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A Comprehensive Review on Osmotically Controlled Drug Delivery Systems

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ABSTRACT
Conventional immediate-release dosage forms sometimes fail to maintain constant plasma drug concentrations, resulting in inappropriate therapeutic effects. This limitation has driven the evolution various controlled drug release systems for improvement in drug release profiles and patient compliance. Among these, osmotic drug release systems (ODDS) have emerged as a promising platform due to capability to provide controlled and predictable drug release rates. ODDS represent a class of novel drug delivery systems that utilize osmotic pressure as the principal mechanism to regulate the release of active pharmaceutical ingredients. These systems are suitable for both oral and implantable applications and operate by the movement of water through a semi-permeable membrane to facilitate the medicament release. For optimal performance, the drug must possess adequate aqueous solubility to generate the required osmotic gradient. Structurally, these systems consist of a medicament containing core surrounded by a semi-permeable membrane. Upon exposure to a hydrated environment, water penetrates through the membrane, creating osmotic pressure inside the core, which facilitates the controlled release of the drug through an orifice. The rate and extent of drug release from these systems are overblown by multiple factors such as the osmotic pressure, drug solubility, dimensions of the delivery orifice, and the physicochemical properties of the semi-permeable membrane.
This review provides a concise overview of the fundamental principles governing osmotic drug delivery systems and discusses the various types and design considerations associated with their development.

KEYWORDS: Osmotically controlled systems, osmotic pumps, osmosis, controlled release, semipermeable membrane.

INTRODUCTION
Oral drug delivery is the traditionally preferred delivery route of drug administration providing appropriable method for attaining local as well as systemic effects[1]. In the traditional oral drug delivery systems, there will be a minute control over the release of the drug. The fruitful concentration of drug at the location site can be achieved by fragmented administration of surplus amount of drug[2].
Traditionally, controlled drug delivery systems have been developed to overcome the limitations associated with fluctuating drug concentrations observed in conventional dosage forms[1]. The continuous discovery of new therapeutic molecules for the treatment and prevention of emerging diseases has further emphasized the need for efficient delivery mechanisms. Drug delivery systems play a critical role in ensuring that active pharmaceutical ingredients reach their intended site of action, as pharmacological efficacy alone is insufficient for therapeutic success. Current research efforts are focused on identifying and designing novel compounds with enhanced pharmacokinetic and absorption profiles. To address the limitations of conventional formulations, various advanced delivery approaches such as buccal patches, transdermal systems, implants, and oral controlled-release dosage forms have been employed[3,4]. Although the development of such systems involves considerable cost, it remains significantly lower than the expense of

discovering entirely new drug molecules. Consequently, there is a sustained interest in designing innovative drug delivery systems capable of achieving controlled spatial and temporal release of active agents.

Among these, osmotically controlled drug delivery systems (OCDDS) represent one of the most reliable and efficient controlled release technologies for oral administration[5]. The osmotic driving mechanism in these systems provides several advantages over other controlled release methods, including ease of formulation, simple operation, improved patient compliance, reduced dosing frequency, and sustained therapeutic efficacy with consistent plasma drug levels. Furthermore, drug release from ODDS is independent of physiological factors such as pH and gastrointestinal motility because of presence of a semipermeable rate-controlling membrane and a precisely engineered delivery orifice. These design features enable a high degree of in vitro–in vivo correlation, making ODDS a highly favourable approach for consistent and predictable drug delivery[6].

FORMULATION CONSIDERATIONS OF OCDDS

Osmosis refers to the movement of a solvent from a region of lower solute concentration to the, higher solute concentration across a semipermeable membrane. It can also be described as the spontaneous migration of solvent molecules through an ideal semipermeable membrane that permits only the passage of the solvent while restricting solute movement. The application of osmotic pressure on the side with higher solute concentration counteracts or halts this solvent flow.

Osmotically controlled drug delivery systems generally comprise two main components: the core and the semipermeable membrane coating. The core contains the active pharmaceutical ingredient along with osmotic agents, hydrophilic or hydrophobic polymers, flux-regulating agents, and wicking materials. The coating, on the other hand, consists of a polymeric film combined with coating solvents, plasticizers, and pore-forming agents. Each component plays a vital role in modulating water influx, controlling osmotic pressure, and maintaining a consistent rate of drug release from the system[7,8].

Drug: Criteria are acceptable for the formulation[9]:

a. It should show low half-life.
b. It should be used in prolonged treatment.
c. Prolonged release is desired by the drug used.
d. It should show potent nature.
e. Low or high solubility can be attained by the drug.

Semi permeable membrane: The semipermeable membrane plays a crucial role in the functioning of OCDDS. Since the membrane allows the passage of water but not solutes, the rate of drug release remains largely independent of the environmental pH. Consequently, the appropriate selection of membrane material is a critical aspect in the formulation of these systems. A wide range of polymers can be employed to fabricate semipermeable membranes, and their selection depends on factors such as the solubility of the drug and the desired rate of drug release. The membrane material must exhibit stability in both internal and external environments of the dosage form and should possess sufficient rigidity to maintain the dimensional integrity of the device throughout the release period. Commonly used polymers for membrane formation include cellulose derivatives such as cellulose acetate, cellulose acetate butyrate, ethyl cellulose, and cellulose triacetate[9]. In addition to these, other polymers such as agar acetate, β-glucan acetate, cellophane, amylose triacetate, poly (vinyl methyl ether) copolymers, poly (orthoesters), ethylene–propylene copolymer, polyvinylidene fluoride, polyacetals, and polylactic acid have also been utilized as film-forming materials for the preparation of semipermeable membranes[10,11].

Ideal characteristics of semipermeable membrane are:

a. Adequate wetting ability and water penetrability
b. It must possess biocompatible nature
c. It must be invariable and non-swelling
d. It must be ample thick to withstand pressure within the device.

Hydrophilic and Hydrophobic Polymers: These polymers are extensively utilized in the development of osmotic drug delivery systems, primarily for the formulation of the drug matrix core. In hydrophobic matrices, highly water-soluble drugs can be efficiently encapsulated, whereas hydrophilic matrices are more suitable for drugs with moderate aqueous solubility, thereby achieving a more controlled and sustained release profile. Often, a combination of both hydrophilic and hydrophobic polymers is employed to optimize the release characteristics of water-soluble drugs in osmotic pump systems. The choice of polymer depends

largely on the solubility of the drug and the desired release kinetics. The polymers used in these systems may exhibit either swellable or non-swellable behaviour. Swellable polymers are generally preferred for formulations containing drugs of moderate water solubility, as their expansion upon hydration increases hydrostatic pressure within the core, promoting controlled drug release. Conversely, non-swellable polymers are selected for highly water-soluble drugs to prevent excessive pressure buildup and uncontrolled release. Due to their osmogenic properties, ionic hydrogels such as sodium carboxymethyl cellulose are frequently employed in these formulations. Other commonly used hydrophilic polymers include hydroxyethyl cellulose, carboxymethyl cellulose, hydroxypropyl methylcellulose, and high–molecular weight poly(vinylpyrrolidone). In contrast, hydrophobic polymers such as ethyl cellulose and various wax-based materials are also incorporated to modulate the permeability and drug release characteristics of the system[12,13].

Wicking Agents: A wicking agent is a material capable of drawing water into the porous structure of an osmotic system. These agents enhance the wetting and penetration of aqueous fluids within the formulation, thereby increasing the surface area of contact between the drug and the dissolution medium, which facilitates a more efficient and controlled release of the drug through the delivery orifice[14].Wicking agents may be either swellable or non-swellable in nature. Their primary characteristic is the ability to undergo physisorption with water- a process in which solvent molecules adhere loosely to the surface of the wicking material through Van der Waals interactions. This interaction aids in the uniform distribution of water within the system, ensuring consistent drug release dynamics. Commonly used wicking agents include colloidal silicon dioxide, low-molecular-weight polyvinylpyrrolidone (PVP), polyesters, titanium dioxide, alumina, sodium lauryl sulfate, bentonite, kaolin, magnesium aluminium silicate, and polyethylene. Among these, sodium lauryl sulfate, colloidal silica, and PVP are categorized as non-swellable wicking agents[15,16].

Solubilizing Agents: The incorporation of a solubilizing agent within the core of the tablet enhances the solubility and dissolution rate of the drug, thereby improving its release profile. Non-swellable solubilizing agents are generally classified into three categories based on their mechanism of action[17,18]:

a. Complex-forming or crystal growth-inhibiting agents: These substances improve solubility by either preventing the crystallization of the drug or by forming inclusion or molecular complexes with it. Examples include polyvinylpyrrolidone (PVP), polyethylene glycol (PEG 8000), and β-cyclodextrin.

b. Hydrophilic–lipophilic balance (HLB) micelle-forming anionic surfactants: These agents enhance solubilization through micellar formation and include surfactants such as Tween 20, Tween 60, Tween 80, polyoxyethylene-based surfactants, and long-chain anionic surfactants like sodium lauryl sulfate (SLS).

c. Anionic surfactants in combination with citrate esters: Mixtures containing complexing agents along with anionic surfactants are particularly effective and are therefore commonly preferred for improving the solubility of poorly water-soluble drugs.

Osmotic Agents (Osmogens): These agents are integral components of osmotic drug delivery systems, responsible for generating osmotic pressure within the formulation. Drugs with low aqueous solubility typically exhibit a slow, near–zero-order release profile; hence, the inclusion of an osmotic agent is necessary to enhance the drug release rate. These agents establish a high osmotic pressure gradient across the semipermeable membrane, thereby facilitating the continuous and controlled delivery of the active ingredient[19]. Upon penetration of biological fluids through the semipermeable membrane, the osmogens dissolve, resulting in an increase in internal osmotic pressure. This pressure acts as the driving force that propels the drug solution or suspension through the delivery orifice to the external environment. Osmotic agents are thus considered essential constituents of osmotic formulations. Commonly used osmogens include inorganic salts such as potassium chloride and sodium chloride, as well as carbohydrates like mannitol, which effectively regulate osmotic pressure and drug release kinetics within the system.

Examples of commonly used osmotic or excipient agents include inorganic salts such as magnesium chloride, magnesium sulfate, lithium chloride, sodium chloride, potassium chloride, sodium hydrogen phosphate, and potassium hydrogen phosphate. Organic salts such as sodium and potassium acetate, magnesium succinate, sodium benzoate, sodium citrate, and sodium ascorbate are also frequently employed. In addition, various carbohydrates-including mannose, sucrose, maltose, and lactose and polymers such as sodium carboxymethyl cellulose, hydroxypropyl methylcellulose, hydroxyethyl methylcellulose, methylcellulose, polyethylene oxide, and polyvinylpyrrolidone are incorporated to optimize osmotic and formulation characteristics [20,21].

Coating Solvents: Coating solvent help in dissolving properties of film-forming polymers and influencing membrane properties. Examples of solvents used include methylene chloride, acetone, methanol, ethanol,

isopropyl alcohol, butyl alcohol, ethyl acetate, cyclohexane, carbon tetrachloride, and water. The mixtures of solvents can also be used such as acetone is used in combination with methanol, ethanol and water [22].

Plasticizers: Plasticizers are incorporated into formulations to modify the physical properties of polymers and to enhance their film-forming characteristics. The addition of these agents can alter the viscoelastic behaviour of polymers, which in turn influences the permeability and mechanical properties of the resulting polymeric films. Such modifications play a crucial role in determining the rate and extent of drug release from modified-release dosage forms, particularly when plasticizers are included in the rate-controlling membrane.

Plasticizers can significantly affect drug release both quantitatively and qualitatively by adjusting polymer flexibility, reducing brittleness, and improving the uniformity of film coatings. Commonly used plasticizers include dialkyl phthalates and other phthalate derivatives, trialkyl phosphates (e.g., trioctyl phosphate), alkyl adipates, triethyl citrate and related citrates, as well as acetates, propionates, glycolates, glycerolates, myristates, benzoates, sulfonamides, and halogenated phenyl compounds[23].

Flux regulators: Flux-regulating agents are incorporated into osmotic systems to modulate the permeability of the membrane to fluids. These agents can be selectively chosen to either enhance or reduce the rate of liquid flux across the polymeric wall, thereby allowing fine control over the drug release profile. In addition to influencing permeability, they also contribute to improving the flexibility and porosity of the membrane or lamina. The concentration of the flux regulator must be optimized to achieve the desired level of permeability, which varies depending on the properties of the film-forming material used. Hydrophilic compounds such as polyethylene glycols (molecular weight range: 300–6000 Da), polyhydric alcohols, and polyalkylene glycols generally increase the flux of aqueous fluids through the membrane. In contrast, hydrophobic materials, including alkyl- or alkoxy-substituted phthalates, tend to decrease the fluid flux. Additionally, insoluble salts and oxides are often employed for this purpose to further regulate permeability and maintain controlled release characteristics[24].

Pore forming Agents: Pore-forming agents are primarily employed in osmotic pump systems designed for poorly water-soluble drugs. These agents facilitate the formation of a porous membrane, which becomes permeable as the pore formers dissolve out during the operation of the system. Pore formers may be inorganic or organic, and can exist in solid or liquid form. Porosity can also develop through the volatilization of components within a polymer solution or as a result of chemical reactions that release gases prior to or during the coating process.

Typical examples include alkali metal salts such as sodium chloride, sodium bromide, potassium chloride, potassium sulfate, and potassium phosphate; alkaline earth metal salts like calcium chloride and calcium nitrate; and various carbohydrates such as sucrose, glucose, fructose, mannose, lactose, sorbitol, mannitol, as well as diols and polyols. These agents collectively enhance the permeability and performance of the osmotic membrane by controlling its pore structure[25].

CLASSIFICATION OF OSMOTICALLY CONTROLLED DRUG DELIVERY SYSTEM

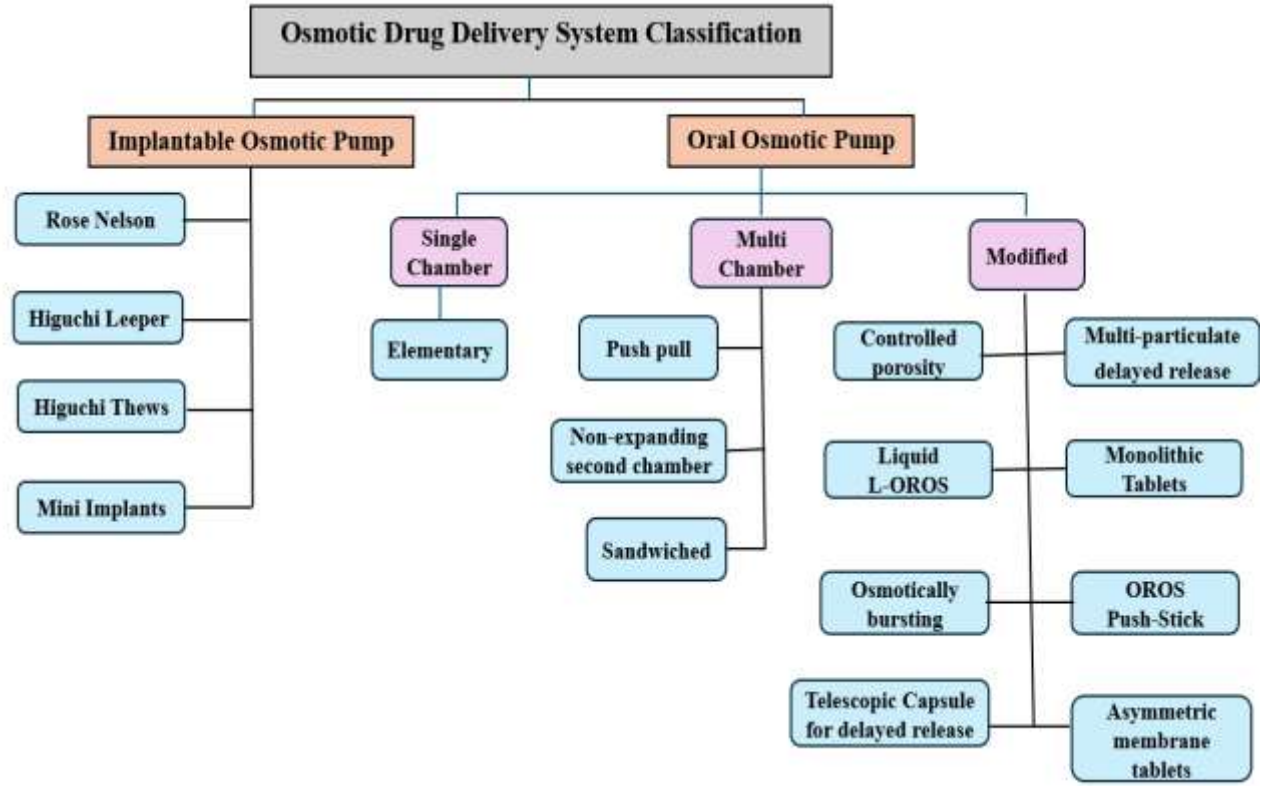

Figure 1: Classification of osmotically controlled drug delivery system [26,27]

1) Implantable osmotic drug delivery system

➢ **The Rose and Nelson pump:** There are three chambers in it which include drug chamber (with an orifice), a salt chamber (with elastic diaphragm which has excess solid salt) and a water chamber. The drug chamber and water chamber are separated by a rigid semi permeable membrane. Water moves through the water chamber into salt chamber due to osmotic pressure difference across the chambers. The increase in the volume of salt chamber due to this water flow results in the separation of diaphragm and pumping drug out of this device. Loading of water priorly is the main drawback with the rose nelson osmotic pump[28].

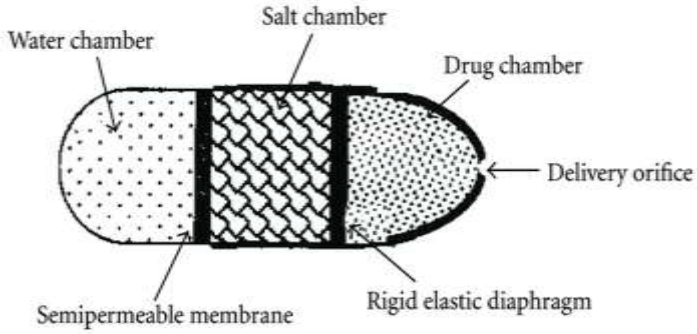

Figure 2: Rose and nelson pump

➢ **Higuchi-Leeper Pump:** Higuchi-Leeper pumps do not have any water chamber. It is simplest form of rose and nelson pump. For activation of this pump water is taken from the surrounding medium. These pumps are mostly used for veterinary purpose. Modified Higuchi-Leeper pump have pulsatile release of the drug also. For the pulsatile release of the drug, critical pressure is produced which results in opening of the delivery orifice and release the drug[29].

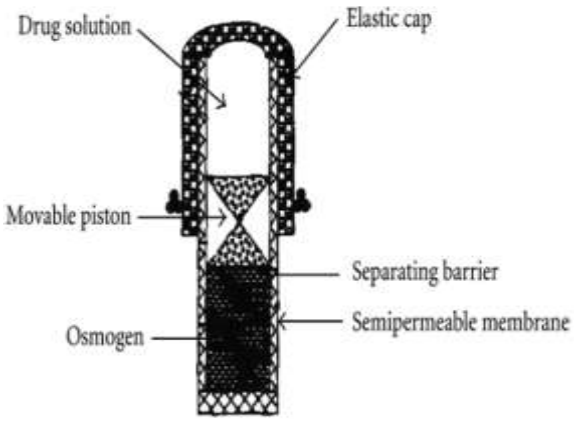

Figure 3: The Higuchi-Leeper pump

➢ **Higuchi-Theeuwes pump:** Higuchi and Theeuwes in 1970 invented this pump that has the rigid housing with semipermeable membrane which serves as the outer casing of the pump. This membrane is will withstand pressure developed inside the pump. The drug is loaded into the pump before use. When the pump is kept in an aqueous environment, the drug release follows a time course that has set for the salt in the salt chamber and the permeation of the outer casing. Higuchi-Theeuwes pumps mostly utilize solid dispersible salt that are placed in a suitable carrier[30].

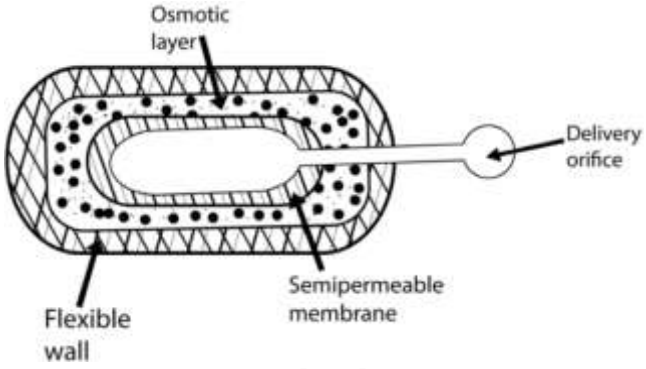

Figure 4: Higuchi-Theeuwes Pump

2) Oral osmotic drug delivery system

A. Single chamber osmotic pump

➢ **Elementary osmotic pump:** This is invented by Theuwes in 1974. In this the rate of drug release is regulated through a semi permeable membrane and characteristics of formulations. In this, the drug is kept in osmotic core and coated with semi-permeable membrane in this a small orifice (0.5 to 1.5 mm) is drilled. When the pump is placed into medium, water imbibes into the core through a semi-permeable membrane generating osmotic pressure. The resulted osmotic pressure inside the formulation, forces the drug solution to come out through the orifice. It is preferred for delivery of moderate water-soluble drugs[31].

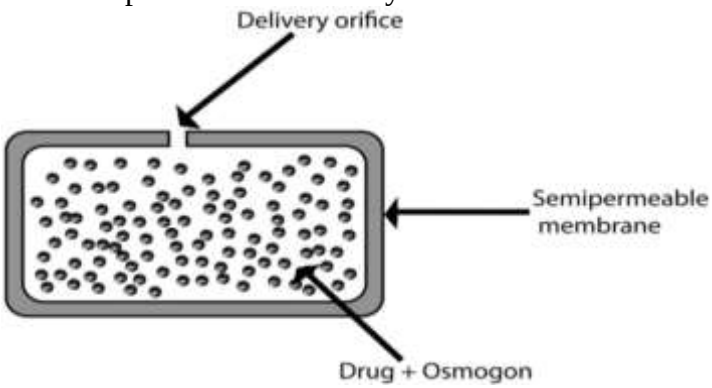

Figure 5: Elementary Osmotic Pump

B. Multi-chamber osmotic pump:

➢ **Push-pull osmotic pump:** It contains two compartments; the upper compartment consists of the drug and an orifice for connection with the outer environment while lower compartment consists of the polymeric osmotic agents without an orifice. This system is quite similar to a regular bilayer tablet in which the upper

layer consists of drug and the lower layer consists of osmotic agent with the tablet excipients. Both the compartments are separated by an elastic diaphragm and when the system is kept in the aqueous surrounding, water is imbibed on both the compartments. Due to expansion of the lower compartment, diaphragm pushing towards the upper compartment and drug is released through an orifice. Main disadvantage with this device high cost and release of drug in local area[32].

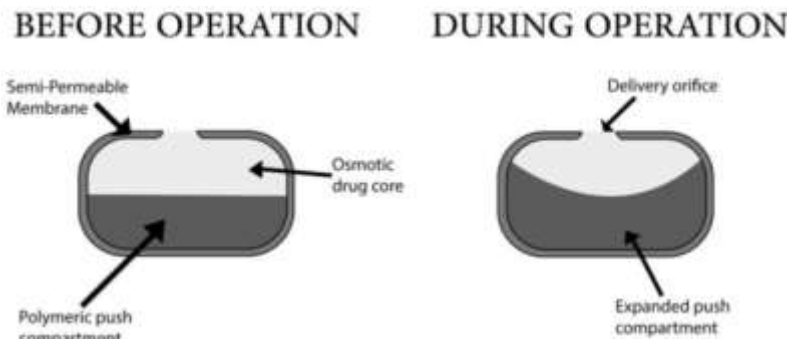

Figure 6: Push-pull osmotic pump (PPOP)

➢ **Sandwiched Osmotic Tablet**

This system contains two compartments of drug and third compartment is of polymers which is sandwiched in between two compartments acts as a push layer. Both the drug compartments consist of orifices for drug delivery. When this system under operation, the middle-sandwiched layer gets swollen due to swelling agents and results in release of the drug through the orifices present in both compartments[33].

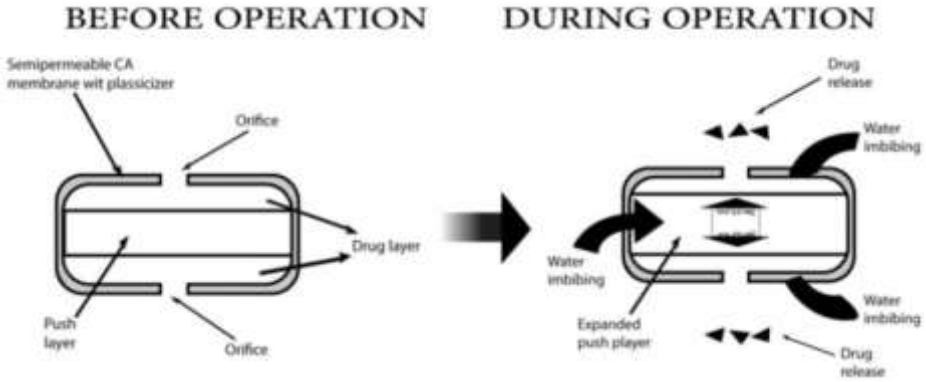

Figure 7: Sandwiched Osmotic Tablet

C. **Specific types**

➢ **Controlled porosity osmotic pump:** Controlled osmotic pump tablet contains a core compartment with drugs coated by an asymmetric insoluble membrane which have selective water permeability. When under operation, water-soluble additives of coating dissolves and leaching out the drug from the micropores in the membrane. Water-soluble additives such as urea, and sodium chloride are used for creation of micro porous channels. This device is suitable for drugs with intermediate water solubility[34,35].

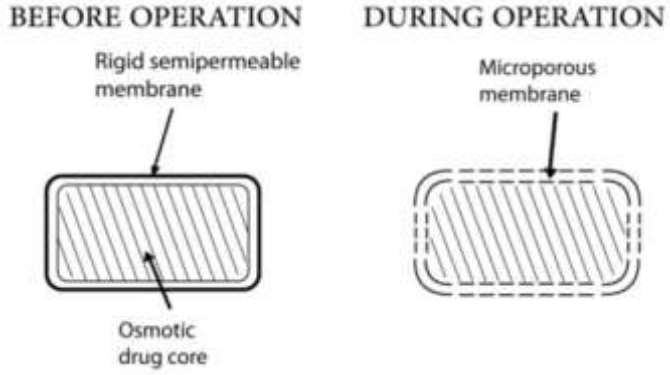

Figure 8: Controlled Porosity Osmotic Pump (CPOP)

➢ **Osmotic bursting osmotic pump:** Baker invented this pump in which orifice is either absent or if present size will be very small. When it is under operation, water from surrounding medium is imbibed and

hydraulic pressure is created inside. Due to this wall will rupture and the contents are released. This system is helpful to give pulsated release. For pulsatile release of drug this pump can be helpful. This system can be used as controlled system by regulating area and width of the semi-permeable membrane[36].

➢ **Liquid OROS**: Liquid drugs are delivered via this system. It consists of two types of delivery systems, L-OROS soft cap and L-OROS hard cap. In L-OROS soft cap, liquid drug formulation is kept in a soft gelatin capsule, which is enclosed with the barrier layer, the osmotic layer, and the rate release controlling membrane. In L-OROS hard cap, liquid drug layer with an osmotic device enclosed in a hard gelatin capsule and coated with semipermeable membrane. In aqueous surrounding, the osmotic layer is enlarged and results in development of hydrostatic pressure which helps in breaking of the hydrated capsule shell and releasing the drug through the orifice. This system is preferred for controlled delivery of lipophilic drugs[37,38].

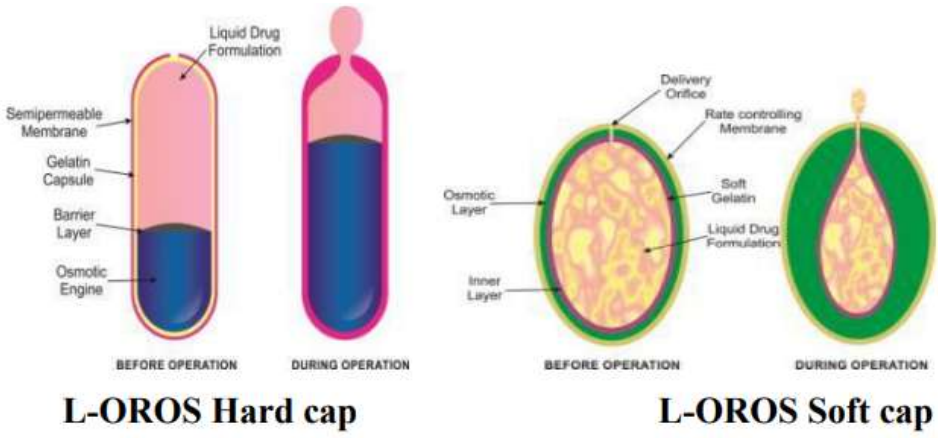

Figure 9: Liquid OROS

➢ **Telescopic Capsule for Delayed Release:** There are two chambers present in this system which are separated by waxy layer. Drug and an orifice are components of first chamber while osmotic agent is present in second chamber. As fluid is imbibed into the device from surrounding, the osmotic agents expand and exerts pressure on the layer that is in between the first and second wall sections[39,40].

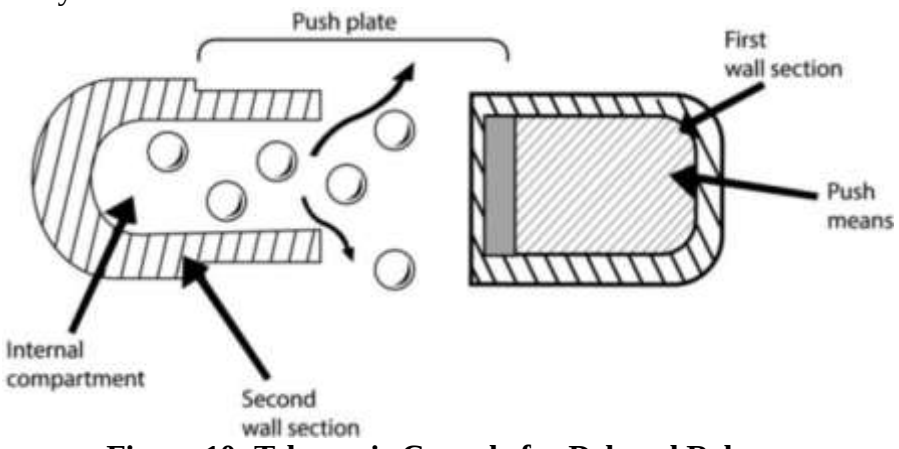

Figure 10: Telescopic Capsule for Delayed Release

➢ **Multi particulate delayed release systems (MPDRS):** Drug with or without osmogene is compressed in form of pellets then it is coated with a semipermeable membrane. When this system is under operation, water from surroundings enters in the core and results in the osmotic pressure gradient. Due to the expansion of membrane, pores are formed in semi-permeable membrane. The release of the drug follows zero order kinetics through the pores[41].

➢ **Pulsatile delivery based on expandable orifice:** These systems are used to deliver the drug at the site of action at appropriate time and amount, thus providing temporal delivery and patient compliance. The circadian cycle of the human body is taken into consideration during the design of these systems. The release of the drug is in pulsatile manner means a complete and rapid drug release follows the lag time. Pulsatile systems can be classified into single and multiple-unit systems. Single-unit systems are commonly designed as either capsule-based or osmotically driven. These systems are often coated with materials that either dissolve or rupture under pressure to facilitate drug release. Multiple-unit systems consist of small individual units (such as pellets), where the pulsatile effect is achieved by altering the permeability of the membrane. The system is in the form of capsule, drug release is controlled by osmotic pressure as moisture from

surrounding enters the capsule, internal pressure gradually builds. Intermittently, the delivery orifice opens to give a pulsatile delivery effect When the pressure drops and the wall returns to its original state, the orifice closes, halting drug flow. This mechanism allows for an intermittent, pulsatile release pattern[42].

- **Longitudinally compressed tablet (LCT) multilayer formulation:** The LCT (Layered Controlled Technology) multilayer formulation represents an advanced approach within osmotic drug delivery systems. This system consists of a hydrophilic osmotic push layer and is designed in multiple drug layers, enhancing the flexibility and precision of drug release profiles compared to traditional single-layer push-pull systems, which typically follow zero-order release kinetics. Upon exposure to surrounding, water is absorbed through the semi-permeable membrane surrounding the tablet. This influx of water causes the osmotic push compartment to swell, initiating drug release from the first drug layer through a laser-drilled orifice in the tablet coating. Following this initial phase, drug release from the second layer begins after a defined lag time and may occur at a different rate, depending on the formulation design. The LCT system can be further optimized by incorporating different pharmacological agents in separate layers, allowing for combination therapy within a single dosage form. This design enables temporal control over the release of each drug, supporting the delivery of complex therapeutic regimens with improved patient compliance and therapeutic outcomes[43].
- **Lipid osmotic pump:** For the poor soluble drugs in water, this type of system is used. The system comprises a lipid-soluble or lipid-wettable drug incorporated into a water-insoluble lipid carrier, which serves to solubilize or wet the drug. The outer wall of the device is microporous and is permeable to the lipid carrier, allowing it to wet the internal structure effectively. Formulation involves initially dissolving the drug in the lipid vehicle. An osmogen is then incorporated by melting it into the lipid phase, after which the mixture is cooled and solidified to form a mass. This solidified mass is subsequently fragmented, and the resulting material is compressed into tablets[44].
- **OSMAT:** This system utilizes hydrophilic polymers in matrix and gel in aqueous medium which act as semi-permeable membrane in situ. Drug release from such matrix system regulated by an osmotic phenomenon. OSMAT represents low cost, simple and easy to counterfeit osmotically controlled drug delivery system[45].
- **OROS Push-Stick Technology:** It consists of a bilayer capsule shaped tablet. It is similar to push pull osmotic pump tablets. It provides the most advantages for compounds with low water solubility and dosage better than 150 mg[46].

Table 1: Examples of some marketed Osmotic drug delivery system[47-49]

Product name	Active Pharmaceutical Ingredients	Osmotic System Type
Acutrim	Phenylpropanolamine	EOP
Alpress LP	Prazosin	Push -pull osmotic pump
Altoprev	Lovastatin	Elementary osmotic pump
Allegra D 24 h	Pseudoephedrine HCl Fexofenadine HCl	Elementary osmotic pump
Cardura CR	Doxazosin Mesylate	Push -pull osmotic pump
Concerta	Methylphenidate HCl	Push-Stick Osmotic Pump
Chronogesic TM	Sufentanil	Implantable osmotic system
Covera HS	Verapamil HCl	Push -pull osmotic pump
Dyna Circ CR	Isradipine	Push -pull osmotic pump
Glucotrol XL	Glipizide	Push -pull osmotic pump
Invega	Paliperidone	Push -pull osmotic pump
Loremex	Pseudoephedrine HCl Loratadin	Elementary osmotic pump
Minipress XL	Prazosin	Push -pull osmotic pump
Oxycontin	Oxycodone	Push -pull osmotic pump
Procardia XL	Nifedipine	Push -pull osmotic pump
Topamax	Topiramate	Push-Stick Osmotic Pump
UT-15C	Treprostinil Diethanolamine	Treprostinil Diethanolamine
Volmax	Albuterol	EOP
Viadur	Leuprolide Acetate	Implantable osmotic system

EVALUATION OF OCDDS

A. Evaluation of Uncoated Tablets [50-59]

a) **Weight variation test for uniformity:** Randomly 20 tablets were selected from every batch and weight was taken for each tablet. Then average weight and standard deviation were calculated. If the % deviation in weight variation was found to be within the permissible limits (± 5%), then the batch passes this test.

$$\% \text{ Deviation} = \frac{\text{Individual weight} - \text{Average weight}}{\text{Average weight}} \times 100$$

b) **Hardness (diametric crushing strength) test:** The force requisite to split a tablet across its diameter. The tablet's strength is indicated by its hardness. The hardness of tablets differs with types of tablets and manufactures. The hardness is measured in kilogram/cm^2. It is measured by the Monsanto hardness apparatus.

c) **Friability:** Friability of tablet is defined as the loss in weight which is due to deportation of particles from the surface. This test is performed to provide assurance that tablets withstand the mechanical shocks during processing, handling, and shipment. The acceptance limit for friability is less than 1.0 %. Ten or twenty tablets were taken from every batch and weighed accurately and kept in a Roche friabilator. The apparatus was rotated at 25 rpm for 100 times then tablets were taken out and weighed. The % friability was calculated by using the formula.

$$\% \text{ Friability} = \frac{W_1 - W_2}{W} \times 100$$

Where, W_1 = Tablets initial weight
W_2 = Tablets weight after rotation

d) **Thickness:** Vernier callipers is used to measure thickness, for these three tablets were taken randomly from every batch and thickness was calculated in millimeter (mm).

e) **Drug content uniformity:** Twenty tablets were taken and weighed accurately. Then average weight was estimated for each tablet and powdered by using pestle-mortar. Powder was weighed equivalent to 100 mg of drug, then it was transferred to 100 ml volumetric flask. It was sonicated for twenty minutes. Then made the volume up to 100 ml with mentioned solvent. The resulted solution was filtered through nylon membrane filter (0.45 µ). Drug content was analyzed by UV- visible spectrophotometer after further dilution of filtrate against blank. The acceptance range for content uniformity should be ±90%

B. Evaluation of Coated Tablets

a) **Percentage (%) weight gain:** Fifty core tablets were randomly taken from each batch of tablets on which coating to be done and weighed (initial weight). After the process coating was completed, tablets were allowed to dry for 10–15 minutes in the coating pan at the temperature 45 °C to remove most of the solvent which is present as moisture. Then these fifty coated tablets were weighed again and the percentage weight gain was estimated. These tablets samples were collected for predetermined weight gain(approximately). For this the coated tablets were dried overnight in tray drier to remove complete solvent. These tablets were weighed again and % weight gain was calculated accurately.

b) **Thickness:** Vernier callipers is used to measure thickness and diameter of coated tablets.

c) **Hardness test:** This test was carried as per the method given under evaluation of uncoated tablets.

d) **In vitro drug release**: There are various methods such as vertically reciprocating shaker, conventional USP dissolution apparatus type I and II, flow-through apparatus etc. for assessment of *in vitro* drug release from osmotic systems.

e) **Effect of pH:** Dissolution media of different pH generally used to determine drug delivery from an osmotically controlled release system**.**

f) **Effect of agitation intensity:** The effect of agitational intensity of the drug release from an osmotically controlled release system media is performed at different rotational in dissolution test apparatus.

g) **In-vivo evaluation**: pH and motility intestinal tract of human beings are quite same to the environment of dog's intestine. Due to this reason, dogs are widely used for *in-vivo* study of drug release from oral osmotic drug delivery systems for establishment of i*n-vitro/in-vivo* correlation (IVIVC). Healthy

human subjects can also use for *in-vivo* drug release study. Further relative bioavailability and pharmacokinetic parameters such as Cmax, Tmax, AUC and MRT are also calculated.

LIMITATIONS OF OCDDS

- ✓ These systems are extravagant to produce.
- ✓ If any film defects occur due to improper coating, it will lead to dose dumping.
- ✓ Size of orifice is evaluative in expression of elementary osmotic pump.
- ✓ Reclamation of therapy is not possible in the case of unanticipated adverse events.

CONCLUSION AND FUTURE PROSPECTS OF OCDDS

Modified versions of conventional dosage forms have been developed to address the inherent limitations of traditional drug delivery systems. These advanced formulations, referred to as controlled-release and sustained release drug delivery systems. Among these, osmotic pump–based systems are extensively utilized due to their reliability in modulating drug release. As outlined in this review, these systems operate on the principle of osmotic pressure. A key advantage is their ability to provide drug release profiles that remain unaffected by pH variations or physiological conditions, thereby enabling predictable and reproducible release kinetics. Future prospectives of these formulations are such as:

- ✓ Osmotic drug delivery systems are moving over the conventional oral tablets into implantable systems, miniaturized devices followed by smart systems.
- ✓ Biodegradable osmotic membranes should be used to avoid the revert of implants.
- ✓ In certain cases, 3D printing techniques are employed for the precise fabrication of osmotic pumps.
- ✓ Nanotechnology-based osmotic systems are used to deliver biological products with the potential for targeted delivery when combined with site-specific targeting strategies.
- ✓ They can also be prepared to deliver the drugs in circadian rhythms, thereby optimizing therapeutic outcomes for time-dependent conditions.
- ✓ These systems can be used for targeted drug delivery when integrated with nanotechnology.
- ✓ These can be used for treatment of chronic diseases, Neurodegenerative disorders etc.
- ✓ Recent advancements include programmable and bio responsive osmotic systems, which can respond dynamically to physiological uses.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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