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A Review on Osmotic Drug Delivery System As A Part of Modified Release Dosage Form

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Abstract: *Osmotic drug delivery systems (ODDS) represent an advanced approach within modified-release dosage forms, designed to provide uniform and predictable drug release independent of physiological variables. These systems operate on the principle of osmotic pressure, utilizing osmogen-driven water influx through a semi-permeable membrane to achieve controlled and nearly zero-order drug delivery. ODDS offer several advantages over conventional and other controlled-release technologies, including minimized influence of gastrointestinal pH and motility, reduced food effects, and improved patient compliance through sustained therapeutic plasma concentrations. Various designs—such as elementary osmotic pumps, push–pull osmotic systems, controlled-porosity osmotic pumps, and multiparticulate osmotic formulations—enable tailored delivery of drugs with diverse physicochemical properties. Despite challenges such as manufacturing complexity and the requirement for specialized coating materials, osmotic systems continue to gain prominence in oral drug delivery due to their reliability, precision, and capability to enhance the efficacy and safety of therapeutic agents. This review highlights the principles, design considerations, advantages, limitations, and recent advancements in osmotic systems as a key component of modified-release dosage technology.*

Keywords: Osmosis, osmotic pressure. Zero order release, GI motility

I. INTRODUCTION

Oral ingestion is one of the oldest and most extensively used routes of drug administration providing a convenient method of effectively achieving both local and systemic effects. Novel drug delivery systems (NDDS) are the key area of pharmaceutical research and development.[1]

In recent year, considerable attention has been focused of development of NDDS osmotically controlled drug delivery system (ODDS) are the type of NDDS which utilize osmotic pressure for controlled delivery of active agent. The release of drug form osmotic system is independent of gastric PH & gastric motility. However, drug release from oral controlled release dosage form may be affected by pH, GI motility & presence of food in the GI tract.[2]

The role of novel drug delivery system is to develop an optimized product that will be therapeutically effective with additional benefits such as

- Enhanced bioavailability.
- Reduced inter patient variability.
- Decreased dosing frequency.
- Improved patient compliance.
- Reduced side effects.[3]

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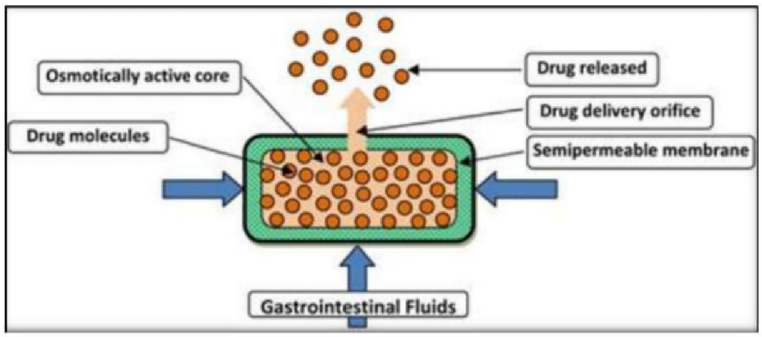

fig no. 1. Osmosis[5]

II. CLASSIFICATION

Osmotic drug delivery devices in general can be divided into two categories

A. Implantable

B. Oral

A. IMPLANTABLE OSMOTIC PUMPS

1. Rose-Nelson Pump
2. Higuchi Leeper Pump
3. Higuchi Theuwespump[6]

B. ORAL OSMOTIC PUMPS

- Elementary Osmotic Pump
- Push pull osmotic pump
- Controlled porosity osmotic pump
- Osmotic bursting pump
- Monolithic osmotic systems
- Multi particulate osmotic pump
- Sandwiched osmotic pump
- Liquid Oral Osmotic System(L-OROS)
- OROS – CT.[7]

A. IMPLANTABLE OSMOTIC PUMPS

1. Rose-Nelson Pump

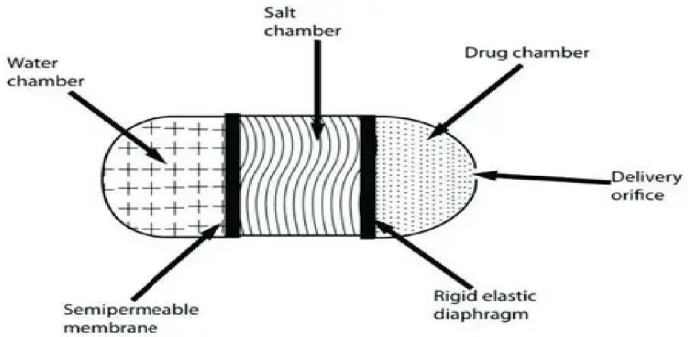

fig no.2. Rose nelson pump[8]

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2. Higuchi Leeper Pump

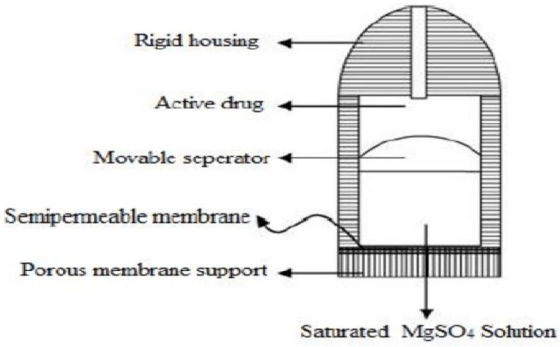
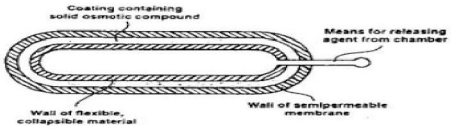


Fig no. 3. Higuchi leeperpump[9]

3. Higuchi Theuwes pump



Higuchi Theeuwes Osmotic Pump

Fig no. 4.Higuchitheuwespump[10]

B. ORAL OSMOTIC PUMPS

1. Elementary Osmotic Pump

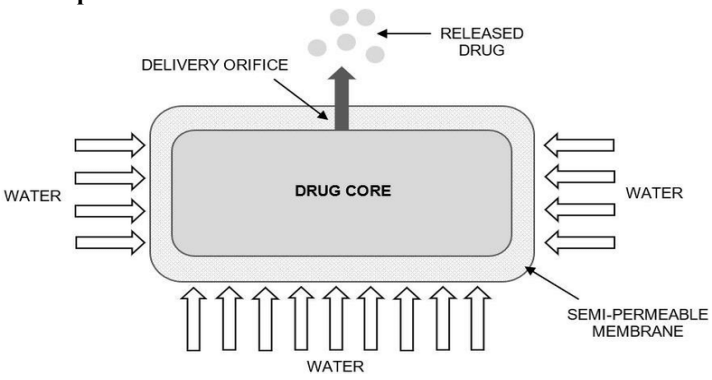


Fig no.5. Elementary osmotic pump[11]

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2. Push pull osmotic pump

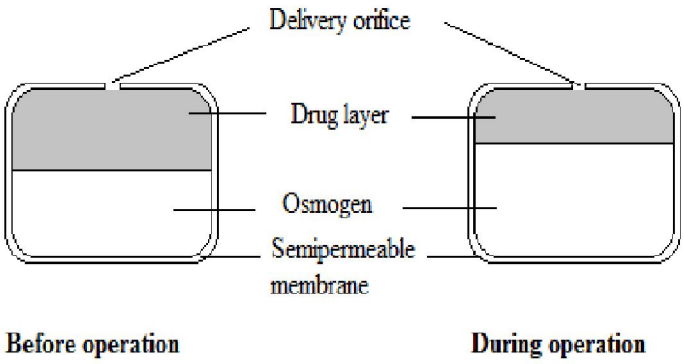

Fig no. 6.pull push osmotic pump[12]

3. Controlled porosity osmotic pump

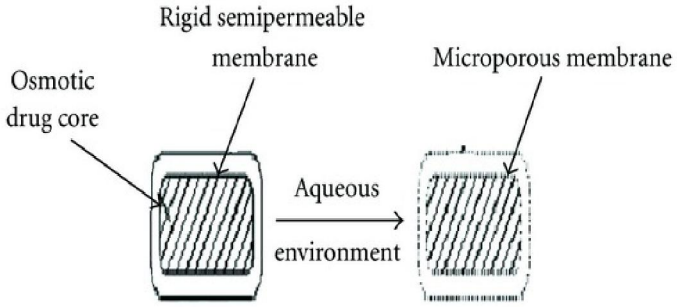

Fig no. 7. Controlled porosity osmotic pump[13]

4. Osmotic bursting pump

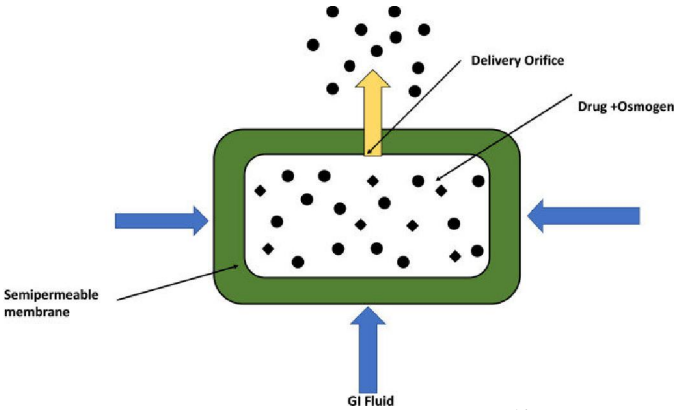

Fig no. 8. Osmotic bursting pump[14]

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5. Monolithic osmotic systems

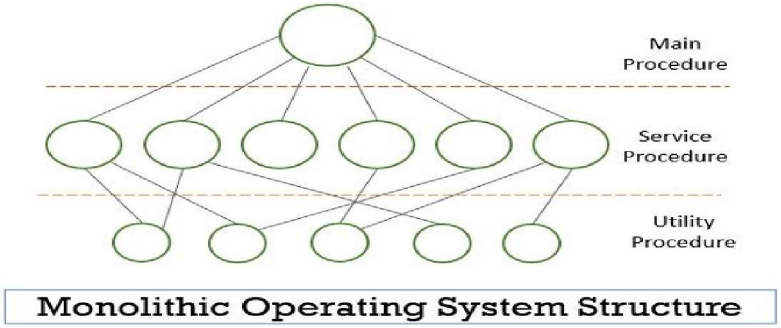

Fig no.9. Monolithic osmotic system[15]

6. Multi particulate osmotic pump

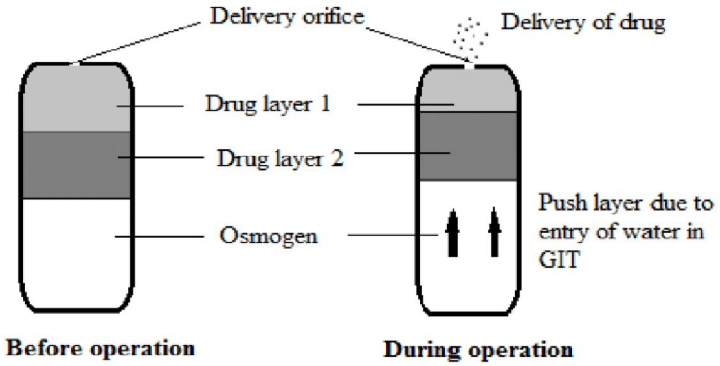

Fig no.10. Multi particulate osmotic pump [16]

7. Sandwiched osmotic pump

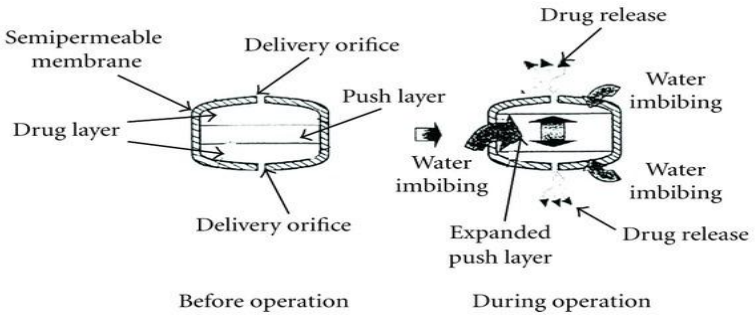

Fig no.11. Sandwiched osmotic pump[17]

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8. Liquid Oral Osmotic System(L-OROS)

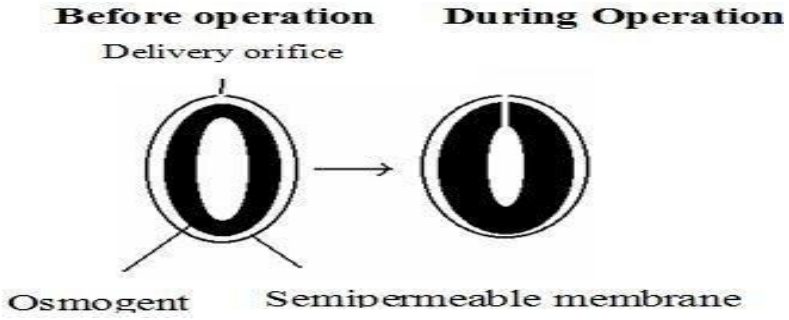

Fig no.12.Liquid oral osmotic system[18]

9. OROS – CT.

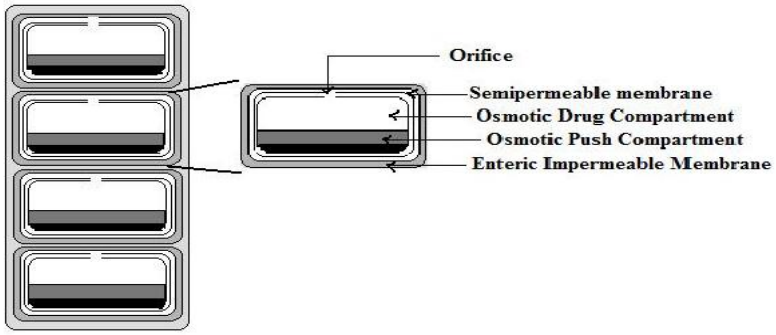

Fig no.13 OROS CT [19]

III. TO STUDY, HOW TO IMPROVED BIOAVAILABILITY

The availability of drug from these formulation may differ significantly depending on factor such as the physiochemical property of the drug, presence of excipient and various physiological factor such as the presence or absence of food, GI motility and the pH of the GI tract.[20]

Conventional matrix or reservoir formulation often encounter issues with fluctuating bioavailability due to changes in gastric pH. Additionally, the drug release from these system can be influenced by the body hydrodynamic condition. The rate and degree of drug absorption from conventional formulation may vary significantly depending on factor such as the drug physicochemical properties, presence of excipient, physiological factor like the presence / absence of food & the pH of the gastrointestinal tract (GI). [21]

3.1 Strategies:

- Optimize osmotic agent: choose an osmotic agent that generates sufficient osmotic pressure to drive drug release.
- Control membrane properties: adjust membrane thickness, porosity, and permeability to regulate drug release rates.
- Formulation optimization: Ensure uniform drug distribution and solubility within the system.
- Targeted delivery: Design the system to release the drug in a specific region of the GIT tract.
- Solubility enhancement: Use solubilizing agent or pH modifiers to enhance drug solubility and bioavailability.
- Formulation design: Optimized formulation composition and structure to enhance solubility, permeability, and stability.
- Controlled release system: Design system that maintain therapeutic drug level over an extended period.

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- Nanotechnology: Use nanoparticle to enhance solubility and permeability.
- Lipid based formulation: Use lipid to improve solubility and bioavailability.

3.2 Benefits:

- Predictable release: osmotic system consistent release profiles.
- Zero order kinetics: constant release rate, independent of drug concentration.
- Improved bioavailability: Enhanced absorption due to controlled release.

3.3 Physiochemical properties:

- Solubility: Enhance solubility through formulation strategies like solid dispersion or complexation.
- Permeability: Optimize molecular structure or use permeability enhancer.
- Molecular size and weight: Larger molecules may have reduced permeability.

The bioavailability of drug from these formulation vary significantly, depending on factor such as physicochemical property of drug, physiological factor, such as GI motility, GI tract, presence or absence of food.[22]

IV. TO STUDY, HOW TO MINIMIZE GI MOTILITY

Research has led to development of novel drug delivery system among which osmotic controlled drug delivery system utilized osmotic pressure for controlled delivery of drug. Drug delivery from these system is independent of physiological factor of GI tract. Release of drug from the formulation is dependent on various formulation factors such as

- Solubility of drug.
- Osmotic pressure gradient of the system.
- Size of the delivery orifice.
- Nature and thickness of rate controlling membrane. (semi permeable membrane)[23]

The release of drug from osmotic system is independent of gastric pH & gastric motility. However, drug release from oral controlled release dosage forms may be affected by pH, GI motility and presence of food in the GI tract. Drug from osmotically controlled drug delivery system is independent of pH and hydrodynamic conditions of the body because of the semi permeable nature of the rate controlling membrane and the design of deliver orifice used in osmotic system, so a high degree pf In vitro/ In vivo correlation is achieved.[24]

The form of NDDS knows as an osmotically regulated drug delivery system (ODDS) uses osmotic pressure to deliver an active ingredient under control. stomach pH and stomach motility have little impact on the release of drug from the osmotic system.[25]

Conventional matrix or reservoir formulation often encounter issues with fluctuating bioavailability due to changes in gastric pH. Additionally, the drug release from these system can be influenced by the body hydrodynamic condition. The rate and degree of drug absorption from conventional formulation may vary significantly depending on factor such as the drug physicochemical properties, presence of excipient, physiological factor like the presence / absence of food & the pH of the gastrointestinal tract (GI).[26]

The rate and extent of drug absorption from conventional formulation may vary greatly depending on the factor such as physicochemical properties of the drug, presence of excipient, physiological factor such as presence / absence of food, pH of the gastro intestinal tract and so on. however, drug release from oral controlled release dosage form may be affected by pH. GI motility and presence of food in GI tract.[27]

To minimized these effect:

Gastro retentive design:

Floating system: Design system that remain buoyant in the stomach, prolonging residence time and allowing for more consistent drug release.

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Bio adhesive system: Use bio adhesive material that adhere to the gastric mucosa, enhancing retension and reducing the impact of GI motility.[28]

V. TO STUDY, HOW TO REDUCE DOSE FREQUENCY

The term controlled release implies a system that provide continuous delivery of the drug for a predetermined period over a long period of time with predictable and reproducible kinetics, and a knows mechanism of release. The system attempts to control drug concentration in the target tissue / cells. Controlled release mostly overlaps the market because of more advantages than conventional dosage form like ease of administration, reduced dosing frequency. The main goal of these delivery system is to prolonged / sustained release of the drug for an extended period of time.[29]

These system can be used for both route of administration, that is, oral and implantation. Osmotic pup offer many advantages over other controlled drug delivery system, that is, they are easy to formulate and simple in operation, improved patient compliance with reduced dose frequency and more consistence, and prolonged therapeutic effect with uniform blood concentration.[30]

VI. TO STUDY, HOW TO MINIMIZED SIDE EFFECT.

These system release the drug in a controlled manner by using osmotic pressureas their driving mechanism. Osmotic pump tablets generally consist of a core including the drug, an osmotic agent, other excipient and a semipermeable membrane coat. According to these system osmotic drug administration produced superior outcomes than any other controlled release approach because it does not depend on the concentration of the drug. By preserving a largely constant, effective medication level in the body and minimizing negative side effects. controlled drug release system try to maintain drug action at a predetermined rate.[31]

These drug delivery system, there is a little or no control over release of the drug and effective concentration at the target side can be achieved by irregular administration f excessive doses. This kind of dosing pattern results is fluctuation in therapeutic plasma concentrations, leading to marked side effects in some cases. Uncontrolled rapid release of drug may cause local gastro intestinal or systemic toxicity.[32]

On the basis of this principle osmotic drug delivery gives better drug release, not depend on concentration of drug and better results than any other controlled release system attempt to sustain drug action at a predetermined rate by maintaining a relatively constant, effective drug level in the body with minimization of undesirable side effects.[33]

In addition to the drug itself, the correct dose of the drug is also significant for an effective treatment. Controlled release system help maintain drug concentration in the body, finally minimized the side effect of the drug and thus improving patient compliance.[34]

Osmotic drug delivery system provide a uniform concentration of drug at the sites of absorption and thus after absorption allow maintenance of plasma concentration within therapeutic range which minimized side effect and also reduced the frequency of administration.[35]

According to these system, osmotic drug administration produces superior outcomes than any other controlled release approached because it doesn`t depent on the concentration of the drug. By preserving a largely constant, effective medication level in the body and minimized side effects, controlled drug release system try to maintain drug action at a predetermined rates.[36]

VII. ADVANTAGES AND DISADVANTAGES OF OSMOTIC DRUGDELIVERY SYSTEM

7.1 ADVANTAGES

1. Improved patient compliance with reduced dosing frequency.
2. Zero order release profile
3. Drug release is independent of gastric pH and hydrodynamic condition.[37]
4. Reduced side effect.
5. Enhanced bioavailability of drug.
6. Reduced inter patient variability.[38]

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7. Increase the safety margin of high potency drugs, reducing the risk of adverse effects.[39]
8. Less GI irritation is identified.
9. This dosage preparation is very easy than compare other novel drug delivery system.
10. This formulation design is compatible to all types of soluble drugs.[40]
11. Drug delivery rate may be delayed or increased if desired.[41]
12. The drug delivery provides In vitro and in vivo correlation.
13. The rate of drug delivery is predictable.
14. They are well characterized and understood.[42]
15. Easy formulation and simple operation.
16. They are suitable for a wide range of drug.[43]

7.2 DISADVANTAGES:

1. Rapid drug tolerance.
2. Saturated solution of drug may cause local gastric irritation.
3. If coating process is not optimized properly there is a risk of film defects resulting in dose dumping.[44]
4. Expensive.
5. Rapid development of tolerance.[45]
6. Dose dumping may occur if the system is not well formulated.[46]
7. Costly development and manufacturing.[47]

VIII. CONCLUSION

Osmotic drug delivery system are based on osmosis is driving force for drug delivery in especially engineered core. In the osmotic delivery system, the osmotic pressure gradient is responsible for the controlled release of drug. In osmotic drug delivery system, osmotic pressure deliver the driving force for drug release. Osmotic drug delivery system utilize the principle of osmotic pressure for drug delivery system. The drug delivery from osmotic system is independent of the physiological factors of GI tract by optimizing various formulation factor such as solubility, osmotic pressure of core components, size of delivery orifice and nature of rate controlling membrane the drug delivery can be controlled. In the osmotic delivery system, the driving force for drug release is provided by osmotic pressure. As water enters the dosage form, pressure inside increase, prompting the release of the drug one of the major advantages of this system it ability to precisely control zero order or patterned release over an extended **perio**d.

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