipid carrier. The osmogen (e.g. NaCl) is added in melted lipid liquid, then quenched cool to produce lumps. Then this lumps are broken and made in tablets. The micro-porous wall is coated with unheated ambient air at moderate flow (Fig. 13).

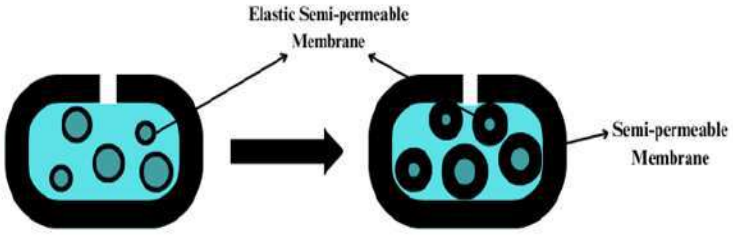

Fig 13. Osmotic Pump for Insoluble Drugs

7. Monolithic Osmotic System

This device system is made by simple dispersion of water-soluble agent within polymer matrix. When this device comes across aqueous media, water gets inside the device and breaks the polymer matrix coating. This results in drug release in outer environment. It has a drawback if the active drug exceed more than 20-30 volumes per liter then this device fails (Fig. 14).

Fig 14. Monolithic Osmotic Pump System

Marketed Products

Trade Name	Active Drug	Design	Dose
Alpress LP	Prazosin	Push-Pull	2.5mg-5mg
Procardia XL	Nifedipine	Push-Pull	30, 60, 90mg
Volmex	Albuterol	Elementary Pump	4mg-8mg
Sudafed 24	Pseudoephedrine	Elementary Pump	30, 60, 120mg
Glucotrol XL	Glipizide	Push-Pull	2.5, 5, 10mg

Advantages

- The drug release mechanism is independent of concentration of drug.
- The blood level are sustained as well as consistent seen in therapeutic window.
- Side effects are reduced.
- Deliveries can be pulsed if desired.
- Drug delivery is independent of gastric pH.
- Bioavailability of drug get enhanced.
- Dose frequency get reduced.
- Patient compliance get improved.
- The safety margin for high potency drugs get increased.
- Formulations are easy.
- It is easy to attain a better release rate than conventional diffusion.

Disadvantages

- Film defect can be seen if the coating process was not done correctly, resulting in dose dumping.
- Expensive.
- Food presence can alter the drug release through osmotic device.
- Recovery of therapy is not possible if unexpected adverse event occurred.
- Tolerance development is rapid.
- Hypersensitivity can be seen after implantation.
- Patient receiving Nifedipine GITS tablet can show gastro intestinal obstruction.
- MRI of tablet shows non-uniform coating further leads to different drug release pattern.

CONCLUSION

This challenging era requires novel approaches to cure the diseases. This osmotic drug delivery system have an impact in curing the various diseases. It is a reliable controlled drug release system. It also allows targeted delivery of active drug agents. It also gives edge to modification as per requirement. It has a wide scope in future.

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