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A Review on Osmotic Drug Delivery System and Current Status

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ABSTRACT

The purpose of this article brings out the fabrication and recent clinical research in osmotic drug delivery system. The technology of osmotic drug delivery system need to be modified for the conventionally control over their release and almost control the safe and effective concentration in the targeted sites. The certain phenomenon of molecule may have low bioavailability hence to be improve by the fabrication osmotic drug delivery system is most promising system for controlled drug delivery system. The pump and technique most is used to developed the research point of view. The number of marketed oral osmotically driven system (OCDDS) has doubled in the last 11 years. The osmotic pressure utilized for osmotic drug delivery system (OCDDS).

Keywords: Osmotic pressure, Fabrication, Pump, Controlled drug delivery system, Technology.

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INTRODUCTION

Osmotic pump have excellence control on the drug delivery now research were conducted to achieve therapeutic objective[16]. There are many more novel drug delivery systems in the market for the modified release dosage form gives the better patient compliance and administration is easy [1]. The drug release from the system is pH dependent and other physiological parameters for optimize the properties of drug and system [2]. The first and important osmotic delivery system is patent (U.S. patent 3, 845, 77) by in Nov 5, 1974 (Osmosin ®) - Indomethacin and propanolamine - (Acutrim ®)[3]. The conventional oral drug delivery systems are known to provide an immediate release. In the recent years pharmaceutical research has led to development of novel drug delivery [4]. The drug can be delivered in a controlled manner for longer period of time by osmosis [5]. The osmotic drug delivery system costly type of drug delivery system but provides good rate of drug release which acceptance in pharmaceutical world [6]. The clinical performance of technology focuses on food effect and *in vivo* and *in vitro* correlation [7]. The oral drug delivery most widely used in rout of administration by dosage form and design of control also immediate release [10]. The BCS class- I drug having high solubility and high permeability which completely absorb after oral administration hence bioavailability is 25 % and half life is 3-6 hrs. The propranolol hydrochloride is desirable [13]. Among the controlled drug release devices, osmotically controlled hold a stable place because of its reliable to deliver the API at predetermined zero order rate for prolonged period of time so these are used as saturated dosage form for the constant delivery of content [17].

Basics of Osmotic Drug Delivery Systems[3-4]

Osmotic pressure

It is a colligative of the solution and required for the formulation of osmotic drug delivery system.

Osmosis

The osmosis can be defined as the process of movement of solvent molecule from lower to higher concentration through semi permeable membrane.

Principle and Mechanism Osmosis

Osmosis can be spontaneous movement of solvent from lower to higher concentration which is permeable only to the solvent but impermeable to the solute. The pressure applied to higher concentration to inhibit solvent lower called as osmotic pump pressure.

Mechanism of Drug Release from Pump[4]

The basic equation of the osmotic system as follows:

$$dM/dt = dv/dt \times C$$

Where,

dM/dt……..mass release

dv/dt……Volumetric pump release

C……...Concentration of drug

Osmotic Pump and Concept[1]

There are many pumps used in this delivery system for the better therapeutic effect and patient compliance.

Oral Osmotic Pump

This process is continuous at constant rate until solid agent inside the tablet has been dissolved and only solution filled coating membrane is left, generally elementary osmotic pump 60-80% is delivers at constant rate and lag time is 30-60 min.

Controlled Porosity Osmotic Pump

The controlled porosity osmotic pump (CPOP) similar to elementary osmotic pump, once the tablet comes in contact aqueous media in GI the water soluble component dissolve and generation of osmotic pressure.

Push Pull Osmotic Pump

The push pull osmotic pump used for drugs having extremes of water solubility. The drug compartment connected to outside environment via delivery orifice.

OROS-CT System

The OROS-CT ™ system was design for colon target system. The action of osmotic pump results when the coating dissolves in higher pH range (pH->7) of small intestine and transport across the membrane. The swallable portion contains non ionic polymer (PEG) or ionic polymer (Cross-carmelose sodium or sodium starch glycolate) swells and expand after absorption.

Concept of Mechanical Drilling[23, 26]

The technique in which sub millimeter size hole in tablet using the CO2 laser beam (wavelength 16.6 µ) for drilling purpose for example controlled porosity osmotic pump [23]. The wall of the tablet absorbs energy of the beam and gets heated causing piercing of wall takes place [26].

Newer Technology[19, 20]

PORTAB System- Continuous polymer coating

ENSOTROL Technology- Creating network inside the core and increases surface area

ZEROS Tablet Technology- Used in lipophilic drugs

The PORT®-Capsule has 3 parts active and osmotic agent are contains

DURIN Technology- Used in implantable formulation mixed with polymers and copolymer biodegradable polyesters.

Advantages[19, 20]

1. Less expensive with low product cost
2. Easy to formulate
3. Pulsatile and delayed release
4. Zero order kinetic release
5. Reduced dose frequency
6. Prolong drug release and therapeutic effect

Disadvantages

1. Tolerance of rapid development
2. Dumping of dose
3. Expensive
4. Size hole

Factor Affecting Drug Release[1]

On the basis of prudent to deal with some therapeutically proves as follows;

- Use of wicking agents
- Use of crystal habit modifiers
- Effervescent mixture
- Cyclodextrin derivatives
- The alternative salt form
- Use of encapsulated excipients
- Resin modulation approach

Classification of Osmotically Control Drug Delivery System[2]

Implantable

- Rose and Nelson pump
- Higuchi Theeywes pump
- Higuchi deeper pump

Oral osmotic drug delivery system

Single chamber

Elementary osmotic pump

Multiple chamber

Non expanding second chamber, Push pull osmotic pump

Others

- Sandwiched osmotic tablet system
- Colon target (OROS-CT)
- Liquid OROS
- Controlled porosity osmotic pump
- Telescopic capsule

Limitations of Osmotic Drug Delivery System[7]

1. It causes irritation or ulcer due to saturated solution of drug
2. Special orifice required
3. Residence time of the system in the body varies with gastric mobility

Table 1: Osmotic pressure of saturated solution used in ODDS [2]

Mixture	Osmotic pressure (Pump) in (atm.)
KCl	245
NaCl	356
Fructose	355
Potassium Sulphate	39
Manitol	38
Lactose-Sucrose	250
Dextrose-Fructose	450

Components Used in Formulation of Osmotic Pump[18, 23, 24, 27]

Semi permeable membrane

The permeability is important criteria for the selection of semi permeable polymer

Hydrophilic and Hydrophobic polymer

These polymers are used in formulation development of osmotic system containing matrix core.

Wicking agent

The material in which ability of draw water to porous network in a delivery device

Solubilizing agents

Highly water soluble drugs would demonstrate a high release rate that would be zero order kinetic.

Osmogen

Osmogen are dissolving in biological fluid, creates osmotic pressure and build up inside the pump and pushes medicaments outside the pump by orifice.

Surfactants

Useful for wall forming materials

Coating solvent

Solvent suitably used for making polymeric materials.

Plasticizers

Modified the physical property and improve the film forming characteristics of polymers.

Pore forming agent

Control porosity for multi-particulate osmotic pump

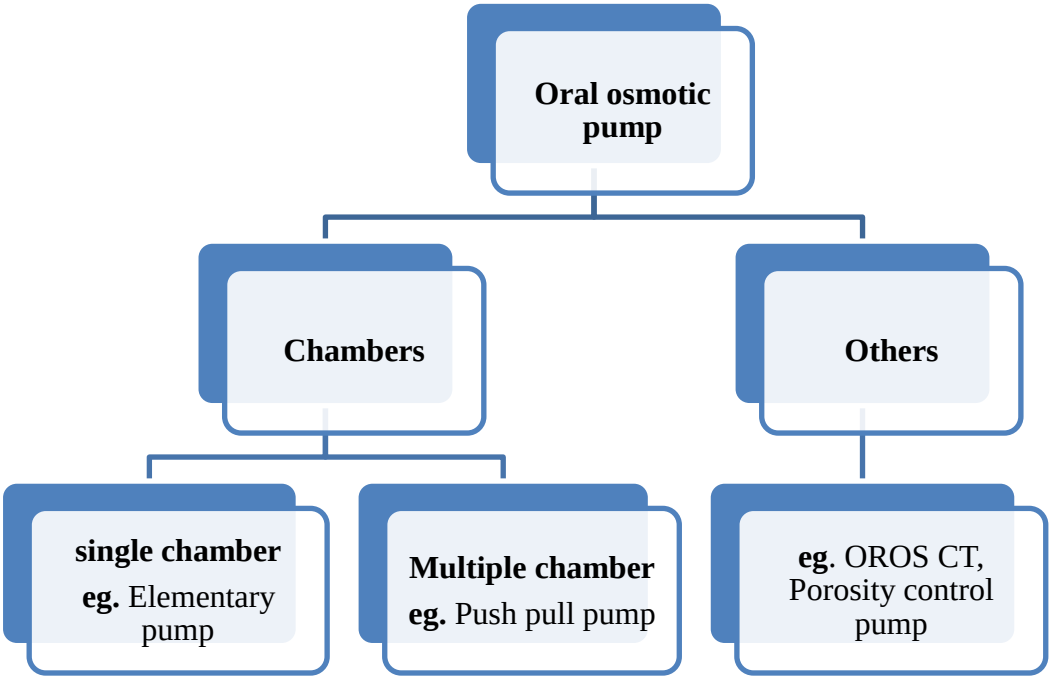

Figure 1: Classification of oral osmotic pumps[21-22]

Flow of Evaluation of Osmotic Tablet[14, 26]

Evaluation of powder

- Bulk density
- Tapped density
- Carr's index
- Angle of repose
- Weight of powder

Evaluation of tablet

- In vitro dissolution study
- Drug content
- Thickness
- Hardness
- Friability

- Weight uniformity

A. Effect of pH on drug release

B. Effect of osmotic pressure

C. Stability

D. Kinetic study

E. Curve fitting analysis

Evaluation of Osmotic Drug Delivery Systems[9]

Visual inspection

The visual inspection required to know about uniformity of drug, smoothness and luster etc.

Coat weigh and uniformity

The coat weight and thickness determined by depleted device using standard analytical and screw gauge etc.

Orifice diameter

The orifice most be determined by microscopically using pre-calibrated ocular micrometer.

Coating uniformity

The before and after coating the uniformity of coating takes place, which determining weight, thickness and diameter of tablet.

***In vivo* evaluation**

The IVIVC from oral drug delivery most be performed by the intestinal tract of the dog this is quit same to that human in terms of pH and mobility.

***In vitro* release**

The conventional USP dissolution apparatus I and II, Flow through cell apparatus etc. are used. This is subsequent of 2-4 hrs, the used in simulated gastric fluid.

Scientific Aspects [17]

The purpose of study was to understand which factor effect on the drug delivery for modeling of drug release and to develop mathematical, statistical model of drug release. The drug properties are tested by two models of drugs i.e. Isradipine (ISR) and Chlorpheniramine (CPA) practically insoluble and freely soluble. The kinetics of mainly controlled by four factors as follows:

1. The drug layer polymer grade
2. The tablet surface area
3. The PEG proportion in membrane
4. The osmotic agent proportion

The scientist Wright et al; in 1992 was studied on osmotic control release bilayer tablet for water soluble drugs. In the market there are 32 products are available having therapeutic aspects, CVS- 50 %, Neurological- 15 %, Seasonal- 20 % and Metabolic disorder – 15 %. These are products available mainly two companies namely Johnson & Johnson and Alza [25].

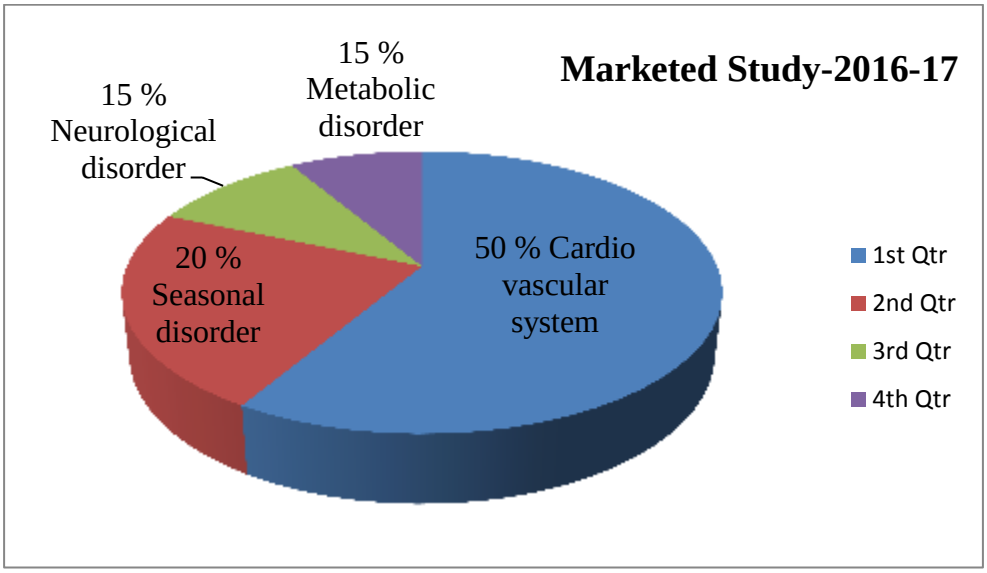

Figure 2: Marketed study [25]

Table 2: Patent number to controlled osmotic pump[11-12]

Patent Number	Pump
4968,507	Porosity osmotic pump
4256,108	Laminated osmotic pump
4160,452	Laminated osmotic pump
4994,273	Modified osmotic pump

Table 3: Target allowing marketed products [3]

API	Brand name	Marketed by
Hydromorphin	Junita	T & J
Isradipine	Dynaoric CR	Alza
Albuterol	Volmax	GSK
Paliperidone	Innega	Xian janssen
Oxycodone	Oxycotin	Alza

Table 4: Specification of controlled porosity[28, 31]

Specification	Materials
5 to 95 % between 10a to 100m	Pore forming additives
1 to 1000, preferably 20-500m	Wall thickness
0 to 40, preferably 0.001 to 40 parts	Surfactants
0 to 50, preferably 0.001 to 50 parts	Flux regulated agents

Table 5: Scale of osmotic pump and main values[29, 31]

Parameters	Rose- Nelson	Theeuwes	Higuchi-Theeuwes	Higuchi-Leeper
Number of components	6	2	4	5
Approximate volume	80	<1	3	35

CONCLUSION

A lot of studies have been done on osmotic drug delivery system by using different kind of drugs and polymer-copolymers, pore former, solvent system, osmogen and coating agents etc. it has been found that research study follow the 3-6 hrs half life drug and zero order kinetics. The osmotic drug delivery shows the prolong release in chronic disease. There are many patents are available to this study. The prominent companies to and investigator made the research and development center growth in commercial level.

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