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Oral Osmotic System: A Review

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ABSTRACT: Osmotic devices are the most likely strategy based system for controlled delivery of drug. The osmotic-controlled release oral delivery system, OROS, is an advanced drug delivery technology that uses osmotic pressure as the driving force to deliver pharmacotherapy. Oral route is one of the most extensively used routes of drug administration because of its obvious advantages of ease of administration, improved patient compliance and convenience**.**Drug can be delivered in a controlled over a long period of time by the process of osmosis. Osmotic pump offers much compensation over other controlled release devices. In this paper, various type of osmotically controlled pump with basic component and factor affecting has been discussed briefly

KEY WORDS: Osmotic pump, Controlled drug delivery, OROS.

I. INTRODUCTION:

Oral drug delivery is the most preferred and convenient choice for medicine. Drug delivery research continues to find new therapies for the prevention and treatment of existing and new diseases. So, a valuable role is played by drug delivery system by providing optimized products for existing drugs in terms of either enhanced or improved presentation of drug to the systemic circulation [1, 2].

Osmotic drug-delivery systems suitable for oral administration typically consist of a compressed tablet core that is coated with a semipermeable membrane coating. This coating has one or more delivery ports through which a solution or suspension of the drug is released over time.The core consists of an osmotic agent and a water swellable polymer. The rate at which the core absorbs water it depends on the permeability of the membrane coating. As the core absorbs water, it expands in volume, which create osmotic pressure that results into the release of drug through the orifice.

Advantages of osmotic drug delivery systems [3, 4]

1. The delivery rate of zero-order is achievable with osmotic systems.
2. Delivery may be delayed or pulsed, if desired.
3. Higher release rates are possible with osmotic systems compared with conventional diffusion-controlled drug delivery systems.
4. The release rate is highly predictable and can be modulated by release control parameters.
5. The release of drug is independent of gastric pH and hydrodynamic conditions.
6. A high degree of in vivo- in vitro correlation (IVIVC) is obtained constant, at least in terms of the amount required for activation and controlling osmotically base technologies.

Factors that influence the design of OCDDS:

Delivery orifice: This system contains at least one orifice in the membrane for drug release. The size of delivery orifice must be optimized in order to control the drug release. Optimum orifice diameter is in the range of 0.075-0.274 mm. Orifice can be creat by mechanical drill, laser drill and modified upper punches. [5].

Drug Solubility [6]: The release rate depends on the solubility of the drug inside the core. Therefore, drugs should have sufficient solubility to be delivered by osmotic delivery. In the case of low solubility compounds, several alternate strategies may be employed. The drug solubility can be modified by compression of the drug with other excipients, which improve the solubility.

Osmotic pressure: The osmotic pressure (π) directly affects the release rate. To achieve a zero-order release rate, it is essential to keep (π) constant by maintaining a saturated solute solution. Many times, the osmotic pressure generated by the saturated drug solution may not be sufficient to achieve the required driving force. In this case, other osmotic agents are added that enhance osmotic pressure [7].

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Osmogens	Osmotic pressure (atm)	Osmogens	Osmotic pressure(atm)
Lactose-fructose	500	Potassium chloride	245
Dextrose-fructose	450	Lactose-dextrose	225
Sucrose-fructose	430	Mannitol-sucrose	170
Mannitol-fructose	415	Sucrose	150
Sodium chloride	356	Dextrose	82
Fructose	335	Mannitol	38

Table no 1: Osmotic pressure of common mixture

Principle of osmotic drug delivery system:

It is based on the principle of osmotic pressure. Osmotic pressure is a colligative property, which is dependon concentration of solute that contributes to osmotic pressure. Solutions of different concentrations having the same solvent and solute system show an osmotic pressure proportionate to their concentrations.Thus, a constant osmotic pressure, and a constant influx of water can be achieved by an osmotic drug delivery system. This results a constant zero order release rate of drug. The rate of drug release from osmotic pump depends on the osmotic pressure of the core and the drug solubility.

Materials used in formulation of osmotic pumps:

- **Semipermeable Membrane:** Since the membrane in osmotic systems is semipermeable in nature, any polymer that is permeable to water but impermeable to solute can be selected.Cellulose acetate is a commonly employed for the preparation of osmotic pumps. Some other polymers are also used e.g.,cellulose esters such as cellulose acetate, cellulose diacetate, cellulose triacetate, cellulose propionate, cellulose acetate e-butyrate, and ethyl cellulose. Apart from this, agar acetate, amylose triacetate, beta-glucan acetate, poly (vinyl methyl) ether copolymers, poly acetals and selectively permeable poly(glycolic acid), poly(lactic acid) derivatives, and Eudragits can be used as semipermeable film-forming materials[7] .
- **Hydrophilic and Hydrophobic Polymers:** These polymers are used in the formulation development of osmotic systems for making drug containing matrix core. The highly water soluble compounds can be co-entrapped in hydrophobic matrices and moderately watersolublecompounds can be co-entrapped in hydrophilic matrices to obtain more controlled release. Generally, mixtures of both hydrophilic and hydrophobic polymers have been used in the development of osmotic pumps of water-soluble drugs. The selection is based on the solubility of the drug. The polymers are of either swellable or non-swellable nature. Mostly, swellable polymers are used for the moderately water-soluble drugs.
- **Wicking Agents:** It is a material with the ability to draw water into the porous network of a delivery device. They are those agents which help to increase the contact surface area of the drug with the incoming aqueous fluid. The use of the wicking agent helps to enhance the rate of drug released from the orifice of the drug. A wicking agent is of either swellable or non-swellable nature[8].
- **Solubilizing Agents:** For osmotic drug delivery system, highly water-soluble drugs would demonstrate a high release rate that would be of zero order. Addition of solubilizing agents into the core tablet dramatically increases the drug solubility. Non-swellable solubilizing agents are classified into three groups,

(i) Agents that inhibit crystal formation of the drugsby complexation with the drugs (e.g., PVP, (PEG 8000) and βcyclodextrin),

(ii) A micelle-forming surfactant with high HLB value, particularly non-ionic surfactants (e.g., Tween 20, 60, and 80, polyoxyethyle and long-chain anionic surfactants such as SLS),

(iii) Citrate esters (e.g., alkyl esters particularly triethyl citrate) and their combinations with anionic surfactants.

- **Osmotic agents:** They are used for generation of osmotic pressure.
- **Surfactants:** Surfactants are particularly useful when added to wall-forming material. They produce an integral composite that is useful for making the wall of the device operative. The surfactants act by regulating the surface energy of materials to improve their

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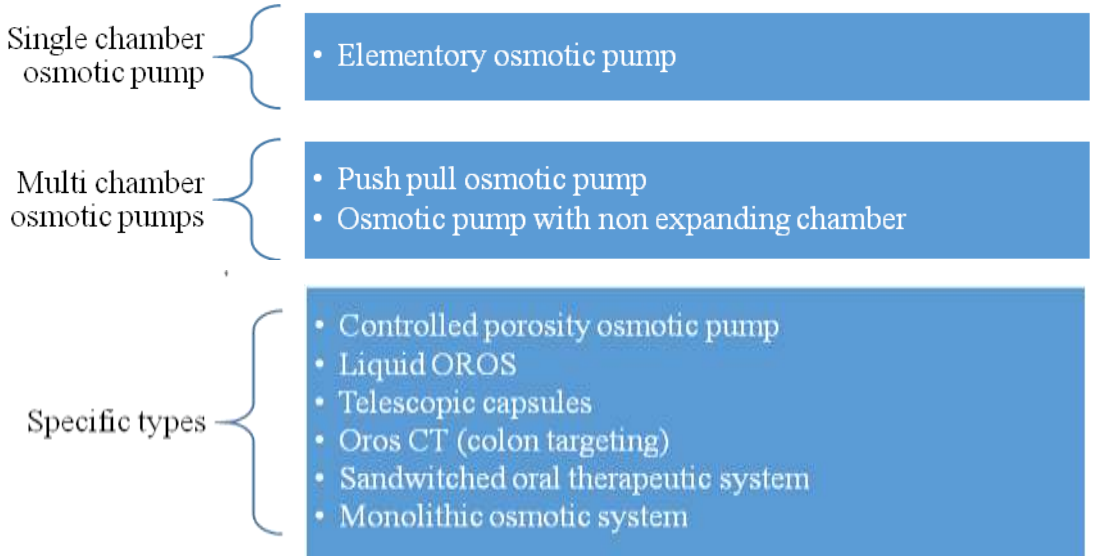
blending into the composite and maintain their integrity in the environment of use during the drug release period.

- **Plasticizers:** In pharmaceutical coatings, plasticizers, or low molecular weight diluents are added to modify the physical properties and improve film-forming characteristics of polymers. Plasticizers can change visco elastic behavior of polymers significantly. They can turn a hard and brittle polymer into a softer, more pliable material, and possibly make it more resistant to mechanical stress [9]
- **Pore-Forming Agents:** These agents are particularly used in the pumps developed for poorly water-soluble drugs. These agents cause the formation of microporous membrane.The pore-formers can be inorganic or organic and solid or liquid in nature.

Classification of osmotic pump:



- **Single chamber elementary osmotic pump:** Elementary osmotic pump (EOP), was first described by Theeuwes in 1975.It delivers the active agent by an osmotic process at a controlled rate. The tablet consists of an osmotic core containing the drug which is surrounded by a semipermeable membrane laser drilled with delivery orifice [10]. Following ingestion, water is immersed into the system dissolving the drug, and the resulting drug +osmogene solution that will create pressure and results into the drug release from the orifice. The drawbacks of the elementary pump are that it is only suitable for the delivery of watersoluble drugs. They allow zero order delivery of drug.

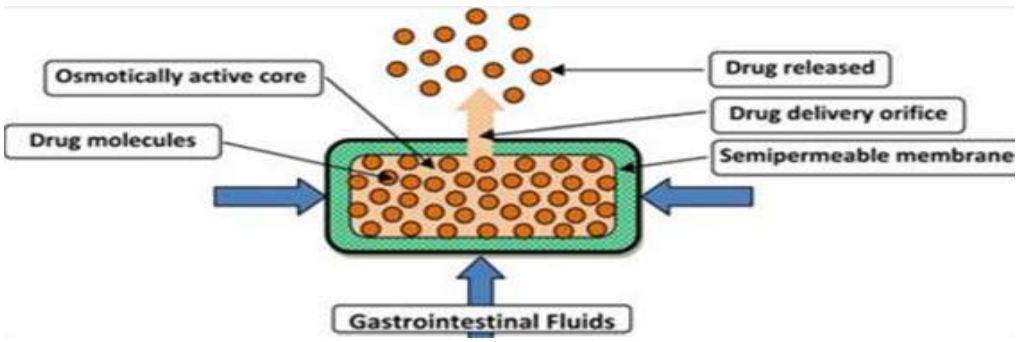


Figure no.1: Elementary Osmotic Pump

- **Multi chamber push pull osmotic pump:** It is a bi-layered tablet which is coated with a semipermeable membrane. Drug osmogentsis present in the upper section & lower section

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consists of polymeric osmotic agent. A delivery orifice is drilled on the drug side of the tablet. When the system comes in contact with the gastric fluids, polymeric osmotic layer swells and pushes the drug layer thereby delivering the drug in the form of a fine dispersion through the orifice. They allow zero order delivery of drug [11]

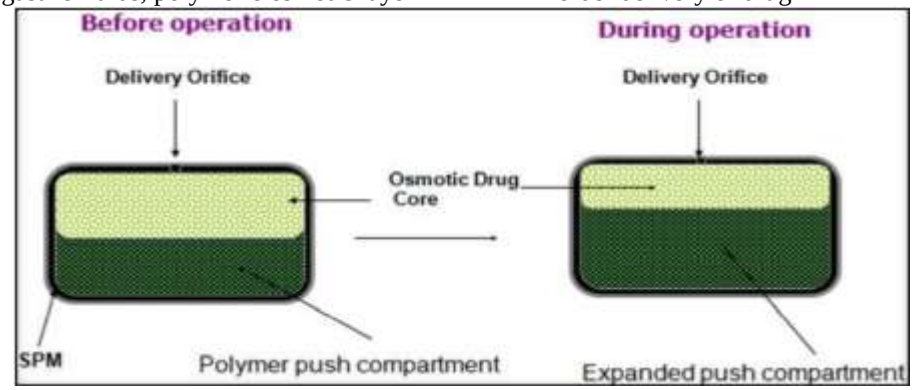

Figure no.2: Push pull osmotic pump

- **Osmotic pump with non- expanding second chamber:** In this case there will be no expansion of second chamber and based on the functioning of this chamber, they are of two types. In the first type, second chamber helps in dilution of drug solution. This is dvantageous because some drugs cause the irritation when they are saturated. In second type, there are two chambers, one consists of the osmotic agent and the other consists of the drug. Primarily osmotic agent solution is formed which enters the drug solution and then their mixture is released out by delivery orifice.

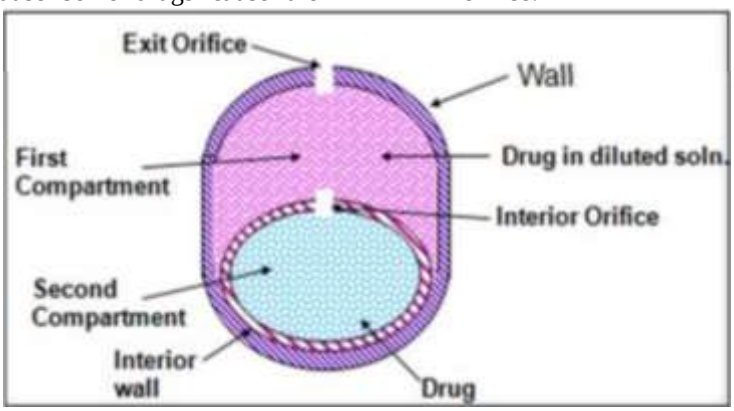

Figure no.3: Osmotic pump with non- expanding second chamber

- **Specific types controlled porosity osmotic pump:** It is adevice where the delivery orifices are formed in situ through leaching of water soluble pore-forming agents incorporated in semipermeable membrane (E.g., urea, sorbitol, etc.). Drug release rate from controlled porosity osmotic pump depends on factors like coating thickness, level of leachable pore-forming agent(s) solubility of drug in tablet core, and the osmotic pressure difference across the membrane.

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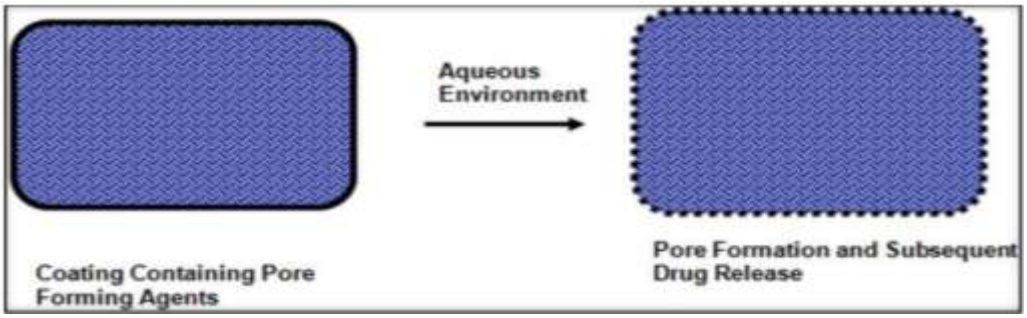

Figure no.4: Controlled porosity osmotic pump

- **Liquid oral osmotic system:** This allows the delivery of liquid drug formulations. A liquid formulation is particularly well suited for delivering insoluble drugs and macromolecules such as polysaccharides and polypeptides [10]. Such molecules require external liquid components to assist in solubilization, dispersion, protection from enzymatic degradation, and promotion of gastro intestinal absorption [11]. This device containing three-lamina (1)rate controlling membrane, (2) osmotic layer and (3) soft gelatine capsule. During operation, water permeates across the rate controlling membrane and causes expansion of the osmotic layer resulting in to development of hydrostatic pressure which forces the formulation out from the orifice.

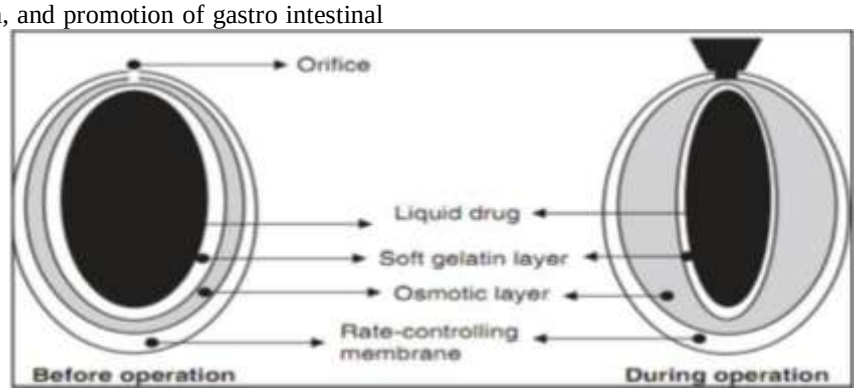

Figure no. 5: Liquid oral osmotic system

- **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. A layer of wax like material separates the two sections. To assemble the delivery device, the desired active agent is placed into one of the sections by manual or mechanical fill mechanism. The open end of the filled vessel is fitted inside the open end of the cap, and the two pieces are compressed together tightly. When fluid is imbibed in the device, the osmotic engine expands and exerts pressure on the slid-able connected first and second wall sections. During the delay period the volume of reservoir containing the active agent is kept constant that will generate a pressure that results into removing of cap and release of drug [12].

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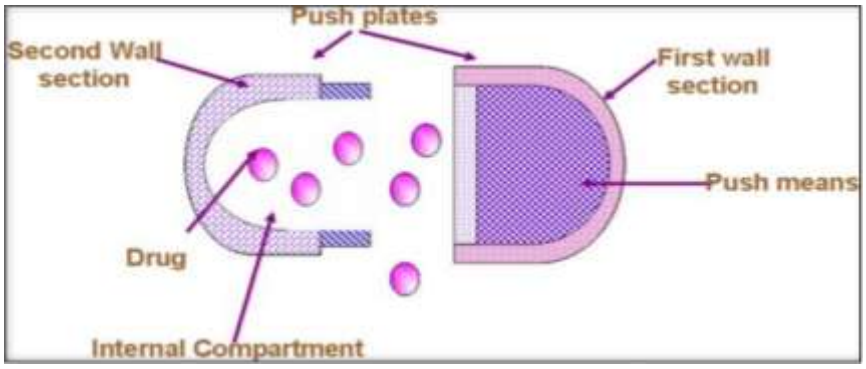

Figure no. 6: Telescopic capsule for delayed release

- **OROS colon targeting:** It is used as a once or twice a day formulation for targeted delivery of drugs to the colon. This can be a single osmotic agent or it can be contained of five to six push pull osmotic unit filled in a hard gelatine capsule. After coming in contact with the aqueous environment, gelatine capsule dissolved and the enteric coating prevents entry of fluids from stomach to the system when system enters into the small intestine the enteric coating dissolves and water is imbibed into the core thereby causing the push compartment to swell. At the same time flowable gel is formed in the drug compartment, and released in the controlled manner. [13]
- **Sandwiched oral therapeutic system:** In this system a tablet core composed of polymeric push layer sandwiched between two drug layers with two delivery orifices. When device is placed in the aqueous environment the middle push layer which containing the swelling agent swells and the drug is released from the two orifices situated on opposite sides of the tablet and thus these systems can be suitable for drugs prone to cause local irritation of the gastric mucosa.

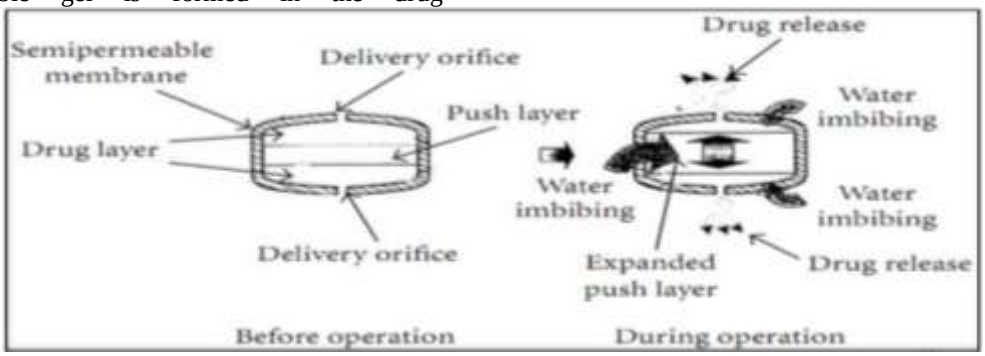

Figure no.7: Sandwiched oral therapeutic system

- **Monolithic osmotic system:** It constitutes a simple dispersion of water-soluble agent in a polymer matrix. When the system comes in contact in with the aqueous environment water imbibition by the active agents cause rupturing the polymer matrix capsule and the drug is release. However this system fails if more then 20 –30 volumes per liter of the active agents are incorporated in to the device [13].

EVALUATION PARAMETERS:

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Pre-formulation	Post formulation
Bulk density Tapped density Hausner's ratio Carr's index Angle of repose	Hardness Thickness Friability Content uniformity Effect of pH on drug release Measurement of orifice diameter In vitro drug release Stability studies

II. CONCLUSION:

In osmotic delivery systems, osmotic pressure delivers the driving force for drug release. Increasing pressure inside the device from water imbibition causes the drug to release from the system. The major advantages include accurate controlled release over an extended time period, and reduce side effect. Effective plasma levels are maintained longer in osmotic systems, avoidance of trough plasma levels over the dosing interval is possible. Though, a complex manufacturing process and higher cost compared with conventional dosage forms limit their use.Further, with the discovery of newer and potent drugs by the biotechnology industry are also delivered through this system.

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