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Formulation Development, Optimization And Evaluation Of Solid Self Micro Emulsifying Drug Delivery System (SMEDDS) Of Dexlansoprazole

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Self-micro emulsifying drug delivery system are prepared in different dosage forms, in which one of the filling in soft and hard hard gelatin capsules resulted in leakage and difficult in manufacturing and loss of material. Dexlansoprazole is a second-generation proton pump inhibitor (PPI) used in the treatment of symptoms of gastroesophageal reflux disease (GERD) and erosive esophagitis (esophageal damage caused by acid in stomach), but because of poor solubility, stability and oral bioavailability. To overcome with the problems the present work was undertaken with an objective to formulate, optimize and evaluate solid SMEDDS (self-micro emulsifying drug delivery system) of Dexlansorazole. The 3^2 Full factorial designs was applied for the solid SMEDDS formulation of Dexlansoprazole. Prepared capsules were reported and comparisons of in-vitro dissolution of prepared tablet with marketed formulation were performed.

Keywords: Dexlansoprazol, SMEDDS, Solid, Capsule, Dissolution.

Introduction

Dexlansoprazole reduces gastric acid production by blocking the final stage of acid secretion. It specifically targets the H/K ATPase enzyme on the surface of gastric parietal cells, which plays a key role in releasing hydrochloric acid. The H/K ATPase acts as a proton pump, exchanging hydrogen ions (H+) from the cell's cytoplasm with potassium ions (K+) in the canaliculus, leading to the secretion of hydrochloric acid into the stomach.[1-2] Self-micro emulsifying drug delivery system are basically discovered for BCS class-II drugs, because of drug with low solubility and high permeability i.e. that is results in poor bioavailability such types pf drugs can be improve the solubility. Solubility can be improved by using oil, surfactant, co-surfactant and solvents they can easy to formulate and improve the bioavailability and stability. [3-4]

The present work was undertaken to formulate, optimize and evaluate a solid self-micro emulsifying drug delivery system containing drug.

Material and Methods

Formulation Development of Solid Self Micro Emulsifying Drug Delivery System (S-SMEDDS)[5]

The 3^2 Full factorial designs was applied for the solid SMEDDS formulation of Dexlansoprazole. The composition is as shown below:

Table 1: 3^2 Full factorial design for S-SMEDDS

Ingredients(mg)	T1	T2	T3	T4	T5	T6	T7	T8	T9
S-SMEDDS	120	120	120	120	120	120	120	120	120
Lactose monohydrate	74			69			64		
Mannitol		74			69			64	
Microcrystalline cellulose- 102			74			69			64
Pre-gelatinized starch	5	5	5	10	10	10	15	15	15
Magnesium stearate	1	1	1	1	1	1	1	1	1
Total(mg)	200	200	200	200	200	200	200	200	200

Evaluation: The prepared capsules were evaluated by following tests[6-7].

Weight variation: Every individual capsules in a batch should be in uniform weight and weight variation within permissible limits. Weight control is based on a sample of 20 capsules. Twenty capsules were randomly selected and accurately weighed using an electronic balance. The results are expressed as mean values of 20 determinations.

In -Vitro Dissolution Testing: As per standard method mentioned in IP.

Comparison of In-vitro dissolution of prepared tablet with marketed formulation: Here in-vitro dissolution of prepared tablet is compared with the marketed tablet formulation.

Results and Discussion

The formulated batches T1 to T9 were evaluated and the results were mentioned in table 2. All parameters were found to be satisfactory and within the specification for Dexlansoprazole. All batches shows average 72% drug released within 10 minutes but among this batch T4 shows 77.8 % drug released in 10 minutes which was faster as compare to other batches. Only batch T4 and T7 prepared form lactose monohydrate shows almost 90 % drug released within 20 min. In batch T7 amount of disintegrant pregelatinized starch was higher (7.5%) as compare to batch T4 (5%) so batch T4 was considered as an optimized batch and was used for further study

Table 2: Weight variation and Disintegration time

Batch	Evaluation Parameters	
	Weight variation (mg)	**Disintegration time (sec)**
T1	265.4 ± 1.1	55
T2	257.3 ± 1.4	74
T3	270.6 ± 1.5	75
T4	262.5 ± 1.4	32
T5	255.9 ± 2.6	60
T6	264.7 ± 2.3	65
T7	266.8 ± 2.6	45
T8	271.2 ± 1.6	55
T9	254.1 ± 1.8	59

Table 3: In-vitro dissolution study of S-SMEDDS formulations

Time (min)	%Drug released								
	T1	**T2**	**T3**	**T4**	**T5**	**T6**	**T7**	**T8**	**T9**
0	0	0	0	**0**	0	0	0	0	0
10	71.5	70.5	70.5	**77.2**	73.2	72.6	73.3	71.8	72.6
20	88.2	80.7	84.1	**90.2**	80.7	85.3	89.9	86.1	84.5
30	93.3	87.2	93.5	**94.6**	86.2	93	94.4	90.4	92.4
60	97.1	92.2	97.4	**97.6**	92.3	99.3	97.7	95.3	96.6
75	99.4	96.6	98.4	**98.9**	94.4	98.2	98.4	99.8	100.2
120	100.1	97.6	101.2	**101.4**	96.2	99.8	99.9	99.5	101.1

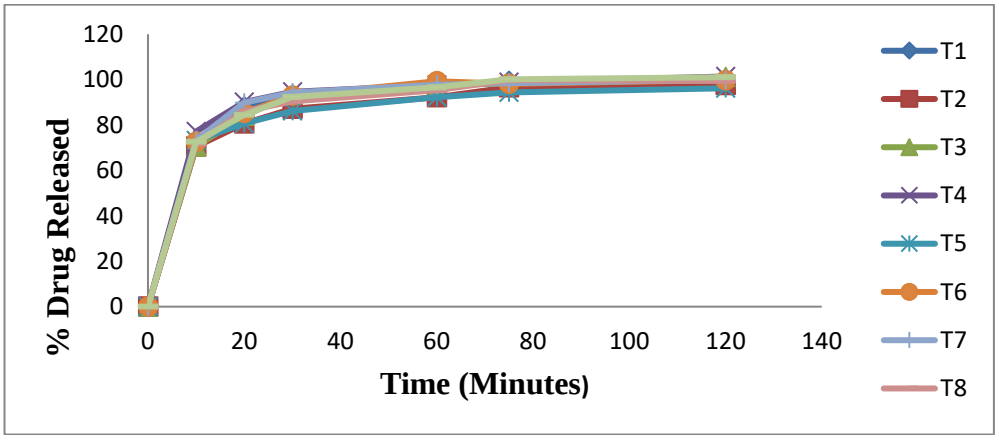

Figure 1: In-vitro dissolution of batch T1 to T9

In-vitro drug release (Table 3) of batch T4 was compare with the marketed formulation. The Marketed formulation shows 55.1% drug release in 10 min whereas formulated batch T4 shows 77.2 % drug release in same time. Batch T4 shows 89.8 % drug release in 20 min whereas marketed formulation shows 90.1 % drug release in 60 min.

Table 3: In-vitro dissolution comparison of M and T4

Time (min)	% Drug released	
	M	T4
0	0	0
10	55.1	77.2
20	75.3	89.8
30	85.5	94.6
60	90.1	97.6
75	97.5	98.9
120	99.8	101.4

Conclusion

This results obtained indicate that by formulating Solid SMEDDS formulation, solubility and thus dissolution profile was increased when both formulations were compared. So data showed that both formulations were dissimilar with respect to in-vitro drug released because of formulation nature.

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