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REVIEW OF OSMOTIC RELEASE PALIPERIDONE CAPSULES USING PUSH PULL TECHNOLOGY

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Abstract:

Osmotic release systems are specialized drug delivery mechanisms that leverage osmosis for controlled drug release over prolonged durations. These systems typically comprise a drug core encased in a semipermeable membrane with a delivery port. Upon exposure to water, osmotic pressure builds, facilitating controlled drug release through the delivery port.

Paliperidone, an antipsychotic medication used for conditions like schizophrenia and bipolar disorder, exists in various formulations such as extended-release tablets and intramuscular injections. Developing an osmotic release capsule for paliperidone using push-pull technology involves integrating paliperidone into an osmotic release system and refining its design to achieve targeted release characteristics.

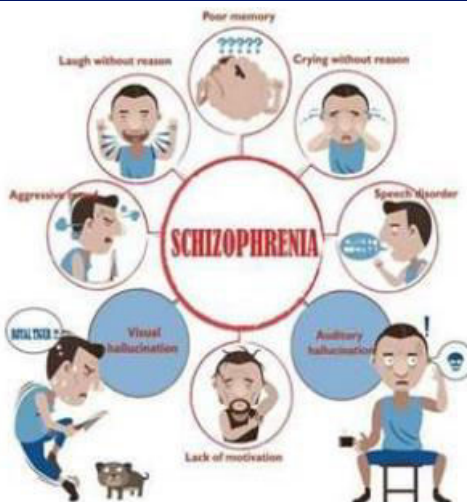
Keywords: Push Pull Osmotic Pump, Cross Linked Hard Gelatin Capsule, Paliperidone, Schizophrenia.

Introduction:

Osmotic release systems are engineered to administer drugs in a controlled manner over extended durations, harnessing osmosis principles for regulated drug release. These systems comprise a drug-filled core encased in a semipermeable membrane. Water permeation into the system creates an osmotic pressure gradient, facilitating controlled drug release through a small orifice.

In the realm of antipsychotic medications, paliperidone stands out for its role in treating conditions like schizophrenia. Developing an osmotic release capsule using push-pull technology involves embedding paliperidone within the osmotic core and optimizing its design to achieve precise release profiles. Push-pull technology denotes the method where internal osmotic pressure propels the drug through the orifice.

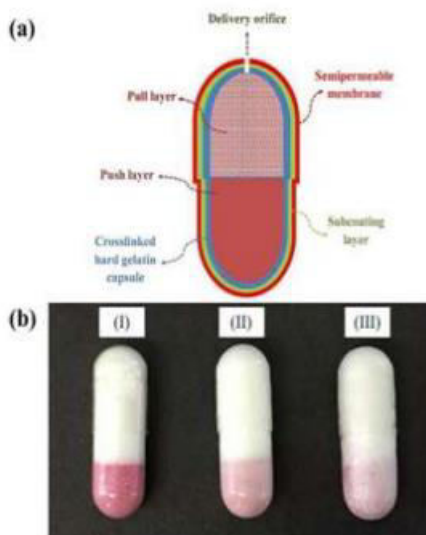
The primary objective of antipsychotic medications is to manage and alleviate symptoms associated with psychosis. Psychosis entails a state where individuals experience detachment from reality, affecting perception, thoughts, emotions, and behavior.



Push Layer: Incorporate a push layer outside the semipermeable membrane, comprising osmotically active agents that draw in water. This influx of water through the semipermeable membrane generates pressure, pushing against the drug core and facilitating controlled release.

Pull Layer: Beyond the push layer, include a pull layer designed to maintain osmotic equilibrium. This layer commonly contains substances such as salts or other osmotically active compounds.

Capsule Shell: Encapsulate the entire system within a conventional gelatin capsule for ease of administration.



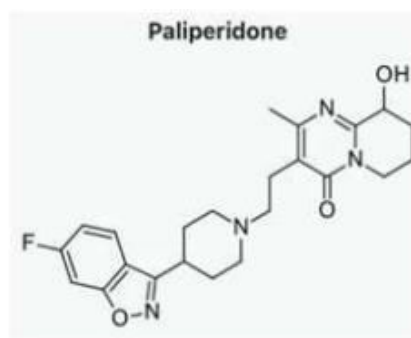
Drug Profile

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

Chemical Formula: C₂₃H₂₇N₄O₃

Molar Mass: 426.492 g·mol⁻¹

STRUCTURE:



Mechanism of Action:

Paliperidone is the active metabolite of risperidone, belonging 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 antagonism helps regulate the balance of neurotransmitters, contributing to its antipsychotic effects.

Pharmacokinetic Data:

- **Bioavailability:** 28% (Oral)
- **Elimination Half-Life:** 23 hours (oral administration)
- **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 alleviate symptoms such as hallucinations, delusions, thought disturbances, and mood disturbances associated with these psychiatric conditions.
3. It is also prescribed to maintain stability in individuals with bipolar disorder.

Side Effects:

Paliperidone, as an antipsychotic medication, may have various adverse effects. Common side effects include:

1. Weight gain
2. Drowsiness

Method:

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

1. **Core Formulation:** Prepare a drug core containing the active ingredient paliperidone and appropriate excipients to ensure desired release characteristics.
2. **Push System:** Develop a capsule containing an osmotic agent, such as a water-soluble material like polyethylene glycol. This capsule functions as the push system that generates osmotic pressure.
3. **Coating:** Surround the drug core with a semi-permeable membrane, usually made of cellulose acetate. This membrane allows water to enter while controlling the passage of the drug.

4. **Drilling:** Create a small aperture or hole in the membrane. This hole enables water to enter, initiating the osmotic process.
5. **Final Coating:** Apply a final coating to the membrane to further regulate the drug release rate and enhance stability.

Conclusion:

The developed Push-Pull Osmotic Pump (PPOP) capsule represents an innovative approach to osmotic drug delivery systems, suitable for delivering both highly and poorly water-soluble drugs. Utilizing push-pull technology for osmotic release paliperidone capsules offers a promising avenue for controlled drug delivery. This approach enhances therapeutic efficacy, minimizes side effects, and ensures sustained release, thereby improving patient compliance. Implementing push-pull technology in formulating these capsules marks a significant advancement in optimizing drug delivery systems and fostering pharmaceutical innovation.

Summary:

Paliperidone, the active metabolite of risperidone, is an antipsychotic medication primarily used to treat schizophrenia and bipolar disorder. Osmotic release paliperidone capsules were prepared using push-pull technology, where the drug is released through a semi-permeable membrane. The "push" component involves a core containing paliperidone and an osmotically active agent, while the "pull" component draws in water, facilitating controlled drug release. This technology ensures gradual and extended release of paliperidone, optimizing therapeutic effects while minimizing adverse effects.

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