Journal of Pharma Creations (JPC)

JPC |Vol.11 | Issue 1 | Jan - Mar -2024

www.pharmacreations.com

DOI : https://doi.org/10.61096/jpc.v11.iss1.2024.21-26

ISSN: 2348-6295

Research

Formulation And Evaluation Of Taste Masked Oral Disintegrating Tablets Of Atenolol

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Published on: 04 Mar 2024

Published by:
DrSriram Publications

Abstract

In the present work, an attempt has been made to develop oral disintegrating tablets of Atenolol, was as Banana Powder, Primojel and Sodium starch glycolate was employed as super disintegrating agents to enhance the solubility and dissolution rate of drug molecule. The effects of disintegrants in different concentration on the release profile of Atenolol ODTs were studied. Developed ODTs were studied for their physicochemical properties and *in vitro* drug release profile. The studied parameters were found to be satisfactory for all ODT formulations of Atenolol. *In vitro* dissolution studies the formulation A3 consisting of Banana Powder was found be best among all the formulations it has exhibited faster disintegrating time (18 sec) when compared to other formulations and it showed 99.73 % drug release in 30min. FTIR studies proved that no chemical interaction between Atazanavir and superdisintegrants of the developed oral disintegrating tablets.

Keywords: Atenolol, Oral disintegrating Tablets, Banana Powder, Primojel, Sodium starch glycolate and direct compression method.

INTRODUCTION

During establishing dosage form for a drug, it requires knowledge about each ingredient i.e. physical, chemical and biological properties along with the compatibility with the active drug, so that the product formed should be palatable, stable and efficacious. Most drugs pass through the barrier by molecular diffusion, or through pores called pore diffusion. In pore diffusion the drug release rate is controlled by the crystal size, molecular size, pore size, pore structure and tortuosity of the polymers. In passive transport (Fick's first law) the drug moves from high concentration to the low concentration, while in active transport energy is required for the movement of drug from low to high concentration region through one or more transport mechanisms. It requires energy or carrier such as enzyme, protein [2].

Oral Disintegrating Tablets

These are tablets which get dispersed or disintegrate when gets in a contact with saliva with the release of active drug, providing maximum drug bioavailability as compared to conventional dosage form. This dispersible property is given by the addition of super disintegrants to the dosage form that releases the drug in mouth increasing the bioavailability [13]. Three different methods for the addition of disintegrants are used, they are intra granular (within the granules), extra granular (addition after granulation) and combination of both processes [14].

ODTs are developed by the addition of super disintegrants like cross linked cellulose derivative; carboxymethyl cellulose, sodium starch glycolate, polyvinylpyrollidone, which gives burst disintegration when gets in contact with water or salivary secretions. Bio availability of drugs may rise due to oral and pregastric absorption, reducing first pass metabolism in gastrointestinal tract[16]

Oral drug delivery is currently the gold standard in the pharmaceutical industry where it is regarded as the safest, the most convenient and most economical method of drug delivery with the highest patient compliance [17].

METHODOLOGY

Formulation development

Drug and different concentrations of super disintegrants (Banana Powder, Primojel, Sodium starch glycolate) and required ingredients were accurately weighed and passed through a 40-mesh screen to get uniform size particles and mixed in a glass motor for 15 min. The obtained blend was lubricated with magnesium stearate and glidant (Talc) was added and mixing was continued for further 5 min. The resultant mixture was directly compressed into tablets by using punch of rotary tablet compression machine. Compression force was kept constant for all formulations.

Table 1: Formulation table showing various compositions

INGREDIENTS (MG)	FORMULATION CODE								
	A1	A2	A3	A4	A5	A6	A7	A8	A9
Atenolol	25	25	25	25	25	25	25	25	25
Banana Powder	30	60	90	-	-	-	-	-	-
Primojel	-	-	-	30	60	90	-	-	-
Sodium starch glycolate	-	-	-	-	-	-	30	60	90
Aspartame	25	25	25	25	25	25	25	25	25
MCC	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
Talc	6	6	6	6	6	6	6	6	6
Magnesium stearate	7	7	7	7	7	7	7	7	7
Total Weight (mg)	200	200	200	200	200	200	200	200	200

Evaluation of tablets

Pre compression parameters of all the formulations were found to be satisfactory. the values are like this.

Table 2: Scale of Flow ability

Compressibility index (%)	Flow character	Hausner Ratio
≤ 10	Excellent	1.00-1.11
11-15	Good	1.12-1.18
16-20	Fair	1.19-1.25
21-25	Passable	1.26-1.34
26-31	Poor	1.35-1.45
32-37	Very Poor	1.46-1.59
> 38	Very, very Poor	> 1.60

Post compression parameters

Tablets were evaluated for various parameters such as hardness, friability, weight variation, wetting ability, content uniformity, assay, disintegration time and in vitro drug release [2 table]. Disintegration testing (8.3Tablets) was performed using modified method.

Disintegration test

Six tablets were taken randomly from each batch and placed in USP disintegration apparatus baskets. Apparatus was run for 10 min. and the basket was lift from the fluid, observe whether all of the tablets have disintegrated.

Dissolution test of Atazanavir

Drug release from Atazanavir tablets was determined by using dissolution test USP 24 type II (paddle). The parameters used for performing the dissolution were pH 6.8 medium as the dissolution medium of quantity 900 ml. The whole study is being carried out at room temperature of 37˚C and at a speed of 75 RPM. 5ml aliquots of dissolution media were withdrawn each time intervals (5,10,15,20,30 min) and appropriate dilution by UV spectrophotometer. The concentration was calculated using standard calibration curve.

RESULTS AND DISCUSSION

Preparation of calibration curve of Atenolol

The regression coefficient was found to be 0.999 which indicates a linearity with an equation of y=0.031 x-0.008. Hence Beer-Lambert's law was obeyed.

Table 3: Calibration curve data of Atenolol in pH 6.8 phosphate buffer

Concentration	Absorbance
0	0
5	0.169
10	0.336
15	0.477
20	0.645
25	0.789

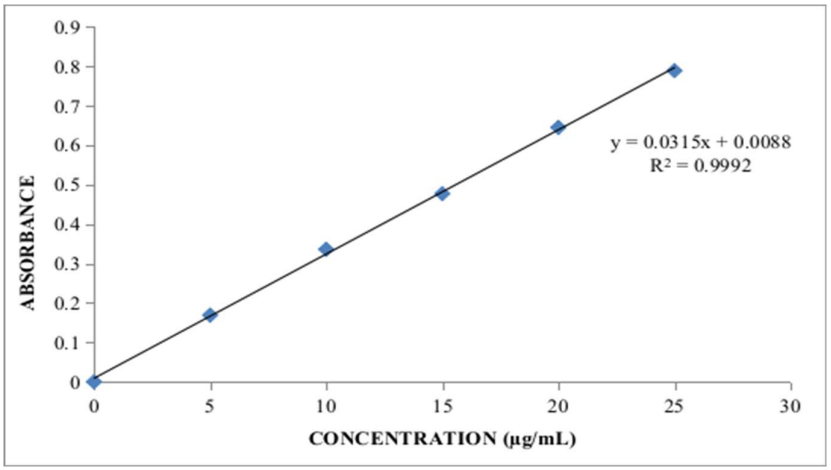

Fig 1: Atenolol in pH 6.8 phosphate buffer

EVALUATION OF PRE-COMPRESION PARAMETERS OF POWDER BLEND

Table 4: Evaluation of pre-compression parameters of powder blend

Formulation code	Angle of repose	Bulk density (gm/mL)	Tapped density (gm/mL)	Carr's index (%)	Hausner's ratio
A1	27.66	0.338	0.494	28.57	1.46
A2	28.34	0.335	0.470	28.72	1.40
A3	27.69	0.353	0.502	29.68	1.42

A4	26.34	0.336	0.502	28.09	1.49
A5	26.01	0.399	0.559	28.62	1.40
A6	22.29	0.736	0.899	18.13	1.20
A7	26.06	0.721	0.910	20.77	1.22
A8	31.09	0.701	0.905	22.54	1.21
A9	30.07	0.694	0.852	18.54	1.05

Tablet powder blend was subjected to various pre-compression parameters. The angle of repose values was showed from 26.01 to 31.09; it indicates that the powder blend has good flow properties. The bulk density of all the formulations was found to be in the range of 0.335 to 0.736 (gm/cm^3) showing that the powder has good flow properties. The tapped density of all the formulations was found to be in the range of 0.470 to 0.910 showing the powder has good flow properties. The compressibility index of all the formulations was found to be ranging from 18.13 to 29.68 which showed that the powder has good flow properties. All the formulations were showed the hausner ratio ranging from 1.05 to 1.49 indicating the powder has good flow properties.

Evaluations of Post Compression Parameters of Atenolol Odts

Table 5: Evaluation of post compression parameters of Atenolol Oral disintegrating tablets

Formulation codes	Average weight (mg)	Hardness (kg/cm^2)	Friability (%loss)	Thickness (mm)	Drug content (%)	*In vitro* disintegration Time (sec)
A1	197.34	4.2	0.36	3.58	98.34	53
A2	199.28	4.3	0.45	3.31	96.57	35
A3	196.48	4.0	0.58	3.72	99.30	18
A4	199.02	4.9	0.72	3.91	97.16	48
A5	195.86	4.6	0.65	3.34	98.67	36
A6	197.32	4.8	0.41	3.77	99.36	25
A7	198.21	4.5	0.58	3.12	96.72	39
A8	196.58	4.8	0.36	3.14	97.43	28
A9	200.02	4.5	0.25	3.93	99.10	20

Weight variation and Thickness of all the formulations were evaluated for uniformity of weight. Hardness and friability of all the ODT formulations were evaluated .The average hardness for all formulations was found to be between (4.049) kg/cm^2. The average percentage friability for all the formulations was between 0.25 - 0.72 which was found to be within the limit. Drug content of all formulations was evaluated. The assay values for all formulations were found to be in the range of (96.57- 99.36).

***In vitro* disintegration time**

In vitro disintegration studies showed from 18-53sec. The A3 formulation showed *in vitro* disintegration time i.e. 18 Sec.

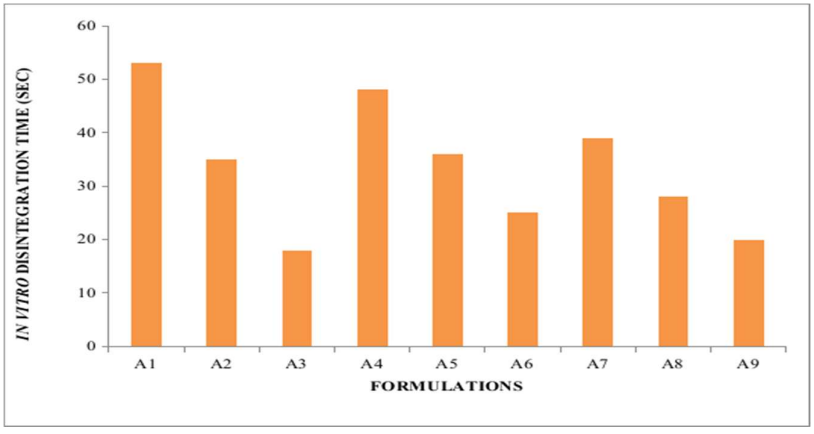

Fig 2: *In vitro* disintegration Time (sec)

***In vitro* drug release studies of Atenolol**

Time (min)	A1	A2	A3	A4	A5	A6	A7	A8	A9
0	0	0	0	0	0	0	0	0	0
5	20.99	25.83	30.59	23.35	31.34	36.91	21.28	28.61	31.59
10	38.15	45.57	49.81	40.27	45.12	50.65	41.36	47.30	45.57
15	50.36	53.91	58.62	51.11	56.90	58. 86	51.71	56.15	53.98
20	61.27	61.25	78.74	62.54	67.76	67.25	65.90	66.88	70.13
25	67.18	81.60	90.44	71.62	81.47	75.11	72.15	75.24	85.29
30	79.05	90.14	99.73	82.97	88.38	90.97	86.74	90.19	95.36

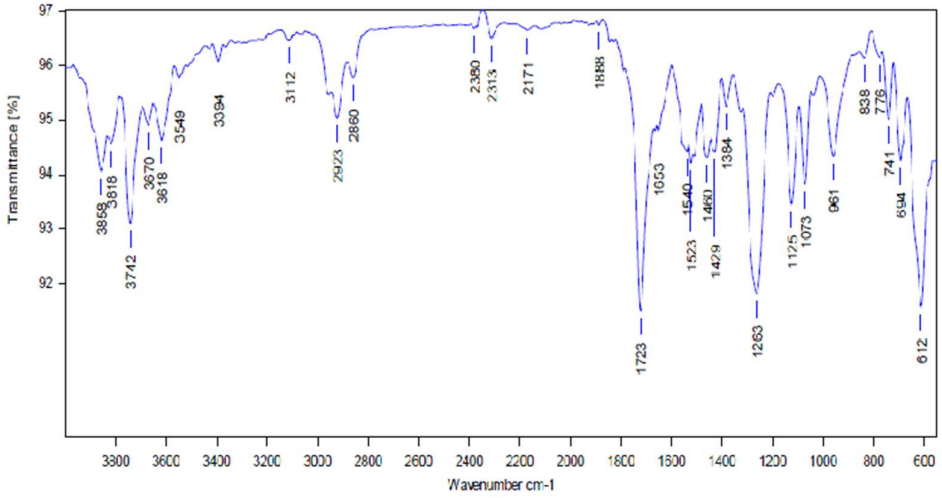

Fig 4: FTIR of Atenolol optimized formulation

Atenolol was mixed with proportions of excipients showed no color change providing no drug-excipient interactions.

CONCLUSION

Orally, disintegrating tablet of Atenolol was successfully prepared with different Super disintegrants by direct compression. The present studies were helped in understanding the effect of formulation process variables especially the concentration of different super disintegrates on the dispersion time and drug release profile. Here Banana Powder, Primojel and Sodium starch glycolate were employed as super disintegrating agents to enhance the solubility and dissolution rate of selected drug molecule. All the formulations were prepared by direct compression method using 7mm punch on 10 station rotary tablet punching machine. The blend of all the formulations showed good flow properties such as angle of repose, bulk density, tapped density. The prepared tablets were shown good post compression parameters and they passed all the quality control evaluation parameters as per I.P limits. Among all the formulations A3 formulation showed maximum % drug release i.e., 99.73% in 30 min, Hence it is considered as optimized formulation. The A3 formulation contains Banana Powder as super disintegrate in the concentration of 90 mg.

ACKNOWLEDGEMENT

We express our best gratitude to the management of vision college of pharmaceutical sciences and research for the support, guidance and valuable suggestions of my research work.

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