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A Review on The Osmotic Drug Delivery System



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ABSTRACT

Traditional drug delivery methods have little control over drug release and essentially none over the concentration that is successfully achieved at the target site. This kind of dosing pattern may result in continuously varying, random plasma concentrations. Many innovative methods have been developed for controlling drug release. One among them is the Controlled Porosity Osmotic Pump (CPOP). It is the best approach for developing controlled-release dosage form. It is most reliable and employed as oral drug delivery system. About 75 years after the discovery of the principle of osmosis, the drug delivery systems were clearly designed.

INTRODUCTION

Oral drug administration is the most preferred and common route for existing and new drug delivery The simplicity of its administration may be the cause. Although, sometimes it also entails with certain major disadvantages such as first-pass metabolism, gastrointestinal enzymatic degradation, and poor bioavailability. The sustained/controlled medication delivery method was developed to address the previous disadvantages of the traditional dose form.

Drugs can be delivered in a controlled prototype over a long period by the controlled or altered release drug delivery systems. They contain dosage forms for oral and transdermal organization as well as injectable and implantable systems. For most of drugs, oral route remains as the most satisfactory route of administration.

Development of an extended-release dosage form also requires sensible absorption throughout the gastro-intestinal tract (GIT). Among the obtainable techniques to improve the bioavailability of these drugs production osmotic drug delivery system is the most appropriate one^[27].

The drug is delivered in a controlled manner with controlled porosity osmotic pumps. Osmotic drug delivery system is a significant advancement for oral NDDS[.] A better pattern of delivery is to deliver the drug from sustain release system which releases at slow rate throughout the delivery period. Several advancements have been made in development of new drug delivery. They are Capable of controlling rate of drug delivery, Sustaining the duration of therapeutic activity and Targeting the delivery of drugs to tissues.

OSMOTIC DRUG DELIVERY SYSTEM

In the osmotic Controlled drug delivery system, the osmotic pressure is employed as the driving force to release the therapeutic agent in a controlled way. Osmotic drug delivery system consists of a tablet core that is coated with a semipermeable membrane that has an orifice drilled. Therapeutic agents can be effectively delivered in a controlled pattern over a long period of time.

PRINCIPLE OF OSMOSIS

Osmosis is the process of moving a solvent over a semi-permeable membrane from a solute

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with a lower concentration to one with a higher concentration. Pfeffer measured the effect by utilizing a membrane that is selectively permeable to water but impermeable to sugar.

The membrane separated sugar solution from pure water. When a pressure p was applied to the sugar solution, Pfeffer saw a flow of water into the solution stop. According to Pfeffer's theory, the sugar solution's osmotic pressure varies in direct proportion to the solution's concentration and absolute temperature.

Van't Hoff developed the term to establish the similarity between the ideal gas laws and the Pfeffer findings.

$\pi = n2RT$

Where n2 represents the molar concentration of sugar (or other solute) in the solution,

R - Gas constant, T - Absolute temperature

If the semipermeable membranes are ideal and the solute concentrations are low, then this equation remains true.



Fig.1: principle of osmosis

History of osmotic drug delivery system:

The Australian Scientists Rose and Nelson were initiators of the delivery of osmotic drugs^[26]. A three-chamber implantable pump with a drug chamber, a salt chamber containing extra solid salt, and a water chamber was created in 1955. In 1975 there was the introduction of the elementary osmotic pump for oral drug delivery.

The pump consists of an osmotic core that contains the drug and is encircled by a membrane that is only partially permeable. When this pump is exposed to water, the core osmotically absorbs water at a regulated rate, defined by the water permeability of the membrane and the core formulation osmotic pressure.

Since the membrane cannot be expanded, the increase in volume caused by water imbibition leads to the development of hydrostatic pressure within the tablet. This pressure is eased through the delivery orifice by the flow of saturated solution out of the device. The development of implanted osmotic pumps in the 1970s marked a significant advance in the administration of several drugs and hormones.

ADVANTAGES

The release of drugs from controlled porosity osmotic pump tablets follows zero-order kinetics^[25].

Pulsatile and delayed release are observed in the osmotic drug delivery system.

The drug delivery provides a high degree of in vitro in vivo correlation.

The delivery rate of drugs can be predicted and programmed in CPOP systems.

Some osmotic systems are no need of laser drilling to create holes ex.CPOP

Reduced interpatient variability.

Increased safety margin of high potency drugs.

With osmotic tablets that simulate a liquid dose form made on-site, the medicine is delivered in solution form and is ready for absorption.

The osmotic system is independent of pH and other physiological factors.

The rise of drug concentration in the blood can be reduced by this system.

They maintain sustained and consistence blood levels within the therapeutic window.

It gives enhanced bioavailability.

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LIMITATIONS

If the coating is not even it causes film defects resulting in dose dumping.

The medicine cannot be retrieved if unanticipated side effects occur.

If drilling is required, it is costly.

The size of the pore is important in various osmotic drug delivery techniques.

It is challenging to preserve the drug's uniformity and integrity.

Osmotic tablet formulations require inert components.

Special equipment are necessary for drilling orifices except for CPOP.

Rapid development of tolerance is seen.

The osmotic tablets cannot be crushed or chewed.

COMPONENTS USED IN THE FORMULATING OF OSMOTIC PUMPS

1.Semipermeable Membrane:

Any polymer that is permeable to water but impermeable to solute can be used since the membrane in osmotic systems is semipermeable by nature. For the creation of osmotic pumps, cellulose acetate is a semipermeable polymer that is frequently used. It comes in a variety of acetyl content grades.

Particularly, acetyl content of 32% and 38% is widely used. The degree of substitution (DS), or the typical number of hydroxyl groups on the anhydroglucose unit of the polymer replaced by the substituting group, is a measure of acetyl content. Cellulose esters like cellulose acetate, cellulose diacetate, cellulose triacetate, cellulose propionate, cellulose acetate butyrate, and cellulose ethers like ethyl cellulose are some of the polymers that can be utilized for the reason stated above^[24].

Apart from cellulose derivatives, some other polymers such as agar acetate, amylose triacetate, beta-glucan acetate, poly (vinyl methyl) ether copolymers, poly(orthoesters), poly acetals and selectively permeable poly (glycolic acid), Eudragit and derivatives of lactic acid

can be utilized to create semipermeable films. The choosing of semipermeable polymers must take consideration of their permeability.

2. Hydrophilic and Hydrophobic Polymers:

These polymers are used to formulate osmotic systems to make drugs that contain the core of the matrix. The extremely water-soluble compounds can be concentrated in hydrophobic matrices, and moderately water-soluble compounds can be concentrated in hydrophilic matrices for more controlled release^[23]. Mixtures of hydrophilic and hydrophobic polymers were commonly used in the formulation of water-soluble drug osmotic pumps. The selection is dependent on the drug's solubility and the amount and rate of the drug to be released from the pump. The polymers are either swellable or non-swellable in nature. In the pumps containing relatively water-soluble drugs, swellable polymers are mostly used. Because of their swelling nature they increase the hydrostatic pressure inside the pump, the non-swellable polymers are used for highly water-soluble drugs. Ionic hydrogels such as sodium carboxy methyl cellulose are usually used due to their osmogenic property. Through integrating these polymers into the formulations, more precise controlled release of drugs can be achieved.

3. Wicking Agents:

A substance that can draw water into a delivery device's porous structure is referred to as a wicking agent. To enhance the drug's surface area in contact with the incoming aqueous solution, wicking agents are used^[22]. Increased drug release from the drug's orifice is made possible by the application of wicking agents. Both swellable and nonswellable substances can act as wicking agents. They are distinguished by their capacity for physisorption with water. Through Van der Waals interactions between the surface of the wicking agent and the adsorbed molecule, physisorption is a type of absorption in which the solvent molecules may only gently hold to the surfaces of the wicking agent. The function of the wicking agent is to carry water to surfaces inside the core of the tablet, thereby creating channels or a network of increased surface area.

4. Solubilizing Agent[:]

Highly water-soluble drugs would demonstrate a high release rate of zero order for the osmotic drug delivery system. Therefore, the majority of drugs with limited intrinsic water

solubility are poor candidates for osmotic distribution. Drug solubility can be adjusted in the core, too. The solubility of the drug is greatly increased by adding solubilizing agents to the core tablet.

5. Osmogens:

Osmogens are an essential ingredient of the osmotic formulations. Osmogens are dissolved in biological fluid when it enters the osmotic pump through a semipermeable membrane. This causes an increase in osmotic pressure inside the pump and forces the medication out through the delivery orifice. They include inorganic salts and carbohydrates^[21]. Mannitol, sodium chloride, and potassium chloride are the three most common osmogens. To produce the ideal osmotic pressure inside the system, mixtures of osmogens are often utilised.

6.Surfactants:

Surfactants are a very valuable addition to the wall-forming substance. They produce an integral composite that can be used to make the device's wall operational. To enhance the materials' mixing into the composite during the drug release period and maintain their integrity in the usage environment, the surfactants function by controlling the surface energy of the components. The composition also includes glycerol (sorbitan oleate, stearate, or laurate), polyoxyethylene glyceryl ricinoleate, polyoxyethylene castor oil including ethylene oxide, and glyceryl laurates.

When applied to a substance that forms walls, surfactants are very helpful. They create an integrated composite that helps activate the device's wall. To enhance materials' blending into the composite and maintain their integrity in the environment of use during the drug release phase, surfactants work by controlling the surface energy of the components^[20].

Typical surfactants such as poly oxyethylene glyceryl ricinoleate, polyoxyethylenated castor oil having ethylene oxide, glyceryl laurates, and glycerol (sorbitol oleate, stearate, or laurate) are incorporated into the formulation.

7. Coating Solvents:

Inert inorganic and organic solvents that are not harmful to the core and other materials are among the solvents that are ideal for creating the polymeric solution that is utilized to manufacture the wall of the osmotic device. Methylene chloride, acetone, methanol, ethanol,

isopropyl alcohol, butyl alcohol, ethyl acetate, cyclohexane, carbon tetrachloride, and water are examples of common solvents. Acetone-methanol (80:20), acetone-ethanol (80:20), acetone-water (90:10), methylene chloride-methanol (79:21), and methylene chloridemethanol-water (75:22:3) are some examples of the solvent mixes that can be employed.

8. Plasticizers

Plasticizers or low molecular weight diluents are frequently used in pharmaceutical coatings to alter the physical properties of polymers and enhance their capacity to form films. Plasticizers can change the elastic behavior of polymers significantly^[18]. Plasticizers can turn a hard and brittle polymer into a softer, more pliable material, and possibly make it more resistant to mechanical stress. Plasticizers enhance the workability, flexibility, and permeability of the coating solvents while also lowering the temperature of the second-order-phase transition of the wall or the elastic modulus of the wall. In general, 100 parts of costing materials include 0.001 to 50 parts of a plasticizer or a combination of plasticizers.

Semipermeable membranes are made with PEG-600, PEG-200, triacetin (TA), dibutyl sebacate, ethylene glycol monoacetate, ethylene glycol diacetate, triethyl phosphate, and diethyl tartrate as plasticizers.

9. Pore-Forming Agents

These substances are especially utilised in the creation of multiparticulate or controlled porosity osmotic pumps as well as pumps designed for medications that are not easily soluble in water. These pore-forming agents cause the formation of microporous membranes ^{[17].}

A pore-former can build the microporous wall in place by leaching it while the system is in use. The pore-formers may be solid, liquid, or inorganic in composition. For example, alkaline metal salts such as sodium chloride, sodium bromide, potassium chloride, potassium sulfate, potassium phosphate, and so forth, alkaline earth metals such as calcium chloride and calcium nitrate^[15]. As pore-forming agents, diols and polyols such poly hydric alcohols, polyethylene glycols, and polyvinyl pyrrollidone can be utilised together with sugars including sucrose, glucose, fructose, mannose, lactose, sorbitol, and mannitol^[16]. To make pores in the membrane, triethyl citrate (TEC) and triacetin (TA) are also used. With the addition of HPMC or sucrose, membrane permeability to the medication is significantly boosted.

CLASSIFICATION OF OSMOTIC DRUG DELIVERY SYSTEM^[14]

Implantable:

The Rose Nelson pump

Higuchi Leeper pump

Higuchi- Theeuwes pump

Mini Osmotic Pumps

Oral Osmotic pump:

Single chamber osmotic pump

Elementary osmotic pump

Multi-chamber osmotic pump:

Push-pull osmotic pump

Osmotic pump with non-expanding second chamber

Sandwiched osmotic tablets

Specific types:

Controlled porosity osmotic pump.

Monolithic osmotic systems.

Osmotic bursting osmotic pump.

Liquid Oral Osmotic System

Asymmetrical Membrane Osmotic Tablet

Self-Emulsified Osmotic Tablet

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Novel Technologies:

Osmodex® Technology

Duros Technology

Table 1: osmotic pressure for different compounds

s.no	OSMOGEN	OSMOTIC PRESSURE
1.	Sodium chloride	356
2.	Fructose	355
3.	Potassium chloride	345
4.	Sucrose	150
5.	Xylitol	104
6.	Sorbitol	84
7.	Dextrose	82
8.	Citric acid	69
9.	Tartaric acid	67
10.	Mannitol	38

Table no: 2 osmotic pressures for combined osmogen

s.no	COMBINED OSMOGEN	OSMOTIC PRESSURE
1.	Lactose – fructose	500
2.	Dextrose – fructose	450
3.	Sucrose – fructose	430
4.	Lactose – dextrose	225
5.	Mannitol – lactose	130

1.Rose and nelson pump

The Australian Researchers Rose and Nelson invented osmotic medication delivery. For the administration of medications to the sheep and bovine abdomen, they created an implanted pump in 1955^[12].

Three chambers make up the Rose-Nelson implantable pump: a medication chamber, a salt chamber that contains solid salt, and a water chamber. The salt from the water chamber is separated by a semipermeable barrier. The difference in osmotic pressure across the membrane affects how much water moves from the water chamber to the salt chamber^[13]. The rubber diaphragm separating the salt and drug chambers is stretched, theoretically increasing the volume of the salt chamber, which finally causes the drug to be pushed out of the device.



Fig.2: RoseNelson Pump

2. Elementary Osmotic Pump

In 1974 Theuwes invented an elementary osmotic pump. Using an osmotic mechanism to administer the medicine at a regulated pace, the elementary osmotic pump is a revolutionary drug delivery technology. Within this system's semipermeable membrane, there is an osmotically active substance. Using a tableting machine, a medication with an appropriate osmotic pressure is compressed into a tablet to create the device. The tablet is then coated with a semi permeable membrane, usually cellulose acetate, and a small hole is drilled through the membrane coating. The drilling may be done by mechanical drilling, laser drilling.

The water permeability of the semipermeable membrane and the osmotic pressure of the core formulation influence the rate at which the core imbibes water when the dosage form is exposed to an aqueous environment. The amount of solvent taken in equals the amount of saturated medication solution that is given. As long as there is an excess of solid inside the device, the rate of solute delivery by the system remains constant. However, as the concentration falls below saturation, the rate parabolically declines towards zero order and the solute is released at a regulated rate from the delivery orifice in the membrane. Although the Elementary Osmotic Pump Devices (EOP) release 60–80% of the medicine at a constant rate, there is typically a lag period of 30–60 minutes as the system hydrates before zero order distribution from the system starts. These delivery methods are appropriate for medicines with moderate water solubility.



Fig.3:Elementary Osmotic Pump

3. ALZET Osmotic Pump

It is an implantable pump used for research in mice, rats, and other laboratory animals. Without the need for regular handling or external connections, these infusion pumps give medicines, hormones, and other test agents continuously at regulated rates for one to six weeks^[11]. They don't require frequent night or weekend dosing because they operate unsupervised. By using osmotic displacement, ALZET pumps work. An empty reservoir within the core of the pump is filled with the drug or hormone solution to be delivered. ALZET pump can be given through intravenous, intracerebral, or intra-arterial infusion with the help of catheter.



Fig.4: Alzet osmotic pump

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It can be used for targeted drug delivery to localize the drug effect. The liver, spinal cord, spleen, wound healing sites, and organ or tissue transplants are just a few examples of specific organs or areas where it is utilized to administer the medicine. Hundreds of various molecules, including antibodies, chemotherapeutic medicines, cytokines, growth factors, hormones, and peptides, have been effectively delivered using ALZET pumps.

4. Push Pull Osmotic Pump

A modified EOP is push-pull osmotic pump. At constant rate it can deliver both poorly soluble as well as highly water-soluble drugs. It is similar to the bilayer coated tablet in which first layer contain drug in polymeric formulation, osmotic agents and additives. This polymeric osmotic agent can form a suspension of drug in an appropriate position^[10]. When this upper layer absorbs water the other layer contains polymeric formulation, osmotic agents and additives. Afterwards all the layers are bind and pressed together to get a single layer. Then coating was applied and then drilling was done.



Fig.5: push pull osmotic pump

5. Sandwiched Osmotic Tablets (SOTS):

It consists of two drug layers with two delivery orifices placed between a polymeric push layer. The SOTS can be used for medications that are likely to locally irritate the stomach mucosa^[9]. When placed in an aqueous environment, the middle push layer, which contains the swelling agent, expands and the drug is released from the two orifices located on opposite sides of the tablet.



Fig.6: sandwiched osmotic pump

6.Osmotic Pump with Non-Expanding Second Chamber:

The second category of multi-chamber devices comprises a system containing a nonexpanding second chamber. The purpose of the second chamber allows for the division of this group into two subgroups. In one category of these devices, the second chamber is used to dilute the drug solution leaving the devices. This is helpful because in some situations, if the drug exits the oral osmotic devices with a saturated solution, GI tract discomfort is a possibility^[8]. Two rigid chambers make up this sort of device; the first chamber holds a physiologically inert osmotic agent, such as sugar or a simple salt like sodium chloride, while the second chamber houses the medicine. Through the semi-permeable membrane enclosing the chamber, water is pulled into it when in operation. The osmotic agent solution that was created in the first chamber then travels through the connecting hole to the drug chamber, combines with the drug solution there, and then leaves via a microporous membrane that is a component of the wall enclosing the chamber. Insoluble drugs can be delivered by this device^[9].



Fig.7: Osmotic Pump with Non Expanding Second Chamber:

7.Osmotic Bursting Osmotic Pump

The only difference between this system and an EOP is that there is no delivery orifice, and the size could be smaller^[6]. When it is placed in an aqueous environment, water is imbibed and hydraulic pressure is built up inside until the wall ruptures and the content are released to the environment^[7]. Varying the thickness as well as the area of the semipermeable membrane can control release of drug. Pulsatile release can be achieved by this system.

8. Controlled Porosity Osmotic Pump:

The pump can be made in single or multi-purpose dosage form, in either form, the delivery system consists of a core of the drug surrounded by a membrane with an asymmetric structure. The membrane consists of a phase inversion process controlled by a mixed solvent system evaporation Membrane is water-permeable, but it is impermeable to solutions and insensitive pore-shaping additives that are spread across the surface.



Fig.8: controlled porosity osmotic pump

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Low water-soluble additive amounts are leached from polymer products that were waterpermeable but remained insoluble when exposed to water. The sponge-like structure that was created as a consequence had walls with regulated porosity and was largely permeable to both water and pharmacological ingredients that had been dissolved^[5]. The permeability of the semi-permeable membrane to water, the coating thickness, the amount of soluble components, the solubility of the drug in the tablet core, and the difference in osmotic pressure across the surface all affect how quickly these systems release substances. However, these systems are not affected by the pH or agitation of the release medium, the rate at which drugs are released, or the osmotic pressure. All these variables are under the designer's influence and do not differ under physiological conditions, resulting in the above-mentioned robust results.

The rate of flow of water into the device can be given as

$$dv/dt = Ak / h (Dp-DR)$$

Where k = Membrane permeability,

A = Area of the membrane,

Dp = Osmotic pressure difference,

DR = Hydrostatic pressure difference.



Fig.9: controlled porosity osmotic pump

9.Effervescent Osmotic Tablet (EOT)

This technique involves fusing gassy compounds with the medication. This compound reacts with the acid which is present in the outside atmosphere. Carbon dioxide is produced as a result. This gas increases in volume, disperses the precipitated medication, and stops the

aperture from being blocked. The drugs having poor solubilility at small pH are precipitated in the gastrointestinal pH where they block the delivery aperture, so this method is used for those drugs.

10. Monolithic Osmotic System:

The monolithic osmotic system consists of a simple dispersion of water-soluble agent in the polymer matrix. The drug particles are encapsulated by polymers. The water imbibition by the active agents occurs when the system comes into contact with the aqueous environment, rupturing the polymer matrix capsule encapsulating the medication and releasing it to the outside environment^[4]. Initially, this process occurs at the outer environment of the polymeric matrix, but gradually proceeds towards the interior of the matrix in a serial fashion. This system follows zero order kinetics. The principle energy is osmotic pressure.



Fig.10: monolithic osmotic pump

11.Colon Targeted Oral Osmotic System (OROS-CT)

This system can use for once or twice a day formulation for targeted delivery of drugs to the colon. For targeted colonic medication administration, the device is coated with 5–6 enteric coatings and push–pull osmotic units contained in hard gelatin capsules. When the outer shell of a gelatin capsule dissolves after coming into touch with GI fluids, the outer shell of the system inhibits the entrance of fluid from the stomach and it dissolves after entering the intestine. The push compartment and core will enlarge as a result of the water ingestion. The flowable gel is created simultaneously and is pushed out of the delivery aperture at an appropriate speed.



Fig.11: Colon Targeted Oral Osmotic System

12.Liquid Oral Osmotic System

With this design, liquid drug administration offers a high rate and extent of absorption as well as the benefits of a longer release. A liquid drug formulation that is self-emulsifying and lipophilic is considered desirable for this system. An osmotic push layer is enclosed by a semi-permeable membrane. This design, which comes in three variations (hard cap, soft cap, and delayed liquid bolus), is modeled after a drug layer. After being exposed to an aqueous environment, water ingestion activates the osmotic agent layer. This expands the push layer, and hydrostatic pressure pushes the drug out of the device's system. Alza designs these systems. This system increases the permeation ability of drugs.



Fig.12: Liquid Oral Osmotic System

13. Multiparticulate Delayed-Release System:

In this system, pellets containing pure drugs with or without osmotic agent are coated with a semipermeable membrane like cellulose acetate^[3]. When this system interacts with an aqueous environment, water penetrates into the core and creates a saturated solution of soluble components. The osmotic pressure gradient causes a water inflow, which causes the membrane to expand quickly and the holes to develop. The release of osmotic ingredients and the drug through these pores tends to follow zero-order kinetics. Schultz and Kleinebudde studied, lag time and dissolution rates which are dependent on the coating level and osmotic properties of the dissolution medium.

14.Self Emulsified Osmotic Tablet:

Self emulsifying system improves the bioavailability of drug, controls release rate and make the plasma concentrations more stable by self emulsifying agent^[2]. It emulsifies the hydrophobic drugs.

In the case of slightly soluble or practically insoluble drugs, self-emulsifying agents have been added to the tablet-core composition. About 40% drugs are available which are poorly aqueous solubility.



Fig.13: Self Emulsified Osmotic Tablet

15.Telescopic Capsule for Delayed Release:

This device consists of two chambers, the first chamber contains the drug and an exit port,

and the second contains an osmotic engine. The two sections are separated by wax-like materials. To assemble the delivery device, the desired active agent is placed into one of the sections by manual or mechanical fill mechanism.

The convex osmotic layer of the bilayer tablet with the osmotic engine is pointed into the closed end of the cap, the barrier layer into the closed end of the cap, and the barrier layer is exposed towards the cap opening. The tablet is then inserted into the finished cap section of the capsule ^[1]. The cap, osmotic bilayer tablet, and vessel are all pushed together until they securely fit together. The open end of the filled vessel is inserted into the open end of the cap. The osmotic engine expands and applies pressure to the linked first and second wall portions when fluid is ingested into the device. A slight pressure differential between the environment of use and the interior of the reservoir occurs because the volume of the reservoir holding the active substance is maintained constant during the delay period. Since little surrounding fluid is flowing through the reservoir as a result of the pressure there, no agent is being administered for the time being.



Fig.14: Telescopic Capsule for Delayed Release

16.Osmotic Matrix Tablet (OSMAT):

This sort of system makes use of the hydrophilic polymer's swelling characteristic, which causes the material to expand and gel in an aqueous environment, generating an in-place semipermeable barrier. The addition of osmogent to a matrix delivery system has an impact on the system's release. OSMAT is a low-cost technique that delivers drugs without agitation.



Fig.15: Osmotic Matrix Tablet

CONCLUSION

Osmotic systems are the most reliable controlled drug delivery systems (CDDS) and can be employed as oral drug delivery systems. Osmotic pressure is used as the driving force for these systems to release the drug in a controlled manner. Osmotic drug delivery system can be a promising tool in oral drug delivery. Controlled porosity osmotic can be used for designing various formulations containing the osmotic agent, pore former and ratecontrolling membrane. Optimization of these parameters can control the release of drugs as per the period require. By using this technique, the release may be pulsed for the specific time in chronotherapy.

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