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Formulation and invitro evaluation of almotriptan fast dissolving tablets

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ABSTRACT

The present work is done on preparing fast dissolving tablets of almotriptan. Almotriptan is used to treat severe migraine. The major problem in oral drug formulations is low and bioavailability, which mainly results from poor aqueous solubility. The concept of formulating fast dissolving tablets using super disintegrants offers a suitable and practical approach of faster disintegration and dissolution characteristics. Among the various method of preparation fast dissolving tablets were prepared by using super disintegrants like CCS, CP and SSG by direct compression. The prepared tablets of Almotriptan were evaluated for precompression parameters like angle of repose, bulk density, tapped density, Carr's index and post compression parameters like the hardness, friability and weight variation, drug content, disintegration time, and *IN VITRO* dissolution studies. Among the various fast dissolving tablets of Almotriptan F6 formulation was optimized. F6 maximum drug release in 20 min.

Key words: Almotriptan, CCS, CP and SSG

INTRODUCTION

Oral solid dosage forms

A solid dosage form is drug delivery system that includes tablets, capsules, sachets and pills as well as a bulk or unit-dose powders and granules. Among the various dosage forms oral soliddosage forms have greater importance and occupy a prime role in the pharmaceutical market. Oral route of drug administration is widely acceptable and drugs administered orally as solid dosage form represents the preferred class of products. Over 90% of drugs formulated to produce systemic effects are produced as solid dosage forms. Because of these reason whenever New chemical entity (NCE) has discovered, which shows a sufficient pharmacological action, first the pharmaceutical company asks whether the drug is successfully administered by oral route or not. The oral route of administration still continues to be the most preferred route due to its manifold advantages [5].

Tablets and capsules represent unit dosage forms in which the accurate dose of drug to show sufficient pharmacological action can be administered. In case of liquid oral dosage forms such as Syrups, Suspensions, Emulsions, Solutions and Elixirs the patient is asked to administer the medication of 5-30 ml. Such dosage measurements are typically error by factor ranging from 20-50 %, when the drug is self administered by patient[6].

Solid dosage forms are less expensive to shipping and less prone for the degradation when compared to liquid dosage forms[4].

In 1843, the first patent for a hand operated device used to form a tablet was granted." Tablets are

defined as solid preparations each containing a single dose of one or more active ingredients and obtained by compressing uniform volumes of particles. They are intended for oral administration, some are swallowed whole, some after being chewed. Some are dissolved or dispersed in water before being administered and some are retained in the mouth, where the active ingredient "liberated". Tablets are used mainly for systemic drug delivery but also for local drug action. For systemic use drug must be released from tablet that is dissolved in the fluids of mouth, stomach and intestine and then absorbed into systemic circulation by which it reaches its site of action[8]. Tablets remain popular as a dosage form because of the advantages, afforded both to the manufacturer [e.g. simplicity and economy of preparation, stability and convenience in packing, shipping and dispensing] and the patient [e.g. accuracy of dosage, compactness, portability, blandness of taste and ease of administration][10].

They may differ greatly in size and weight depending on the amount of drug substance present and the intended method of administration[2]. They may have lines or break-marks and may bear a symbol or other markings. Tablets may be coated.

AIM & OBJECTIVE

Aim of the study

The aim of present work is to develop a fast dissolving solid oral dosage form of Almotriptan.

Objectives

Primary Objective

1. To formulate and evaluate fast release Almotriptan.

Secondary Objectives

1. To perform preformulation studies.
2. To develop various formulations with different super disintegrants[3].
3. To study the effect of excipient concentrations on the tablet characteristics.
4. To achieve fast release profile for the developed formulation.

METHODOLOGY

Formulation

Table no 1: Formulation of almotriptan fast dissolving tablets

Ingredients	F1(mg)	F2(mg)	F3(mg)	F4(mg)	F5(mg)	F6(mg)	F7(mg)	F8(mg)	F9(mg)	F10(mg)
Almotriptan	5	5	5	5	5	5	5	5	5	5
SLS	3	3	3	3	3	3	3	3	3	-
CP	10	15	20	-	-	-	-	-	-	-
CCS	-	-	-	10	15	20	-	-	-	20
SSG	-	-	-	-	-	-	10	15	20	-
Mg.stearate	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Aerosil	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
MCC	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s
Total weight	200	200	200	200	200	200	200	200	200	200

Formulation Planning

The fast dissolving tablets containing Almotriptan were prepared with a total tablet weight of 200mg[1].

Manufacturing Procedure

Micro crystalline cellulose, cross Carmellose sodium/sodium starch glycolate/cross povidone, sodium lauryl Sulphate were weighed and sifted through 40 mesh.To the above blend Almotriptan was

added and sifted through 18 mesh.The sifted material was placed in poly bag and mixed for 5 min.To the above blend add mg.stearate and Aerosil, and this lubricated blend was added and placed in poly bag and mixed for 2-3 min.The lubricated blend was compressed using 8 mm round punches.

RESULTS

Compatibility studies

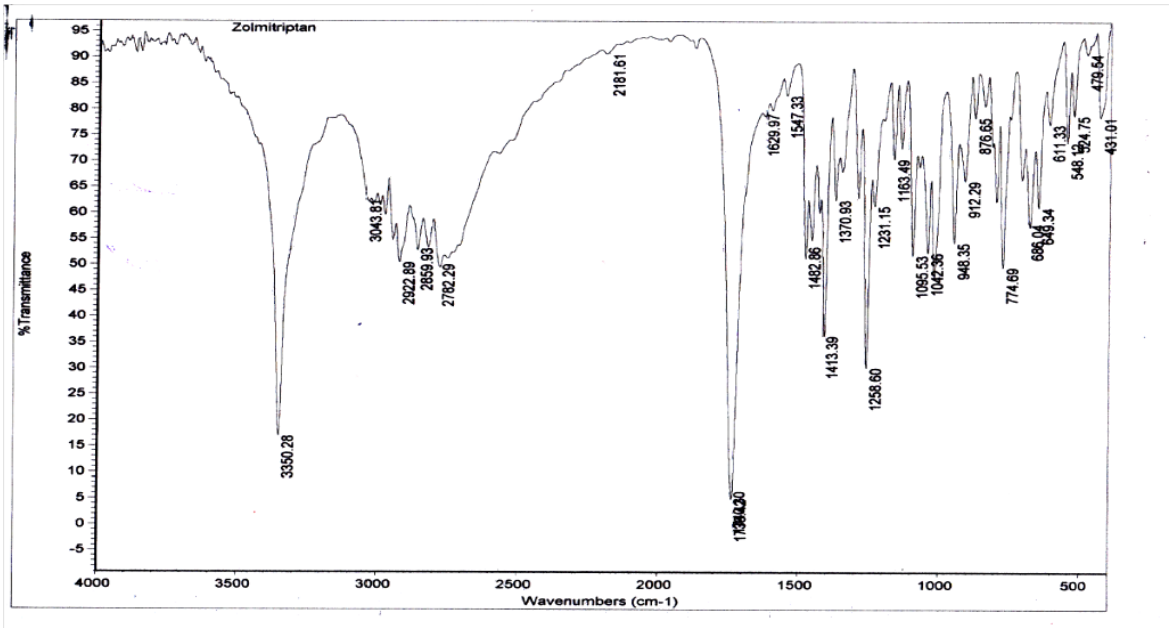

Fig No 1: FTIR Graph of Almotriptan

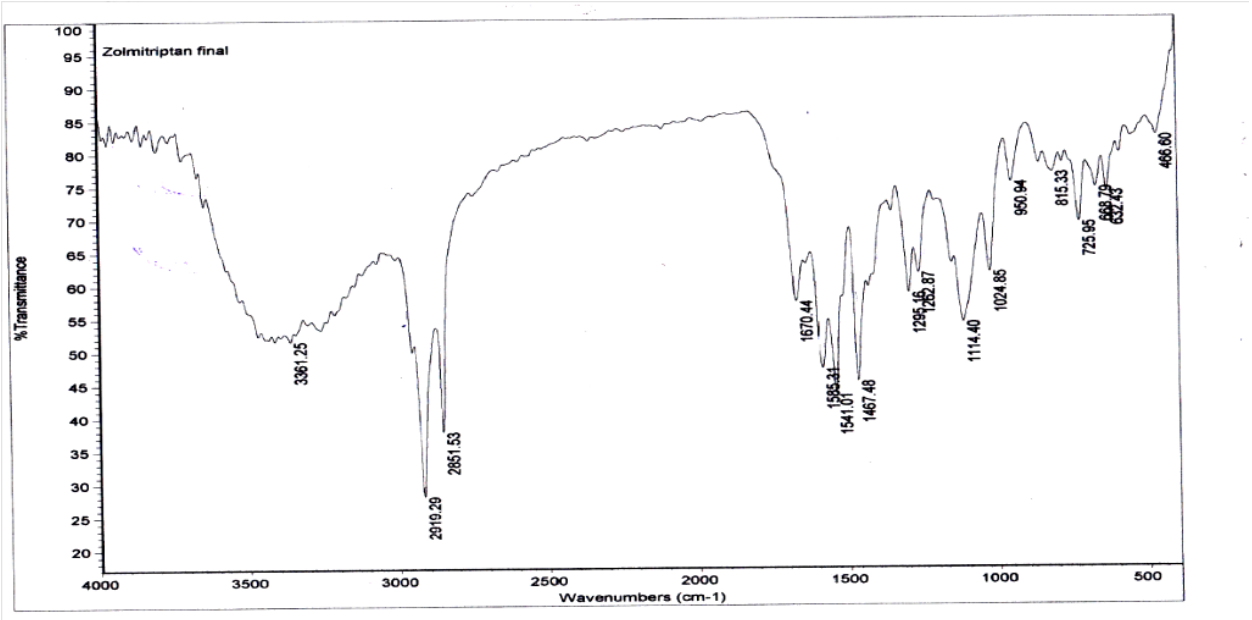

Fig No 2: FTIR Graph of Optimized formulation

Evaluation of Blend

Table No 2: Bulk density, Tapped density, % Compressibility index, Hausner ratio and Angle of repose. (Precompression studies)

Table no 2: Micromeritic properties

FORMULATION	BULK DENSITY gm/ml	TAPPED DENSITY gm/ml	CARR'S INDEX %	Hausner ratio	Angle of repose	Property
F1	0.453	0.689	34.252	1.520	35	FAIR
F2	0.489	0.710	31.126	1.451	32	FAIR
F3	0.710	0.873	19.714	1.251	31	FAIR
F4	0.721	0.870	17.126	1.206	32	FAIR
F5	0.718	0.871	18.513	1.223	36	FAIR
F6	0.410	0.483	15.113	1.178	29	FAIR
F7	0.420	0.482	15.010	1.131	32	FAIR
F8	0.541	0.691	21.62	1.276	38	PASSABLE
F9	0.484	0.615	21.30	1.270	44	PASSABLE
F10	0.450	0.585	23.07	1.300	41	PASSABLE

Evaluation of Tablets

Table no 3: Post compression studies

Formulation code	Weight variation	Hardness (kg/cm^2)	Friability (%)	Thickness (mm)	Content uniformity	Disintegration Time (min)
F1	204	5.5	0.65	3.41mm	99.28	2min
F2	200	5.3	0.67	3.43mm	99.16	48sec
F3	202	5.0	0.68	3.45mm	101.1	27sec
F4	201	5.4	0.64	3.42mm	98.68	1min 20 sec
F5	202	5.1	0.64	3.44mm	99.41	44 sec
F6	202	5.0	0.65	3.42mm	99.28	20 sec
F7	200	6.2	2.3	3.4mm	102.6	15sec
F8	199	5.5	1.8	3.4mm	99.5	18sec
F9	202	5.3	0.68	3.43mm	99.6	35sec
F10	201	5.0	0.69	2.60mm	100.4	1min 24sec

In -vitro drug release study

Paddle method Dissolution data of fast dissolving formulations of Almotriptan by Paddle method (USP II) are reported in Table.

Table no 4: Dissolution Values

Time in min	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
0	0	0	0	0	0	0	0	0	0	0
5	35	40	46	38	45	55	42	44	47	30
10	67	72	76	71	77	84	60	75	78	49
15	75	83	84	79	81	90	76	87	85	72
20	84	90	90	87	92	99	84	93	92	88
30	92	96	96	92	96	-	89	98	96	94
45	97	-	-	98	-	-	95	-	98	98

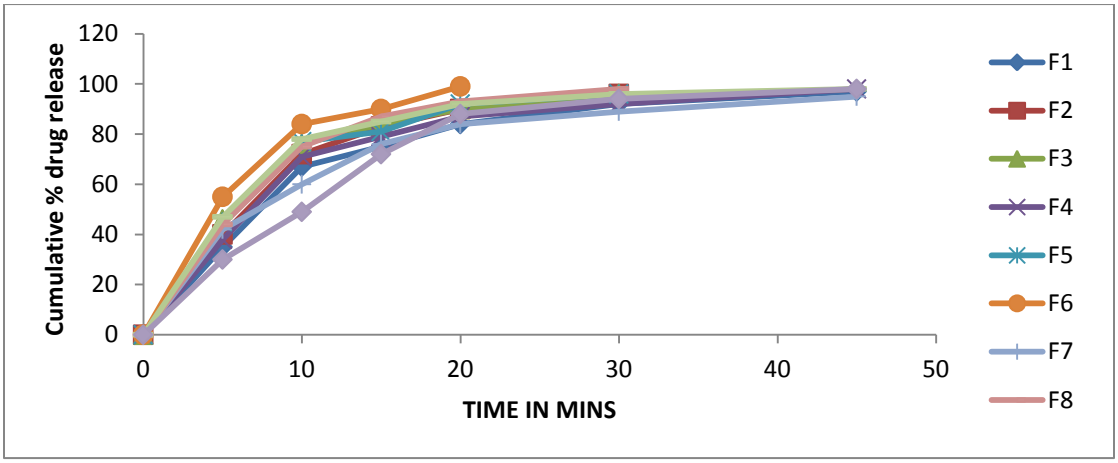

Fig no 3: Cumulative % drug released for formulations F1-F9

Stability data

Storage Conditions: $40^0C \pm 2^0C$ at 75%±5%RH

Table no 5: Stability Data of optimized F6 Almotriptan fast dissolving tablet

SNO	Tests	Initial 0 month	After 3 month
1.	Dissolution Profile (Cumulative % drug release)	5min- 55 10min - 84 15min - 90 20min - 99	5min- 50 10min - 81 15min - 90 20min -98
2.	Assay	99.28%	98.2%

DISCUSSION

All the formulations evaluated for the preformulation studies, all the formulations shows good flow properties. The optimized formulation F6 shows 99% drug release in 20 min.

CONCLUSION

The major problem in oral drug formulations is low and bioavailability, which mainly results from poor aqueous solubility.

The concept of formulating fast dissolving tablets using super disintegrants offers a suitable and practical approach of faster disintegration and dissolution characteristics. Among the various method of preparation fast dissolving tablets were prepared by using super disintegrants like CCS, CP and SSG by direct compression. The prepared tablets of Almotriptan were evaluated for precompression parameters like angle of repose, bulk density, tapped density, Carr's index and post compression parameters like the hardness, friability and weight variation, drug content, disintegration time, and *IN VITRO* dissolution studies. Among the various fast dissolving tablets of Almotriptan F6 formulation was optimized. F6 maximum drug release in 20 min.

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