Journal Homepage: www.ijarpr.com ISSN: 3049-0103 (Online)

International Journal of Advance Research Publication and Reviews

Vol 02, Issue 08, pp 166-172, August 2025

Formulation and Evaluation of Immediate Release Zolmitriptan Tablets Using Natural Banana Powder as an Excipient

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ABSTRACT:

The present study focuses on the formulation and evaluation of immediate-release oral disintegrating tablets (ODTs) of Zolmitriptan using natural banana powder as a disintegrant. Zolmitriptan, a selective 5-HT1B/1D receptor agonist used for migraine treatment, suffers from poor aqueous solubility, which limits its therapeutic efficacy. The research aimed to improve its dissolution profile and patient compliance through the incorporation of natural excipients. Nine different formulations (F1–F9) were prepared via direct compression method using banana powder, pregelatinized starch, and corn starch as disintegrants. The tablets were evaluated for physicochemical properties such as hardness, friability, weight variation, and drug content, which were all within pharmacopeial limits. In vitro drug release studies in 0.1 N HCl revealed that the banana powder-based formulation F3 demonstrated superior dissolution characteristics, releasing 95.17% of the drug within 18 minutes and achieving nearly complete release at 21 minutes. The λmax of Zolmitriptan was determined to be 217 nm using a UV-Visible spectrophotometer. The study concludes that banana powder is an effective natural disintegrant capable of enhancing the dissolution rate of Zolmitriptan tablets, making it a promising alternative to synthetic excipients for immediate-release formulations.

Keywords: Agonist, Disintegrant, Excipients, Immediate, Powder, Zolmitriptan

1. INTRODUCTION:

The oral route is one of the most preferred methods of drug delivery due to its ease of administration, patient compliance, and flexible formulation design[1]. Immediate release formulations aim to release the drug immediately upon administration to ensure rapid onset of action. Zolmitriptan, a selective 5-HT1B/1D receptor agonist used for migraine treatment, has poor aqueous solubility, which limits its bioavailability[2]. Enhancing solubility and dissolution rate is crucial to improving therapeutic efficacy. Natural excipients such as banana powder are being explored as alternatives to synthetic disintegrants for their biocompatibility, availability, and cost-effectiveness[3].

2. MATERIALS AND METHODS

2.1 Materials

Zolmitriptan was obtained from Pharma Train. Banana powder, pregelatinized starch, corn starch, MCC, magnesium stearate, and purified talc were procured from S.D. Fine Chemicals, Mumbai. All other chemicals used were of analytical grade[4,5].

Table 1: List of Materials Used

S. No.	Materials	Source
1	Zolmitriptan	Pharma Train
2	Banana powder	S.D. Fine Chemicals Limited, Mumbai
3	Pregelatinised starch	S.D. Fine Chemicals Limited, Mumbai
4	Corn starch	S.D. Fine Chemicals Limited, Mumbai
5	MCC	S.D. Fine Chemicals Limited, Mumbai
6	Pippermint flavour	S.D. Fine Chemicals Limited, Mumbai
7	Magnesium Stearate	S.D. Fine Chemicals Limited, Mumbai
8	Purified Talc	S.D. Fine Chemicals Limited, Mumbai

Table 2: List of Equipment's used

SL. NO.	**EQUIPMENT**	**MODEL/ SOURCE**
1	UV-spectrophotometer	LabindiaUv 3000+
2	Digital Balance	Scale-Tec
3	Digital pH meter	Systronic Electronics, Mumbai
4	Dissolution apparatus	Electrolab TDT-08L
5	Hot air oven	Tempo Instruments &Equipments, Mumbai
6	Hardness tester	Monsanto Hardness Tester
7	Friability test apparatus	Roche FriabilatorElectrolab, Mumbai
8	Tablet punching machine	Cadmach, Ahmedabad

3.METHODOLOGY:

3.1 Preparation of 6.8 phosphate buffer:

27.22g of monobasic potassium phosphate was weighed and diluted up to 1000 ml to get stock solution of monobasic potassium phosphate. 8g Sodium hydroxide was weighed and diluted up to 1000ml to get 0.2M sodium hydroxide solution. 50 ml of the monobasic potassium phosphate solution was taken from the stock solution in a 200-mL volumetric flask and 22.4 ml of sodium hydroxide solution from stock solution of 0.2M sodium hydroxide solution was added and then water was used to make up the volume.

3.2 Determination of λ_{max} of Zolmitriptan in 6.8 phosphate buffer:

Procedure:

Working standard: 100mg of Zolmitriptan was weighed and dissolved in 10ml Methanol and then make up to a volume of 100ml with 6.8 phosphate buffer it give 1000µg/ml concentrated stock solution.

Dilution 1: From the working standard solution 10ml was diluted to 100ml with 6.8 phosphate buffer it will give 100µg/ml concentrated solution.

Dilution 2: From the dilution1, 10ml solution was diluted to 100ml with 6.8 phosphate buffer it will give 10µg/ml concentrated solution.

This solution was scanned at range of 200-400nm wavelength light corresponding scan spectrum curve was noted the corresponding wavelength having highest absorbance is noted as λ_{max} [6].

3.3 PREPARATION OF ZOLMITRIPTAN FAST DISINTEGRATING TABLETS

Direct compression method:

Oral disintegrating tablets of Zolmitriptan were prepared by direct compression method[7,8]. All the ingredients were powdered separately and passed through # 40 mesh sieve separately. The drug and directly compressible excipient were mixed by adding small portion of each at a time and blending it to get a uniform mixture and kept aside[9-11]. Then the other ingredients were mixed in geometrical order, in an inflated polyethylene pouch magnesium stearate and talc were added last and mixed for further two minutes and the tablets were compressed using 6-8mm flat round punches to get tablets of 150 mg weight.

Table 3.3: Formulae of Zolmitriptan Oral Disintegrating Tablets

INGREDIENTS	F1	F2	F3	F4	F5	F6	F7	F8	F9
Zolmitriptan	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Banana powder	10	20	30	-	-	-	-	-	-
Pregelatinised Starch	-	-	-	10	20	30			
Corn starch	-	-	-	-	-	-	10	20	30
MCC	133	123	113	133	123	113	133	123	113
Pipperment flavor	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Mg.Stearate	2	2	2	2	2	2	2	2	2
Talc	2	2	2	2	2	2	2	2	2
Total wt (mg)	150	150	150	150	150	150	150	150	150

4. RESULTS AND DISCUSSION:

The absorbance of the solution was measured at 217nm, using UV spectrometer with 6.8phosphate buffer as blank. The values are shown in table no 5. A graph of absorbance Vs Concentration was plotted which indicated in compliance to Beer's law in the concentration range 5 to 25 µg/ml

Table 4: Standard Calibration graph values of Zolmitriptan in 6.8phosphate buffer

CONCENTRATION (µg/ml)	ABSORBANCE
0	0
5	0.139
10	0.275
15	0.432
20	0.553
25	0.702

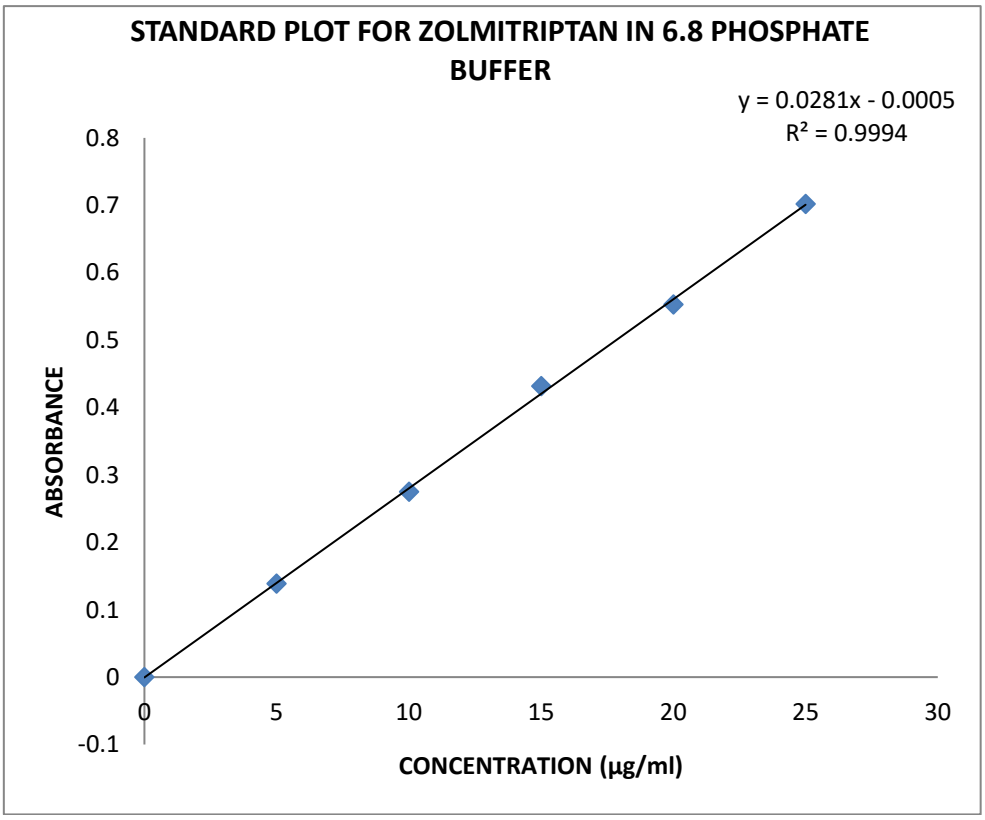

Figure 1: Standard calibration curve of Zolmitriptan in 6.8 phosphate buffer

INVITRO DISSOLUTION STUDIES OF ZOLMITRIPTAN TABLETS:

Table 5: dissolution profile

Parameter	**Details**
Dissolution apparatus	USP -Type II (paddle)
Medium	0.1 N HCL
Volume	900 ml
Speed	50rpm
Temperature	37± 0.5 ºC
Sample volume withdrawn	5ml
Time points	3, 6, 9, 12, 15, 18, 21, 24, 27 and 30minutes
Analytical method	Ultraviolet Visible Spectroscopy
λ_{max}	217nm

Table 6: Dissolution data of various oral dissolving tablets of Zolmitriptan

TIME (min)	% DRUG RELEASE								
	F1	F2	**F3**	F4	F5	F6	F7	F8	F9
0	0	0	**0**	0	0	0	0	0	0
3	24.32	26.83	**24.08**	14.63	16.18	22.57	17.63	25.83	24.87
6	35.67	39.12	**31.38**	21.24	22.03	31.65	25.14	32.72	36.12
9	41.38	46.87	**53.97**	26.71	28.67	39.05	33.62	39.86	42.87
12	52.67	57.71	**68.78**	31.38	34.85	47.74	46.74	53.12	51.83
15	59.83	65.87	**81.23**	35.13	42.09	56.93	58.65	64.89	59.97
18	67.74	74.14	**95.17**	40.05	49.84	67.33	64.13	72.01	71.86
21	75.13	89.12	**99.12**	47.13	57.83	75.65	67.67	79.86	82.93
24	82.71	93.14		54.02	64.18	81.83	74.68	83.98	89.87
27	89.73	97.98		59.13	71.71	85.90	80.25	86.18	95.63
30	94.68			62.95	79.84	91.62	84.47	91.74	98.54

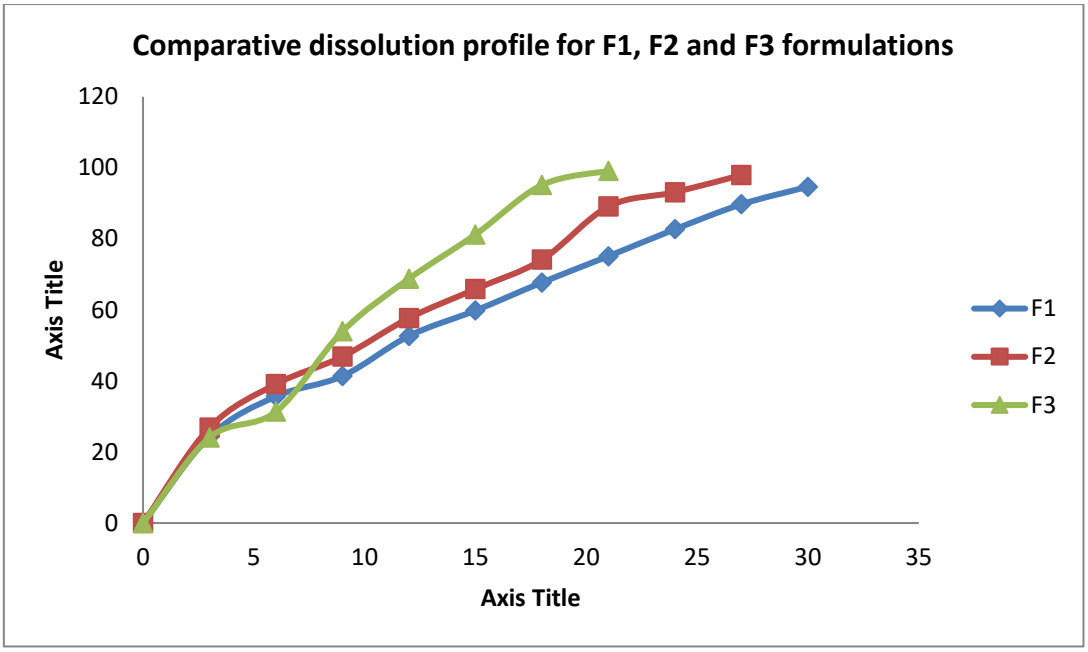

Figure 2: Comparative dissolution profiles for Banana powder used formulations

5. CONCLUSION:

Suitable analytical method based on UV-Visible spectrophotometer was developed for Zolmitriptan. λ_{max} of 217 nm was identified in 6.8phosphate buffer. Direct compression method was established to manufacture oral disintegating tablets of Zolmitriptan. Oraldisintegating tablets of Zolmitriptan were successfully prepared using pregelatinized starch, banana powder and Corn starch. In the present study, oral disintegating tablets were prepared by direct compression method. Evaluation parameters like hardness, friability, weight variation and drug content indicate that values were within permissible limit for all formulations. *In vitro* drug release study was carried out and based on the results; F-3 was identified as the best formulation among all the other formulations. The banana powder used formulation has shown better release profile than compared with other formulations. Thus, we are able to achieve our objective of preparing oral disintegrating tablets of Zolmitriptan with minimum excipients and simple method of manufacture and enhance the solubility of the drug.

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