

Review on Osmotic Release Paliperidone Capsule by Using Push Pull Technology

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ABSTRACT: Osmotic release systems are a type of drug delivery system that utilize osmosis to control the release of a drug over an extended period of time. These systems typically consist of a drug core surrounded by a semipermeable membrane and a delivery orifice. When the system comes into contact with water, osmotic pressure is generated, causing the drug to be released through the delivery orifice at a controlled rate.

Paliperidone is an antipsychotic medication used to treat conditions such as schizophrenia and bipolar disorder. It is available in various formulations, including extended-release tablets and intramuscular injections. The development of an osmotic release paliperidone capsule using push-pull technology would involve incorporating paliperidone into an osmotic release system and optimizing the design to achieve the desired release profile.

KEYWORDS: Push Pull Osmotic Pump, Cross Linked Hard Gelatin Capsule, Paliperidone, Schizophrenia.

I. INTRODUCTION:-

Osmotic release systems are designed to deliver drugs in a controlled manner over an extended period of time. These systems utilize the principles of osmosis to regulate the release of the drug. The core of the osmotic release system contains the drug, which is surrounded by a semipermeable membrane. This membrane allows water to enter the system, creating an osmotic pressure difference. As a result, the drug is released through a small orifice at a controlled rate. In the context of paliperidone, which is an antipsychotic medication, the development of an osmotic release capsule using push-pull technology would involve incorporating paliperidone into the osmotic core and optimizing the design to achieve the desired release profile. The push-pull technology refers to the mechanism used to control the drug release, where the osmotic pressure generated inside the

system pushes the drug out through the orifice. The main goal of antipsychotic medications is to help manage and alleviate the symptoms associated with psychosis. Psychosis is a state in which an individual experiences a loss of contact with reality, leading to disturbances in perception, thought, emotions, and behavior.

Schizophrenia :-

Schizophrenia is a weakened mental illness that affects 1% of the population cultures. Psychosocial and family interventions can improve outcomes. After using various drugs, symptoms can be controlled, but all antipsychotic medicines have neurological or physical adverse effects. (e.g. weight gain & diabetes). There is a 10% life-time risk of suicide in patients with schizophrenia.

Push Pull Osmotic Pump :-

Creating a capsule with a push-pull osmotic pump involves designing a system where osmotic pressure drives the release of a drug. Typically, it consists of an inner core containing the drug surrounded by a semipermeable membrane.

Inner Core: Fill the core with the drug formulation you want to release. This can include active ingredients and excipients.

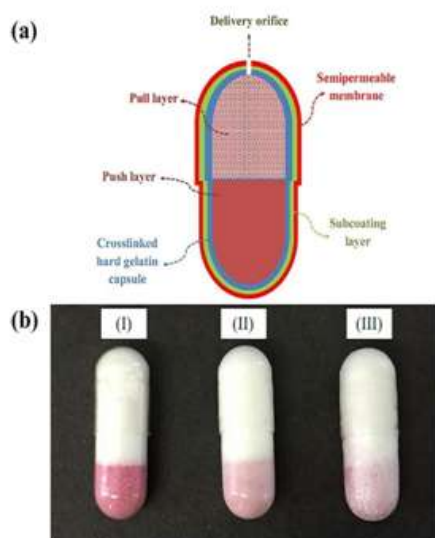
Semipermeable Membrane: Surround the core with a semipermeable membrane that allows water to enter but prevents the drug from escaping directly. This membrane is essential for the osmotic process.



Push Layer: Outside the semipermeable membrane, include a push layer. This layer contains osmotically active agents that attract water. As water enters through the semipermeable membrane, it creates pressure, pushing against the drug core and facilitating release.

Pull Layer: Beyond the push layer, include a pull layer that helps maintain osmotic balance. This layer typically contains substances like salts or other osmotically active compounds.

Capsule Shell: Encapsulate the entire system in a standard gelatin capsule to make it easier to administer.



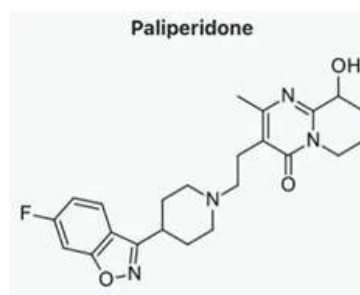
DRUG PROFILE

IUPAC name:-(RS)-3-[2-[4-(6-fluoro-1, 2 - benzoxazol-3-yl) piperidin-1-yl] ethyl]-9-hydroxy-2-methyl- 6, 7, 8, 9-tetrahydropyrido [1, 2-a] pyrimidin-4-one

Formula: -C₂₃H₂₇FN₄O₃

Molar mass: -426.492 g·mol⁻¹

STRUCTURE:



Mechanism Of Action :-

Paliperidone is the active metabolite of risperidone, and it belongs to the class of atypical antipsychotic medications. Its mechanism of action involves antagonism of dopamine receptors, particularly D₂ and D₃ receptors in the brain. This helps to regulate the balance of neurotransmitters and is thought to contribute to its antipsychotic effects.

Pharmacokinetic Data :-

Bioavailability :- 28 % (Oral)

Elimination Half Life :- 23 hours (by mouth)

Excretion :- 1% unchanged in urine

18% unchanged in feces

Uses :-

1. Paliperidone is primarily used in the treatment of schizophrenia and schizoaffective disorder.
2. It helps to alleviate the symptoms such as hallucinations, delusions, thought disturbances and mood disturbances associated with these psychiatric conditions.
3. It also Prescribed to maintain stability in individual with bipolar disorder.

Side Effects :-

Paliperidone is the antipsychotic medication, may have various adverse effects. Common side effects includes ;

1. Weight gain
2. Drowsiness

3. Muscle stiffness
4. Neuroleptic malignant Syndrome

Method :-

The manufacturing process of osmotic release paliperidone capsules using push-pull technology generally involves the following steps:

Core Formulation: Create a drug core containing the active ingredient paliperidone along with excipients to ensure proper release characteristics.

Push System: Formulate a capsule containing an osmotic agent, such as a water-soluble material like polyethylene glycol. This capsule serves as the push system that generates osmotic pressure.

Coating: Surround the drug core with semi-permeable membrane, typically made of cellulose acetate. This membrane allows water to enter while preventing the passage of the drug.

Drilling: Create a small hole or aperture in the membrane. This hole allows water to enter, initiating the osmotic process.

Final Coating: Apply a final coating to the membrane, which can serve to control the drug release rate and provide additional stability.

II. CONCLUSION :-

The developed PPOP capsule was an alternative device for osmotic drug delivery systems and is applicable for delivery of high and low water soluble drugs. However, employing the push-pull technology for developing osmotic release paliperidone capsules offers a promising avenue for controlled drug delivery. This innovative approach enhances therapeutic efficacy, minimizes side effects, and ensures a sustained release, thereby improving patient compliance. The implementation of push-pull technology in formulating these capsules represents a significant stride towards optimizing drug delivery systems and advancing pharmaceutical innovation.

III. SUMMARY :-

Paliperidone is 9-hydroxyrisperidone, the principal active metabolite of risperidone. It was the antipsychotic medicine, substantially used to treat schizophrenia and bipolar disorder. Osmotic release paliperidone capsule was prepared by using drive technology. A system where the medicine is released through a semipermeable membrane. The

“drive” element involves an bilobular core with paliperidone, while the “pull” is eased by an osmotically active agent drawing in water, causing controlled drug release. This technology ensures a gradual and extended release of paliperidone, optimizing therapeutic effects of medicine and minimizing adverse effects.

REFERENCES :-

- [1]. Jain NK, Naik SU. Design of a slow-release capsule using ray drilling. *J Pharm Sci.* 1984;73(12):1806-11.
- [2]. Verma RK, Mishra B, Garg S, osmotically controlled medicine delivery. *Drug Dev Ind Pharm.* 2000;26(7):695-708.
- [3]. Canuso C, Bossie C, Turkoz I, et al. 2006a. Direct and circular goods of paliperidone extended-release tablets on negative symptoms of schizophrenia. *Int J Neuropsychopharmacol.*
- [4]. Canuso C, Youssef E, Dirks B, et al. 2006b. Paliperidone extended-release in oppressively ill cases with schizophrenia. Presented at the Institute on Psychiatric Services, October 5–8 2006, New York, NY, USA.
- [5]. Janicak P G, Winans E A, 2007, Paliperidone ER- A review of clinical trial data. *Neuro psychiatry. Treat.* 3: 869-872.
- [6]. Kane J, Canas F, Kramer M, et al. 2007. Treatment of schizophrenia with paliperidone extended-release tablets: A 6-week placebo-controlled trial. *Schizophrenia Res.* 90:147–61
- [7]. Owen R T, 2007, Extended-release paliperidone: efficacy, safety and tolerability profile of a new atypical antipsychotic *Drugs Today*, 43, 249-258
- [8]. Wichianprakit N, Kulvanich P. osmotically controlled medicine delivery system using a crosslinked and non crosslinked hard gelatin capsule. In : *Asian Federation of Pharmaceutical Sciences*, Fukuoka, Japan, October 2009. P 193
- [9]. Gurny N, 2009, Oral osmotically driven systems: 30 years of development and clinical use, *European Journal of Pharmaceutics and Biopharmaceutics.* 73 (3): 311–23
- [10]. Brahma P. Gupta, Navneet Thakur, Nishi P. Jain. Osmotically controlled medicine delivery system with associated medicine *J Pharm Pharmaceut Sci* 2010; 13 (3):571-588.



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- [11]. Tanmoy Ghosh, Amitava Ghosh, Drug delivery through bibulous systems-An overview, Journal of Applied Pharmaceutical Science 01 (02); 2011: 38-49
- [12]. Monton C, Kulvanich P. Characterization of crosslinked hard gelatin capsules for a structural assembly of elementary osmotic pump delivery system. J Pharm Invest. 2019;49:655–65.
- [13]. Sofia von malortie, Ellinor, Gunilla, lena Ringback, New national guidelines for the treatment of schizophrenia in Sweden, 2019