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FORMULATION AND OPTIMIZATION OF ORALLY DISINTEGRATING TABLET OF LABETOLOL

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ABSTRACT

Among the dissimilar routes of administration, oral way of administration continue to be the most chosen route due to different advantages including ease of intake, avoidance of pain, adaptability and most importantly patient fulfillment. The different dosage forms include tablets, capsules and oral liquid preparations. For the past two decades, there has been an enhanced demand for more patient compliance dosage forms. Thus, these conventional dosage forms result in high prevalence of noncompliance and unsuccessful therapy with respect to swallowing specially in the case of geriatric, pediatric, or any mentally retarded persons. Orodispersible tablets or orally disintegrating tablet can be easily administered in the population especially for geriatric, pediatric, or any mentally retarded persons made it a much admired dosage form. Due to the existence of super disintegrants, it gets dissolved quickly, resulting in speedy absorption of drug which provides rapid onset of action. The primary scope of the research is to prepare and evaluate oro dispersible labetolol tablets to overcome the limitations of ordinary tablet formulation.

KEYWORDS: Orodispersible, disintegrating tablet geriatric, pediatric, super disintegrants.

INTRODUCTION

Difficulty in swallowing (Dysphagia) is a common problem in all age groups, especially the elderly and pediatrics, because of physiological changes associated with these age groups. It is common to see those afflicted carrying a small device with them, which is used for crushing tablets, enabling easy ingestion. Other categories that experience problems using conventional oral dosage forms include are the mentally ill, uncooperative and nauseated patients, those with conditions of motion sickness, sudden episodes of allergic attack and coughing. Sometimes, it may be difficult to swallow conventional products due to unavailability of water. These problems led to the development of a novel type of solid oral dosage form called mouth-dissolving tablets, which disintegrate and dissolve rapidly in saliva without the need of the water. They are also known as Oro dispersible tablets, melt-in-mouth tablets, rapimelts, porous tablets, oro-dispersible, quick dissolving or rapidly disintegrating tablets.[1,2]

The fast-melting tablets present the combined benefits of a liquid formulation and a solid dosage form. They are easy to handle and ingestible as a liquid dosage form. An ideal fast-melting tablet should possess the following characteristics. The tablet should melt or disintegrate in the mouth within 60 seconds. The tablets should also be mechanically strong for easier handling, and the production cost should be similar to that of conventional tablets. The use of existing tablet machinery and procedures dictates the low production cost and has another advantage of producing mechanically strong tablets. The ideal fast-melting tablets should also be less sensitive to humidity, thus allowing multi-tablet packaging.[3,4]

The drug releases from the ODT'S due to the action of super disintegrants like cros povidone, cros carmellose sodium, sodium Starch glycollate and polyvinyl pyrrolidone in the formulation.

Superdisintegrants provide quick disintegration due to combined effect of swelling and water absorption by the formulation. As an effect of swelling of superdisintegrant, the wetted surface of the carrier increases, which promotes wettability and dispersibility

of the system and thereby enhance the disintegration and dissolution.[5,6]

METHODOLOGY

Fabrication and characterization of oro dispersible tablet by Direct Compression Method

In this formulation of ODT of labetalol hydrochloride, Each super disintegrant was employed in three concentrations (5,10 and 15%). The composition of ODT of labetalol hydrochloride was shown in Table:. weighed quantities of along with appropriate concentrations of super disintegrant, mannitol-D, microcrystalline cellulose, colloidal silicon dioxide, saccharin sodium were weighed and mixed in geometric progression in a dry and clean mortar. Then the blend was passed through sieve No: 60. Then magnesium stearate was added and mixed well. The dry blend was compressed into tablets using 8 mm punches in a 16 Station Rotary Tablet Machine. Then the Fabricated tablets were evaluated for thickness, diameter, hardness, friability, wetting time, water adsorption ratio, weight variation test, drug content uniformity, uniformity of dispersion, *In- vitro* dispersion time, *In- vitro* disintegration time, and *In-vitro* dissolution studies.[7-10]

Table 1: Fabrication of oro dispersible tablet by Direct Compression Method.

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Labetalol(mg)	100	100	100	100	100	100	100	100	100
SSG	5%	10%	15%	-	-	-	-	-	-
CCS	-	-	-	5%	10%	15%	-	-	-
CP	-	-	-	-	-	-	5%	10%	15%
MCC (mg)	120	115	110	120	115	110	120	115	110
Mannitol	15	15	15	15	15	15	15	15	15
Aerosil	6	6	6	6	6	6	6	6	6
Saccharin sodium	2	2	2	2	2	2	2	2	2
Magnesium stearate	2	2	2	2	2	2	2	2	2

Evaluation of oro dispersible tablets (odt's)

a) Wetting Time

Wetting time is closely related to the inner structure of tablets and to the hydrophilicity of the excipients. A linear relationship exists between wetting time and disintegration time. Thus wetting time is an important step for disintegration process to take place. Method : A piece of tissue paper folded twice was placed in a small Petridish (internal diameter = 6.5cm) containing 6ml of water. A tablet was placed on the paper and the time for complete wetting of the tablet was measured in seconds. Three trials for each batch were performed and standard deviation was also determined.[11,12]

b) Water Absorption ratio

A piece of tissue paper folded twice was placed in a small Petridish (internal diameter = 6.5cm) containing 6ml of water. A tablet was placed on the paper and time required for complete wetting was measured. The wetted tablet was then weighed. Water absorption ratio (R) was determined.[13-15]

c) In – vitro drug release studies

i) *In- Vitro* Dispersion Time

In-vitro dispersion time was measured by dropping a tablet in a measuring cylinder containing 6ml of pH 6.8 (simulated saliva fluid). The time for the tablet to completely disintegrate into fine particles was noted. Three tablets from each batch were randomly selected and *in-vitro* dispersion time was performed.[16,17]

ii) *In – Vitro* Disintegration Time

The disintegration time of the tablets was determined as per Indian Pharmacopoeial monograph. The test was carried out using Tablet disintegration apparatus. Six tablets from each batch were placed and one liter of distilled water was used as the disintegration medium. The time required to obtain complete disintegration of all the six tablets was noted.[18,19]

iii) *In – Vitro* Dissolution Studies

In-vitro drug release studies for the Oro dispersible tablets of labetalol hydrochloride was studied using Dissolution apparatus II USP XX1 model [Paddle type] for the fabricated batches. 650ml of sorenson's buffer solution [pH 6.8] was used as the dissolution medium. The tablet was placed in the dissolution medium and rotated at a speed of 50 rpm maintained at a temperature of 37^{o}C. 1ml of sample was withdrawn at periodic intervals 1st, 2nd, 4th, 6th, 8th and 10th minutes and was made upto 10ml with sorenson's buffer solution. 1ml of fresh dissolution medium [maintained at the same temperature] was replaced after each time of withdrawal of samples. The samples were analyzed spectrophotometrically for the drug content against the respective buffer blank. The mean percentage of labetalol hydrochloride released at various time intervals was calculated from standard graph and plotted against time.[20]

RESULT

Evaluation of fabricated tablets

Wetting Time and Water Absorption Ratio

The results of Wetting time and Water absorption ratio are presented in Table. The Wetting time ranges from 9.84 sec to 13.78 sec and water absorption ratio ranges from 69.13 to 80.83.

Table 2: Wetting Time and Water Absorption Ratio.

Formulation Code	Wetting Time [sec]	Water Absorption Ratio
F_1	12.02 ± 0.23	80. 56
F_2	13.78 ± 0.32	80.83
F_3	12.39 ± 0.27	81.42
F_4	11.16 ± 0.04	76.25
F_5	11.11 ± 0.02	75.79
F_6	11.16 ± 0.08	74.52
F_7	9.87 ± 0.01	69.41
F_8	9.84 ± 0.15	69.13
F_9	9.96 ± 0.01	69.16

***In – vitro* Dispersion Time and *In – vitro* Disintegration Time.**

Table 3: *In-vitro* Dispersion Time and *In-vitro* Disintegration Time.

Formulation Code	*In-Vitro* Dispersion Time (sec) ± S.D [n =3]	*In-vitro* Disintegration Time (sec) ± S.D. [n=6]
F_1	11.16 ± 0.13	13.82 ± 0.11
F_2	11.27 ± 0.06	13.79 ± 0.13
F_3	11.38 ± 0.01	13.80 ± 0.18
F_4	9.01 ± 0.02	12.08 ± 0.14
F_5	10.06 ± 0.01	12.19 ± 0.19
F_6	10.19 ± 0.04	12.21 ± 0.12
F_7	8.79 ± 0.06	10.10 ± 0.02
F_8	8.24 ± 0.08	9.08 ± 0.22
F_9	8.91 ± 0.03	10.04 ± 0.04

***In – Vitro* Dissolution Studies**

1ml of sample was withdrawn at periodic intervals 1st, 2nd, 4th, 6th, 8th and 10th minutes and was made up to 10ml with Sorenson's buffer solution. 1ml of Fresh dissolution medium was replaced after each time of withdrawl of sample. The samples were analyzed spectro photometrically for the drug content against the respective buffer blank. The mean percentage of labetalol hydrochloride released at various time intervals was calculated and plotted against time.

Table 4: In – vitro Dissolution Studies.

Time in min	F1	F2	F3	F4	F5	F6	F7	F8	F9	Market product
1	60.61	63.07	71.5	69.33	72.58	78.0	81.25	81.25	79.08	12.35
2	63.16	69.43	73.78	73.78	80.28	84.62	84.62	84.62	83.54	19.28
4	71.60	73.78	80.28	80.28	84.62	86.80	90.04	88.56	86.80	31.14
6	73.78	78.11	83.54	84.62	91.13	92.23	94.39	93.30	91.13	38.24
8	80.25	82.47	89.96	90.04	93.30	95.47	96.55	97.64	93.30	43.85
10	81.12	84.63	92.24	92.24	95.47	97.65	97.65	99.81	96.55	48.49

The order of enhancement of the dissolution rate with various super disintegrants was found to be CP > CCS > SSG. From the overall observations, formulation F_8 containing 10%w/w concentration of Cros povidone was considered to be the optimized formulation which releases upto 99.81% of the drug in ten minutes. The *In-vitro* Drug release profiles for the optimized formulation F_8 was compared with Marketed tablet. At the end of ten minutes of *in-vitro* dissolution study only 48.49% of the drug was released from Marketed tablet whereas 99.81% of the drug was released from the optimized formulation F_8. The results obtained from the data reveals that enhanced dissolution characteristics of the formulation F_8 which may be due to the high wicking action of Cros Povidone which makes the tablets to swell and facilitates quick disintegration of the tablets.

CONCLUSION

The oro dispersible Tablets (ODT's) of labetalol hydrochloride were prepared by Direct compression method using various super disintegrants. Formulation **F_8** containing 10%w/v concentration of Cros Povidone with appropriate amount of other excipients were considered to be the optimized formulation with the desired drug release. The oro dispersible Tablet formulation of labetalol hydrochloride provides instant relief for inflammation sufferers and helps them to resume their normal function as soon as possible. All formulation were found to have homogenic drug distribution with excellent content uniformity. F8 batch contains 10% CP was optimized. Comparative drug release study revealed that the formulated Oro dispersible tablets release drug more rapidly than the marketed sample. The optimized formulation F_8 was

found to follow First order kinetics, which was revealed by the linearity shown from the plot of logarithm of drug remaining to be released versus time. In future, the developed formulation F_8 can be subjected to Bioequivalence study and suitability to the market.

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