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REVIEW ON FORMULATION ASPECTS OF OSMOTIC DRUG DELIVERY SYSTEM.

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Abstract:

The drug delivery System is a new approach to controlling the release of medicinal forms. A Wide range of drug delivery systems for patented osmosis resistance such as Rose-Nelson pump, Higuchi-leeper pump, higuchi-theeuwes pump, elementary osmotic pump etc. Possibility for poorly allowed medications, release of pulsatile drugs, zero emission order is useful. Different methods for sample ratio are obtained push pull osmotic Pump, osmotic Bursting osmotic pump, liquid oral osmotic system, sandwiched osmotic tablets (SOTS), long period of time delivery osmotic device, and controlled porosity osmotic Pump. Release of the drug from the osmosis pressure system is controlled by various factors, such as the formulation and solubility of the main component osmosis pressure, the degree of opening of the type of supply and control of the membrane. The Development of the extended release capacity measurement structure also requires saving the Wise through channels (GIT). With the help of this drug in the existing technology to get the best bioavailability, which produces osmosis drug distribution system, is essentially unique. This study now highlights the flow of frustration and traffic osmosis treatment with innovation and clinical research.

Keywords: *Oral Controlled Osmotic Drug delivery system (OCODDS), Sandwich Osmotic Pump Tablet (SOPT), Elementary Osmotic Pump (EOP), Semi permeable Membrane (SPM), Magnetic Resonance Imaging (MRI), Liquid Oral Osmotic System (L-OROS).*

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INTRODUCTION:

Principle of Osmosis:

The Process of osmosis for the destruction of low concentrations of molecules at high concentrations in a semi-permeable membrane. (04)

The oral route of drug delivery is normally considered the special and the most user-friendly means of drug administration having the high quantity of patient fulfillment. (18) There has been rising the growth oral osmotic pump in past 20 years.(17) The osmosis Control System (OCODDS) uses osmosis pressure as a source of energy for controlled Drug Administration. Release of the drug from the system consists in self-regulation of the pH of the state channel of pluralism, uniqueness and release it can be easily noted by optimizing the system parameters for its delivery. (24) Part of the drug for the transport system consists of various experts to change the removal of the drug for long and unloading.

(1) The Level and amount of drug consumption by conventional drugs may vary depending on factors such as physical and chemical preparations, appearance of fillers, physiological factors such as appearance or lack of food, pH channels, and so on.

(2) However, releasing the drug from oral controlled release can be valuable from the pH and mobility of GI food in Charm.

(3) The Drug can be delivered in a chain that is controlled for a long period of time through osmosis. The Supply of the drug from the system does not depend on various physiological factors during bowel lumen, and the sign and release can be simply predicted by the nature of the drug and dosage form. (01)

(4) The Structure regulating the delivery base of narcotic drugs, the drug is transferred from the type of higher quantity and feed channel, and the free physiological component from Seron, this structure can be used universally, the same Targeted food preparation. OCODD with the use of osmosis pressure to feed the controlled active ingredient.

(5) In between controlled radiation devices, the position of the osmosis pressure control maintains a constant consistency, giving fire for a period of time in order to zero speed, and creating a common dosage form for this permanent. Content Delivery. Pump Control is a new drug that uses a certain amount of medication as a characteristic and changes the pressure control between the internal and external membranes of the semi-permeable current of the drug. (05)

(6) Recently, the pill with osmosis, which are produced nozzles for the entry of elements dissolved in the coating. Once the tablet is in contact with the aquatic environment, the water-soluble element dissolves and the energy supply system. Then the water spreads through the micro porous membrane to the osmosis gradient, creating the nucleus and thus controlling the release of the drug.(09)

HISTORICAL BACKGROUND:

Nearby 75 centuries later than revelation of the accommodation standard, it was first utilized in the propose of drug distribution systems.(09) They describe two systems, one provides 0.02 ml per day for 100 days, provides 0.5 ml for an additional 4 days, and it is the same for use in pharmacological research. (23) The drug tool consists of three chambers, A Chamber that contains solid hydro chlorine high salt and water chamber. Semi-permeable membrane separating salt and water chambers. The Change of the osmosis load between the two compartments moves from the water to the salt room through the membrane. (08)

The Amount of enlarged salt chamber resulting in a jet of water expands the upper latex, and provides a method of exposing the drug by processing space salts and medications. The Suggestion and regret of this pump is similar to the modern press-full osmosis pump. The Main disadvantage of this pump is the air space required before using the siphon. This pumping speed is known as the complete state of the pump. (09)

$$dM/dt = dV/dt \times c \text{ ----------Eq. no. (1)}$$

There are the different types of pumps are following as:

1) The Rose Nelson pump
2) Higuchi Leeper pump
3) Higuchi Leeper pump

The Rose Nelson pump :

In 1955, the 2 Australian physiologists explained the Australian rose and Nelson pump osmosis in the first place. They are curious to supply drugs in the intestines of sheep and cows.

- Holes and cameras for drugs.
- Salt Room with elastic film contains solid salt and eat too much salt with elastic diaphragm.
- A water chambers.

The Preparation and water chamber are separated by a rigid, semi-permeable membrane. The Change of

osmosis pressure through the membrane directs the water from the brine to the Chamber Hall. The Amount of salt space increases due to the pumping of the drug exposed to the device and the flow of water that radiates the latex membrane for salt and drug chambers ordered.(10)

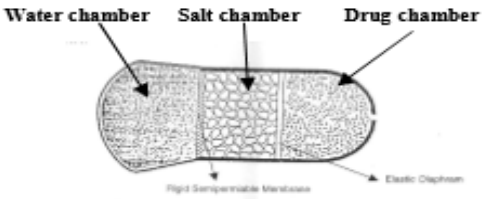

Figure: 1. The Rose Nelson pump (23)

Higuchi Leeper pump:

The Higuchi Leeper pump is a newly organized pump chain Rose Nelson. No Indoor air and the device is activated directly next to the water. This means that the pump can be loaded with the drug and stored for several weeks or months before it is deployed. The Pump is activated by swallowing or assigning to the body. Higuchi-The laser pump contains a rigid case, and the porous structure supports (SPM). These pumps are usually more likely to contain a liquid solution with solid salt and salt chamber. The Newest chain systems are used in pulsatile drug delivery systems. (12)

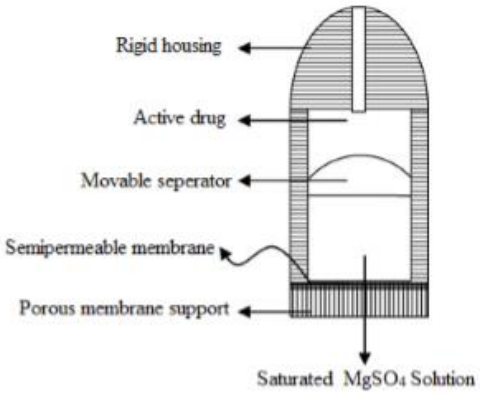

Figure: 2. Higuchi Leeper pump (09)

Higuchi- Theeuwes pump:

In 1970 century, Higuchi and Theewees reworked and fixed a simpler pump, Rose Nelson. The Pump is high- as is clear, the water is extracted in the near surroundings, which causes the effect of osmosis pumps. However, when the rigid body is removed and the outer shell acts as a membrane pump. This membrane is very sturdy and well built, sufficient to maintain pump pressure and has been developed inside the unit. The device is loaded with the required product Before use. If There is a device in the aquatic environment, a long period of salt in the permeability of the salt room and shell outer membrane, then release the drug. Most Higuchi Pumps Use solid scattering salts in a supporting salt room that is suitable for the device. (15)

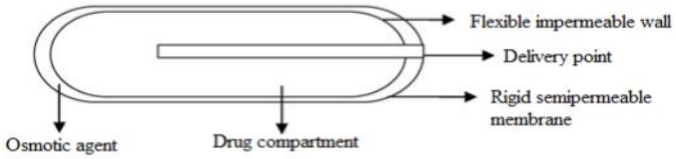

Figure: 3. Higuchi- Theeuwes pump (09)

ADVANTAGES OF ODDS: (09, 11, 03, 13)

- This osmosis system brings zero order rate. You can extend or ripple shipping if you want.
- High emission rates for osmosis systems can be achieved in comparison with conventional drug control systems.
- High water consumption and symmetrical membrane permeability provide greater flexibility in the design phase of previous releases or absorb less solubility in the dosage form.
- Possibility of formulation of dosage forms in the process of conventional pharmaceutical devices without complication of further production.
- Reduce the dosing frequency.
- The Feed Level is the self-regulation of the pH of the environment.
- Delivery is a disease, which means that it is an independent drug supply.
- Stable and constant strength of the plasma drug in the treatment window.
- Better Patient Adherence
- High osmosis Systems reach the level of correlation in vivo.

DISADVANTAGES OR LIMITATIONS OF ODDS :-(09, 11)

- Unique apparatus is essential for manufacturing an cavity in the method.
- Matrix tablets or capsules of ionic particles have a higher cost less than a multi-dosage form.
- It may cause disturbance or ulcer because of arrival of immersed arrangement of medication
- Magnetic resonance imaging scanners provide an explanation that uncoordinated coatings cause specific patterns of release of the drug in batch processing.
- Residence time of the structure in the body changes with the gastric motility and nutrition consumption.

ELEMENTARY CONSTITUENTS OF OSMOTIC METHODS:

1) **Drug :**
The Drug is an ideal choice for organic and low half-life, craving for osmosis structure for instructions. For example, Glipizide, Captopril, Nifidipine etc.

2) **Osmotic agent :**
Osmotic agent supports the process of enrichment through the membrane. They also generate an impulse for water intake and help maintain the consistency of the medications for hydration. It is a good ionic compound consisting of inorganic salts. Sodium Chloride, potassium chloride or sulfate, potassium and lithium, etc.

3) **Wicking agent:**
It is defined as a question of the ability to transport water to the porous mesh of the conveyor unit. They are characterized by the ability to experience physical absorption by water. such as take in colloidal silicon dioxide, sodium lauryl, sulphate, magnesium Aluminium Silicate, Kaolin, Titanium dioxide, alumina, Niacinamide etc.

4) **Semi-permeable membrane:**
The Membrane must have certain uniqueness, such as an impenetrable way of using drugs and other substances present at the site. The Membrane should be inert, triacetate and cellulose of ethyl cellulose, in order to reliably support the osmosis drive from all stocks of active ingredients such as cellulose acetate, Euragitis and cellulose esters such as cellulose triacetate; it should support Reliability of cellulose acetate size, etc. (21)

5) **Flux regulators:**
It can be developed to regulate the permeability of the solution by including the flow control agent on the layer. The flux monitor is Hydrophilic substances such as polyhydric alcohols, polyethethylene glycols, polyalkylene glycols etc.(20)

6) **Pore forming agent:**
It forms a medicine that is applied to drugs that are not soluble in water and expands the correct

absorption of the wound. Pore Formation can be inorganic or organic and liquid in solid or natural. For example, there may be several salts of alkaline metals, such as potassium sulfate, sodium chloride, sodium phosphate, potassium bromide, potassium chloride etc.

7) **Plasticizers:**
They can change the properties of the elastic polymers and such a change can affect the penetrability of the polymer film to indicate the number of different types and plasticizers used in the roofing membrane such as, Ethylene glycol mono-acetate, Polyethylene glycols, Tri-ethyl citrate and the like.

8) **Coating solvent :**
solvent Coatings used on walls developed from the osmotic devices containing mineral and biological solvents that do not negatively harm the core, wall and other problems. The different solvents contain cyclo-hexane, methylene chloride, acetone, water, methanol, butyl-alcohal, ethanol, IPA, ethyl acetate, carbon tetra-chloride and like. (21)

IDEAL CHARACTERISTICS OF DRUGS IN ODDS:

- The drug should be chemically inert.
- The drug should stable at different pH.
- Drug should be non-toxic in nature.
- Drug is do not causing the irritation in GI tract.
- Drug having shorter half-life.

MECHANISM OF ODDS:

The System is designed with a tablet core, including one or more osmosis agents with the drug. Then The tablet form is lined with a semi-permeable membrane, so there is water flowing through GIT. Thus, the resultant pressure of osmosis forces the preparation in the form of solution or suspension of holes through one or several layers through the treatment. The System can pass the solution of the preparation in zero mode of order at the rate determined by this type of coating and formation of the main components of the borehole diameter. (07)

.

FACTORS AFFECTING THE DESIGN OF ODDS:

The several key factors that affect the strategy of osmotic medication conveyance system they are following:

Orifice Size :

Cavities are one of the most important parts of the membrane that radiates drugs. The Size of the hole should be optimized to control the release of the drug by measuring the minutes of the osmosis system in the diaphragm, which can lead to deformation of the delivery system, which may lead to the release of the variable from the drug. (11), using mechanical drill, laser drilling, several ways to determine the feed to the tablet layer osmosis by using a smooth stroke device, do not cover for a period of pause coverage, and use of leachable matter in the coating Indentation that is nothing covered for the period of the varnish method. The grooves were performed on the main tablet using a needle and a custom stroke at the top of the punch. The delivery Size of the class must be less than the maximum size of the Amax to minimize dilution at the time of opening. In Addition, it will be large enough to size the smallest Amin to reduce the hydrostatic pressure in the system and bind it to zero rate of release order. (23)

Laser drill: This technique is known to create a hole in the millimeter unit of the tablets. In general, CO2 lasers (wavelength 10.6μm) are used for drilling intention, which proposals outstanding consistency uniqueness on minimum amount. (9)

Solubility:

For EOP Solubility is one of the most important factors influencing the mechanics of the drug through a osmosis pump. Suppose that the center pill is a pure drug, the speed of the kinetics of the release of the drug to zero is in order. In general, methods can be divided into two classes. First, the swelling of the polymer can cause this effect in the delivery of drugs that do not dissolve into various suspensions. (22) Second, drug solubility can be increased using various methods, for example by compressing drugs with other more soluble excipients (09). ≥ 95% of zero order kinetics according to this equation. (11)

$$F(z) = 1\text{-}s/p \quad \text{----------Eq.no (2)}$$

Where,
S = Solubility of drug.
F(z) = Release of drug in zero order kinetics.
P = Density of core tablet.

Delivery of the drug using osmosis should be water-soluble in the range of 50, and contains 300 mg per ml. However, since the solubility of this therapy is not stabilized in the cell nucleus, the model an effective release for this one otherwise bad candidate drug can be attained. It was his impression that the physiological solution was too scattered to get a saturated solution, and therefore the zero order of delivery to life is expected in the form of dosing. Then the succinate Salt form has the most favorable solubility, and the osmosis pump is formulated in the

form of salt, providing a long time of radiation up to 24 hours. (23)

Osmotic pressure:
After that, the discharge must be controlled, which determines the inclination of the osmosis, which affects the inner compartment and the external environment. (23) The pressure of osmosis affects the radiation level. To evaluate zero return release, it is necessary to maintain a sustainable solution with saturated breast salts. Often the pressure produced by the saturated medical solutions may not be sufficient to realize the force of motivation. In this case, additional osmosis pressure is added to increase the osmosis pressure. For Example, adding bicarbonate of salt to prevent clogging of the opening by including the drug in the acidic environment by the influence of the bladder, as well as to ensure the desired gradient osmosis. (09)

Compound or Mixture	Osmotic Pressure (atm)
Lactose-fructose	500
Dextrose-fructose	450
Sucrose-fructose	430
Mannitol-fructose	415
Sodium chloride	356
Fructose	335
Lactose-sucrose	250
Potassium chloride	245
Mannitol-dextrose	225
Dextrose-sucrose	190
Mannitol-sucrose	170
Sucrose	150
Mannitol-lactose	130
Dextrose	82
Potassium sulfate	39
Mannitol	38
Sodium phosphate tribasic · 12 H2O 36	36
Sodium phosphate dibasic · 7H 2O 31	31
Sodium phosphate dibasic anhydrous	29
Sodium phosphate monobasic · H2O	28

Table: 1. Osmotic pressure of Osmotic Agents. (23)

Semi permeable membrane (SPM) :-
While SPM is absorptive to water and not ion, the release rate basically regulates the pH of the background. In addition, the drug termination method is completely separate from the surroundings to the shipping system. (09) The Permeability of the water membrane can be better by selecting the correct membrane material. The radiation Time of the energy material may vary a thousand times depending on the thickness of the membrane. In General, the speed of release of the drug can be achieved through membrane material with small changes to 5%, the most achievable on the width of the unreliable layer. (11)

TYPES OF OSMOTIC PUMP:

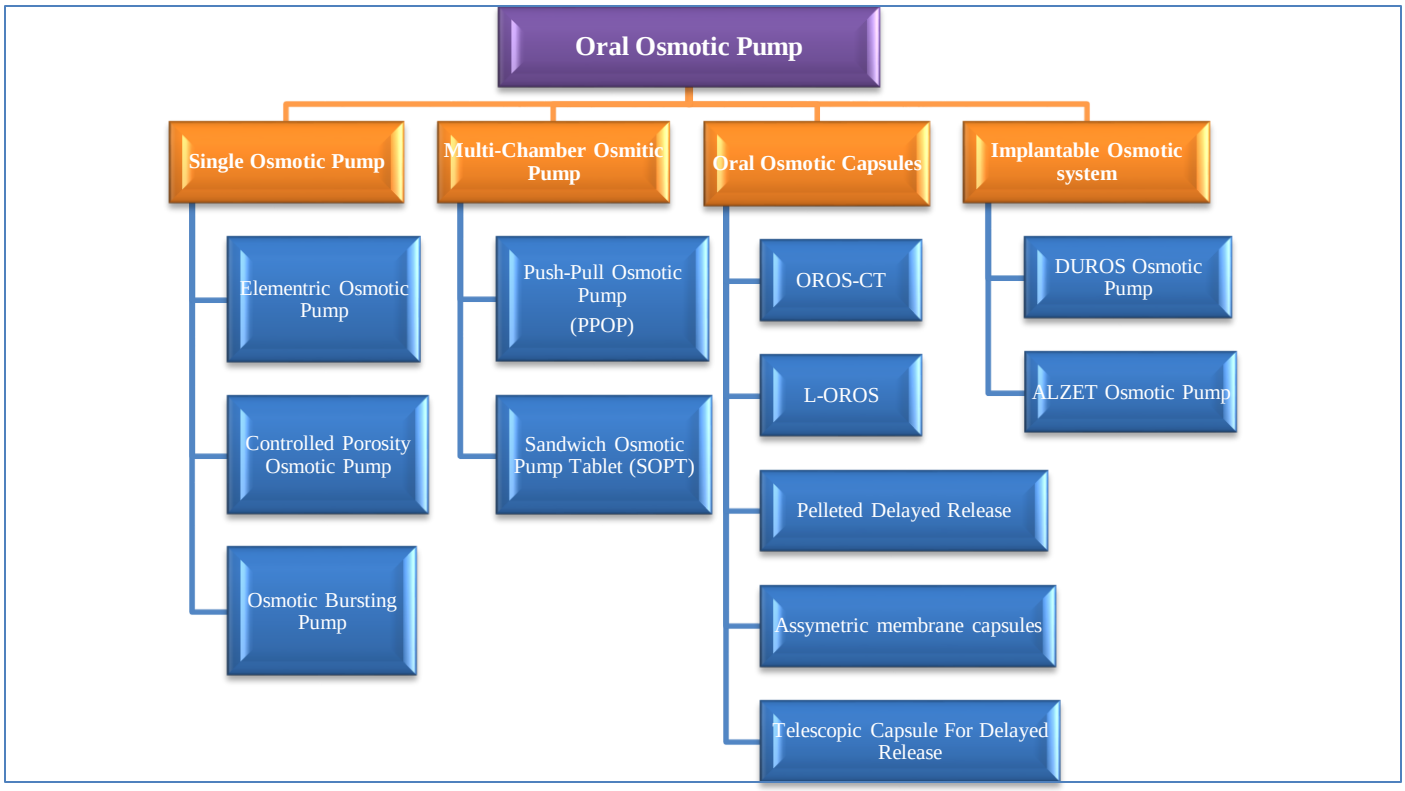

Chart No: 1. Types Of Oral Osmotic Pump. (09)

The delivery System based on their proposals and the active ingredient of the country can be classified as follows:

Single Osmotic Pump:
Single In this design, drugs and osmotic agents are in the same compartment and are surrounded by semipermeable membranes (SPM). The two main components are dissolved in water, which enters the center through osmosis. The restriction is the dilution of the drug solution with an osmotic solution, which upsets the rate of drug release from the system. In addition, drugs that are not water soluble or not water soluble cannot be given effectively with a single space configuration.

In single osmotic pump there are three different types of osmotic pump are following :

Elementary osmotic pump (EOP) :
It is found to determine the main method of nutrition osmosis control drug release is one of the 1974 State osmosis pumps ' Theewes invites (EOP). Cleaning the pump is the versatility of High-theewes pump, and removing the salt chamber is divided into the aid of the drug itself as an osmosis agent. These pills are made by compressing the drug into the proper osmosis pill in the tablets. This Burden is made by a convenient flow of saturated medicinal solution from the device through small openings. (19)

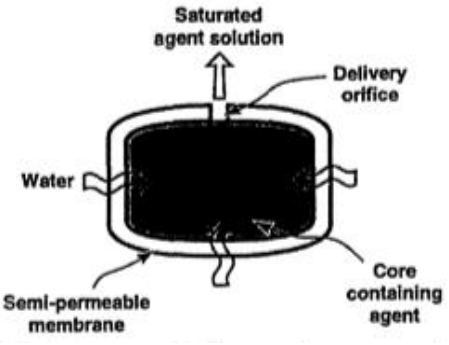

Figure: 4. Elementary osmotic pump (EOP) (09)

The Process continues at a constant rate, and the whole hard drug in the pill is a drug liquid that is continuously supplied. However, the external pressure of osmosis between the environment and the solution of the drug is the moistening of speed as a method. In General, EOP provides 61-81% of the content at a constant speed and has a short delay of 35-65 minutes as the system is received, with EOP releasing the drug to zero order. (11)

Controlled Porosity Osmotic Pump (CPOP)

The Pump can only be prepared by one or more unit of dosed form, in any form, the delivery system consists of a core with a drug film, having the wrong structure, the film is formed in the reverse phase, mixed solvent system controlled by its dehydration. This film is soluble in water, but its resistance to the material melts and other voids are formed by additives scattered across the wall. (07)

CPOP is an attempt to pass basic or automatic equipment for laser drills. In CPOP, the cavity in which the drug is released is formed by the inclusion of a device dissolved in a water-soluble coating. (25)

Water stream dv/dt can be viewed on the device can be represented as:

$$dv / dt = Ak / h (Dp-DR)$$ ---------- Eq.no. (3)

Where,

k = Membrane penetrability.
A = Area of the membrane.
Dp = Osmotic pressure variance.
DR = Hydrostatic pressure variance.

CPOP is because the drug is emitted from the entire surface of the device, not a hole that can reduce the above stimulus, because the diaphragm is formed by the coating process is difficult, there is the advantage that laser drilling is not necessary The one. And pills can be made too small, as drugs, covered with the right film. (11)

Osmotic Bursting Pump:

This structure is parallel to EOP. In a water environment, water is absorbed and hydraulic power is built inside, releasing damage to the barrier and its contents into the atmosphere. By changing the thickness and area, a semi-permeable film can regulate drug release. This method is useful for producing pulsating releases. Destroy the shell capacity that runs out 24 hours later. At the time of the resolution it was decided to say that the tablet would remain credible at GIT. Burst Strength is essential for a critical force to destroy projectiles once the permit is studied. This is determined by the 5 kg load cell and 25mm aluminum tube on the probe surface used for this solution.

Multi-Chamber Osmotic Pump:

Some subjects. In this strategy, the drug is distributed from the osmotic compartment through an elastic film that moves from an increase in pressure in the adjacent osmotic compartment, which in turn moves the solution or suspension of the drug. Multi-chamber systems are basically more efficient than single osmotic pumping and can provide drugs with their own level of water solubility. One of the main advantages of this system is its ability to provide drugs that are incompatible with electrolytes or commonly used osmotic agents. (09)

There are two different pumps in the osmotic multi-chamber pump:

Push-Pull Osmotic Pump (PPOP) :-

The OROS Examination has grown over the last few years, from the original "basic" osmosis pump system to being for traction, and through a multilayer tablet with progressive longitudinal compression (LCT). Push-Pull pump for osmosis EOP is common. Push-

Pull Pumps are developed in 1970 to provide long-term medications for zero-order and are exposed to environmental factors such as pH or mobility. (06)

In order to cope with the supply of dissolved in water drug, the subsequent expansion of engineering shaft development is a double layer of cleaning the press-complete osmosis. Pressing the heart pill consists of a medical material, auxiliary layer and a layer containing a compartment. Upper layer contains active pharmaceutical ingredient drug and further excipients the Push layer enclosed the osmotic polymeric agent and upper drug layer is reported for 60-80% tablet weight .the osmotic polymeric layer is accounts for 20-40% weight.(14)

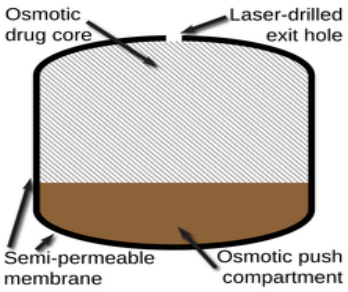

Figure: 5. Push-Pull Osmotic Pump. (PPOP) (14)

Equally layers of the push–pull tablet are osmotically vigorous. When ingested, a 2-layer tablet with water from the gastrointestinal tract forms a suspension or solution for the medicinal coating. The Amount of solution or suspension supplied by the hole corresponds to the amount of water supported by the membrane of the system. (06)

Sandwich Osmotic Pump Tablet (SOPT) :
It consists of a polymer layer that is attached with a trigger that contains two layers of medicine with two holes. If you find a layer squeezed again in the center of the surrounding water, including swelling of the active ingredient of these drugs, the drug is for the medicine, because it is easy to take two holes in the back of the pill to the medication can cause irritation of the mucous Shell of the stomach. (26)

Oral Osmotic Capsules :
The numbers of types oral osmotic capsules are presented in various types of designs are follows such as OROS-CT, OROS-L, hard capsule and soft L-OROS capsule are also available in oral osmotic pump. (16)

OROS-CT :
OROS-CT (Alza Corporation) can use the drug to use topical medications in the colon to fight disease or systemic ingestion, disclosure is not cheap. The Structure of the OROS-CT shaft can be a component of osmosis or a solid gelatin capsule can include a maximum of 5-6 Push units with a diameter of 4mm. Each section is confined to a layer of one layer of Frankie osmosis push layer and the same drug is a semi-permeable membrane. The Hollow cavity was drilled into a layer on the side of the membrane. Immediately After this OROS-CT consists of gelatin, gelatin, spiral brake. Since the medicinal-resistant coating, the water entertainment of each Push-Up device is forbidden to take water in the acidic water around the stomach, and thus there is no cure. (16)

Liquid Oral Osmotic System (L-OROS) :
To gain control over the solubility problem of the drug, Alza install the L-OROS technology. It is an invention of liquid soft gelatin consisting of drugs in midpoint, covered by the limitations of the first production after the lid, then click on the osmosis layer, and then the semi-permeable layer consists of a well. The combined liquid, which is intended to provide medicine as a liquid formulation, combines the advantages and bioavailability of long-term release. They have three types : -

1. L- OROS hard capsule.
2. L- OROS soft capsule.
3. Prolonged liquid bolus delivery system. (11)

Telescopic Capsule for Delayed Release :
This device consists of two parts, the first contains an active substance and an outside opening for opening, and the second is an osmotic machine. The wax layer is similar to the material between two parts. To accumulate dispensers, the preferred active ingredient is in one part with a manual or automatic filling process. The bilayer tablet is placed in a capsule-

enclosed separation by an osmotic machine with an osmotic layer curved at the end of the clogged lid and the obstruction at the end of the lid is closed and a barrier layer is carried to the lumen lid. The open end of the filled container is attached to the inside of the open end of the lid and the two parts are compressed together while the lid, the osmotic bilayer tablet and the gate pair are tight. When the fluid is sucked out of the housing of the lock device, the osmotic motor increases and gives a force to the first and second parts of the wall which are gliding connected. for duration of the long period the number of tanks consisting of active ingredients remains unchanged and leaves little pressure bubbles, including for use in the environment and inside the reservoirs. As a result, the Current net Environmental liquid powered by power is minimal and therefore the active ingredient is not provided during this period. (27)

Implantable Osmotic system:
In the implantable osmotic system are two types of osmotic pump are following:

DUROS Osmotic Pump:
Injection of a dose of drug into a small rod with a titanium rod.

ALZET Osmotic Pump :
The ALZET pump is empty in the core of the pump reservoir, which comes in a salt room with a waterproofing layer covering it and overflowing with a limited drug or hormonal solution. (10)

EVALUATION OF ODDS:

- Categorization of dosage form.
- Effect of osmotic agents.
- Swelling properties.
- Membrane stability and thickness.
- Orifice diameter and drug release.
- In-vitro drug release study.

Zero-order model:

In the dosage form can be expressed as an equation that accumulates the drug brake and does not gradually emit the drug:

Q0 ñ Qt = K0t …….. (1)

Rearrangement of equation (1) yields:

Qt = Q0 + K0t…… (2)

Where,

Qt is the amount of drug brake-down in time t

Q0 is the primary quantity of drug in the solution (many times, Q0 = 0) and

K0 is zero emission to indicate a stable concentration per unit of time. In the case of studies of the kinetics of emissions, the data from the study of releases of the drug in vitro are displayed as the amount of the drug is discarded over time. (02)

CONCLUSION:

The delivery System, dynamic strength provides pressure pressures to release the drug. Basic applications that include certain controls can be returned within a certain period of time or other release templates can be provided regardless of the environmental factors of delivery. Since the osmosis system no longer retains the effective plasma content, It is also possible to avoid low plasma levels during dosing. The Daily wording, based on thought, plays an increasingly important role in improving the patient's performance. The Development of drugs usually provides a good level of mild drug use by the method of loading, but the release of drugs that tend to improve intake in the pharmaceutical world.

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