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Original Research Article

Formulation and Evaluation of Mouth Dissolving Tablets of Metformin HCl by Direct Compression Technique.

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Abstract

Attempts were made to prepare mouth dissolving tablets of Metformin HCl by direct compression method with a view to enhance patient compliance. The two superdisintegrants used in this study were Sodium starch glycolate and Croscarmillose sodium. The prepared batches of tablets were evaluated for uniformity of weight, thickness, hardness, friability, wetting time, water absorption ratio, disintegration time and dissolution study. Using the same excipients, the tablets were prepared, without disintegrants and were evaluated in the similar way. From the results obtained, it can be concluded that the tablet formulation (F4) showed the promising formulation. Also the hardness, friability, disintegration time and dissolution rate of prepared tablets were found to be acceptable according to standard limits.

Keywords: Metformin HCl, Mouth dissolving tablets, In-vitro evaluation, Superdisintegrants.

1. Introduction

Dispersible tablets are novel types of tablets that disintegrate/dissolve/disperse in saliva. Their characteristic advantages such as administration without water, anywhere, anytime lead to their suitability to geriatric and pediatric patients. They are also suitable for the mentally ill, the bed- ridden, and patients who do not have easy access to water. The benefits, in terms of patient compliance, rapid onset of action, increased bioavailability, and good stability make these tablets popular as a dosage form of choice in the current market. Metformin HCl is chemically (N, N dimethyl imidodicarbonimidicdiamide hydrochloride) an orally administered hypoglycemic agent used in the treatment of non-insulin-dependent diabetes 8 (Type 2). As the dose of the conventional tablet is high, it gives the problem of difficulty in swallowing. Other problems like hand tremors, dysphagia incase of geriatric patients and in case of non co-operative patients the problem of swallowing is common phenomenon which leads to poor patient compliance.

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To overcome these drawbacks Mouth dissolving tablets or orally disintegrating tablets or Fast dissolving tablets has emerged as an alternative oral dosage form.

Experimental

Preparation of Mouth Dissolving Tablets of Metformin HCl

All the materials were passed through 60 # screens prior to mixing. Metformin HCl, Croscarmellose sodium, Sodium Starch Glycolate, and Mannitol were mixed using a glass mortar and pestle. All the materials were directly compressible so this uniformly mixed blend was compressed into tablets on a 8-station rotary tablet machine.

Evaluation of Metformin HCl mouth dissolving tablets

Weight variation test

Weight variation test was done by weighing 20 tablets individually, by using Shimadzu balance. Calculating the average weight and comparing the individual tablet weight to the average weight.

Tablet thickness

The thickness was measured by placing tablet between two arms of the Varnier calipers. 5

tablets were taken and their thickness was measured.

Tablet hardness

The tablet hardness, which is the force required to break a tablet in a diametric compression force. The hardness tester used in the study was Monsanto hardness tester, which applies force to the tablet diametrically with the help of an inbuilt spring.

Tablet friability

Friability test was done by Roche friabilator. Ten tablets were weighed and were subjected to combined effect of attrition and shock by utilizing a plastic chamber that resolve at 25 rpm dropping the tablets at distance of 6 inch with each revolution. The percentage friability was calculated as eqn.

$$\textbf{\% Friability} = W0 - W / W0 \times 100$$

Uniformity of weight

Twenty tablets from each batch were individually weighed and their average weight was calculated. From the average weight of the prepared tablets, the standard deviation was determined.

Disintegration time

The test was carried out on 6 tablets using Tablet disintegration tester. Phosphate buffer pH 6.8 at 37ºC ± 2ºC was used as a disintegration media and the time in second taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus was measured in seconds.

In-vitro dissolution study

The release rate of Metformin HCl from mouth dissolving tablets was determined using United State Pharmacopoeia (USP) XXIV dissolution testing apparatus II (paddle method). The dissolution test was performed using 900 ml of 0.1 N HCl as dissolution medium, at 37±0.5℃ and 50 rpm. A sample (5 ml) of the solution was withdrawn from the dissolution apparatus at 5, 10, 15, 20, 25and 30 min.

Results and Discussion

The use of superdisintegrants for preparation of mouth dissolving tablets is highly effective and commercially feasible. The results of tablets were evaluated for uniformity of weight, thickness, hardness, friability, wetting time, water absorption ratio, disintegration time and dissolution study.

Conclusion

It can be concluded that disintegration time and dissolution rate of Metformin HCl can be enhanced to a great extent by direct compression technique with the addition of combination of superdisintegrants. Further investigations are needed to confirm the in-vivo efficiency.

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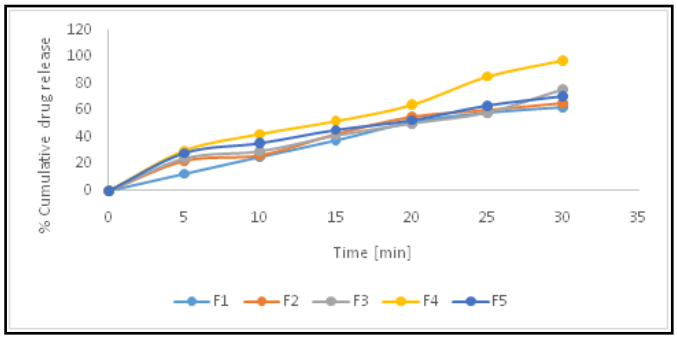

Fig 1: Drug release profile of Metformin HCl MDT from various batches.

Table 1: Formulation of Metformin HCl MDT.

Ingredients	F1	F2	F3	F4	F5
Metformin HCl	300	300	300	300	300
Sodium starch glycolate	10	20	10	20	-
Crosscarmellose sodium	40	40	45	45	-
Lactose	44	34	39	29	94
Mannitol	94	94	94	94	94
Aspartame	6	6	6	6	6
Magnesium stearate	3	3	3	3	3
Talc	3	3	3	3	3
Total	500	500	500	500	500

Table 2: Evaluation of Metformin HCl MDT.

Formulation parameters	F1	F2	F3	F4	F5
Weight variation (%)	502±2.22	497±2.37	498±2.18	500±1.56	402±1.32
Thickness (mm)	4.5	4.3	4.1	4.1	4.2
Hardness(kg/cm2)	2.5±0.19	3.6±0.35	3.2±0.15	3.5±0.46	3.0±0.14
Friability (%)	0.33	0.39	0.38	0.32	0.40
Wetting time (sec)	59±2.20	49±2.70	46±0.90	38±1.35	47±1.20
Water absorption ratio (%)	90.81	91.17	92.47	93.58	90.81
Disintegration time (sec)	38±2.5	34±2.4	35±3.2	28±4.4	36±2.8

Table 3: *In Vitro* Drug Release Profile for Metformin HCl MDT.

Time	F1	F2	F3	F4	F5
0	0	0	0	0	0
5	12.74±0.955	22.32±0.531	24.15±0.849	30.14±0.474	28.12±0.281
10	25.3±0.722	26.53±0.689	29.45±0.788	42.53±0.320	35.46±0.967
15	37.54±0.950	42.23±0.709	41.15±0.656	52.14±0.772	45.29±0.501
20	51.12±0.823	55.12±0.260	50.14±0.416	64.25±0.680	52.45±0.319
25	58.23±0.826	60.14±0.409	58.24±0.257	85.39±0.660	63.47±0.281
30	62.24±0.835	65.34±0.904	75.46±0.579	97.48±0.665	70.36±0.967

Where, ±SD =Standard deviation [n=3]