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Research Article

Formulation and Evaluation of Elementary Osmotic Antidepressant Capsule

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Abstract:

The oral route of administration is considered as the most widely accepted route but the most evident drawback of the commonly used oral dosage forms like tablets and capsules is difficulty in swallowing, leading to patient's incompliance particularly in case of paediatric, geriatric patients, dysphasic, bed ridden, and psychic patients. Thus, a new delivery system developed as in situ pore former osmotic drug delivery system. The purpose of present research work was to develop osmotic drug delivery of Imipramine. Imipramine has been selected as a model drug to study the effect of *in-situ* pore former osmotic capsule because is a tricyclic antidepressant mainly used in the treatment of depression.

Keywords: Osmotic, Capsule, Drug

Introduction:

Dosage forms are a blend of active drug components and nondrug components. Depending on the method of administration they come in numerous types. These are liquid dosage form, solid dosage form and semisolid dosage forms. However various dosage forms may exist for a single particular drug, since different medical conditions can warrant different routes of administration. For example, persistent nausea and emesis or vomiting may make it difficult to use an oral dosage form, and in such a case, it may be necessary to utilize an alternate route such as inhalational, buccal, sublingual, nasal, suppository or parenteral instead. [1] Osmotically controlled oral drug delivery systems utilize osmotic pressure as the energy source for the controlled delivery of drugs. Drug release from these systems is independent of pH and hydrodynamic conditions of the gastro-intestinal tract (GIT) to a large extent, and release characteristics can be easily adjusted by optimizing the parameters of the delivery system [2]. Drug delivery from osmotic system is not influenced by the different physiological factors within the gut lumen and the release characteristics can be predicted easily from the known properties of the drug and the dosage form osmotically controlled drug delivery system, deliver the drug in a large extent and the delivery nature is independent of the physiological factors of the gastrointestinal tract and these systems can be utilized for systemic as well as targeted delivery of drugs. The purpose of present research work was to develop osmotic drug delivery of Imipramine. Imipramine has been selected as a model drug to study the effect of *in-situ* pore former osmotic capsule because is a tricyclic antidepressant mainly used in the treatment of depression.

Experimental work

Method of preparation

Filling of capsule body

For the preparation of osmotic capsule first of all a hard gelatin capsule was taken, than the mixture of Imipramine, Lactose, Nacl, Magnesium sterate and Sodium loaryl sulphate was prepared. The prepared mixture was filled into the body part of capsule by the hand, than the body cap of capsule is placed. [3]

Coating of capsule body

To make insoluble in water, hard gelatin capsule was treated with 1% ethyl cellulose in ethyl alcohol. Hard

gelatin capsules were coated by dip coating method at the room temperature. The coated capsules were then dried at different temperatures ranging from approximately 25 to 50 °C for 15 min. In order to find an optimum temperature for obtaining smooth coat without any shrinkage. Smooth coating was formed when the temperature was 25 °C. Thickness of the semi-permeable film applied to the capsule could be varied by altering the number of coats applied. Number of coats was between 2-5 times and each coating process was carried out after drying the previous coat. [4]

Table 1 Ingredients of formulation of osmotic capsule

S.N.	Ingredients	Quantity (mg)
1.	Imipramine	15
2.	NaCl	2
3.	Lactose	60
4.	Sodium lauryl sulphate	1%w/w
5.	Magnesium stearate	3
6.	Ethyl cellulose	1%
7.	Ethyl alcohol	Q.S

Evaluation of Prepared Osmotic Capsules

Osmotic release study or dye test

The capsule shell of asymmetric membrane containing different types of pores forming agent were filled with a highly water-soluble amaranth dye. The dye was filled in each of the capsule body manually and the cap was snugly fitted to the body of capsule and finally sealed with a sealing solution of ethyl cellulose, to ensure that the no release takes place from the seal. The capsule containing the dye were placed in the distilled water and the solution of sodium chloride (10%w/v) respectively. The capsules were than observed for release of the colored dye in each of the media. The time taken for the initial release of the dye from the capsule was recorded and correlated to the concentration and type of pore forming agent present in the shell of each of the capsule. [5]

***In vitro* release**

For the release study during dissolution apparatus USP apparatus (basket type) was used. In this apparatus 900 ml of solution of phosphate buffer 6.8 pH for 60 minutes at 75 rpm and 37±1°C used. The capsules are placed inside the apparatus and release of drug was evaluated. The samples were filtered and suitably diluted to determine the absorbance at 292 nm in UV spectrophotometer. [6]

Stability study

The purpose of stability study is not only to characterize the degradation of a drug product but also to establish an expiration-dating period or shelf life applicable to all future batches of drug product.

Results and discussion

Osmotic release or dye test

Dye test also revealed that all the prepared systems followed osmotic release. All the asymmetric membrane capsule released dye after a lag time when suspended in distilled water, but none of the system showed the release of the dye when suspended in sodium chloride (10%w/v). This may be attributed to the fact that the osmotic release from the system was inactivated by the higher osmotic pressure of the surrounding medium i.e.10%w/v sodium cholride solution, which did not allowed the system to osmotically release the dye. Thus, the system was shown the osmotic release.

***In vitro* release of prepared osmotic capsules**

The findings were reported in table 2

Table 2: *In vitro* Release Prepared Osmotic Capsules

S.N.	Time (hr)	F1	F2	F3	F4	F5
1	0	0	0	0	0	0
2	1	8.45	9.45	7.594	6.453	6.472
3	2	13.748	15.408	13.16	16.42	13.532
4	3	25.759	29.759	25.654	27.563	25.593
4	4	37.62	42.62	38.147	37.698	38.398
5	6	65.65	68.65	62.157	64.235	63.564
6	8	83.746	87.746	85.245	88.662	84.65
7	10	97.54	95.24	97.59	96.536	98.38

Stability study

The findings of stability study were given in table 3

Table 3: Storage conditions according to ICH guidelines

TYPES	Conditions		Minimum time period at submission(month)
	Temperature (°C)	Relative Humidity (%)	
Short-term testing	40 ± 2	75 ± 5	6
Long-term testing	25 ± 2	60 ± 5	12

Conclusion

Based on the finding of the present investigation, it was concluded that desired environmentally independent and controlled drug delivery of like Imipramine from oral osmotic capsule can be achieved by approximately selecting dispersion, type of membrane and optimizing its thickness, by adjusting the concentration of solubilizing agent and incorporating optimized amount of osmogens.

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