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Research Article

**FORMULATION & EVALUATION OF ALMOTRIPTAN ORAL
DISINTEGRATING TABLETS****Karan Singh¹, Lalit Kumar²***Shri R.L.T Institute of Pharmaceutical Science & Technology, Etawah, Uttar Pradesh***Abstract:**

Oral disintegration tablets are the novel technology for administration of the drug through the oral route. The tablet is the most widely used dosage form because of its convenience in terms of self-administration, compactness and ease in manufacturing. Oral Disintegrating tablets have been found to be the choice for Psychiatric as well as patient suffering from stroke, thyroid disorder, Parkinson's diseases and multiple sclerosis, patients with nausea, vomiting and motion sickness. ODTs may Show increased oral bioavailability, good stability, accurate dosing, easy manufacturing, small packaging size, and easy to handle by patients. This research paper is about to formulation & evaluation of almotriptan oral disintegrating tablets.

Keywords: Disintegration, compactness, bioavailability, stability.

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1.INTRODUCTION:

Oral disintegrating tablets are solid unit dosage forms, which disintegrate or dissolve rapidly in the mouth without chewing and water. An oral disintegration tablets is a solid dosage form that disintegrates and dissolves in the mouth without water within 60 seconds or less. it provides an advantage particularly for pediatric and geriatric populations who have difficulty in swallowing conventional tablets and capsules. ODTs may Show increased oral bioavailability, good stability, accurate dosing, easy manufacturing, small packaging size, and easy to handle by patients.

A solid dosage form containing medicinal substance or active ingredient which disintegrates rapidly usually within a matter of seconds when placed upon the tongue. Orally disintegrating tablets

have been found to be the choice for Psychiatric as well as patient suffering from stroke, thyroid disorder, Parkinson's diseases and multiple sclerosis, patients with nausea, vomiting and motion sickness. These systems are also called melt-in-mouth tablets, Rapid melts, porous tablets, Oro dispersible, quick dissolving or rapidly disintegrating tablets. [Bhaskar Patel et al. 2001; Prabhakar Reddy et al. 2010

Solid Dosage form are preferable alternative for oral administration challenges in other patient groups such as children, mentally, challenged, bed ridden and uncooperative patients These dosage forms are preferable alternative for oral medication in improving the quality of life and patient acceptability.

1.1 MATERIAL & METHODS:

Kyron T-314 from Corel Pharma Company (Ahmadabad), Sodium starch glycolate from HiMedia Laboratories Pvt. Ltd. (Mumbai), Crosspovidone from Akhil Healthcare Private Limited (Vadodara), Starch from HiMedia

Laboratories Pvt. Ltd. (Mumbai). , magnesium stearate from Central Drug House Pvt. Ltd. (New Delhi), Mannitol from RFCL Limited (New Delhi), Microcrystalline cellulose (MCC)from HiMedia Laboratories Pvt. Ltd. (Mumbai).

Table1 Composition of formulation for oral disintegrating tablets

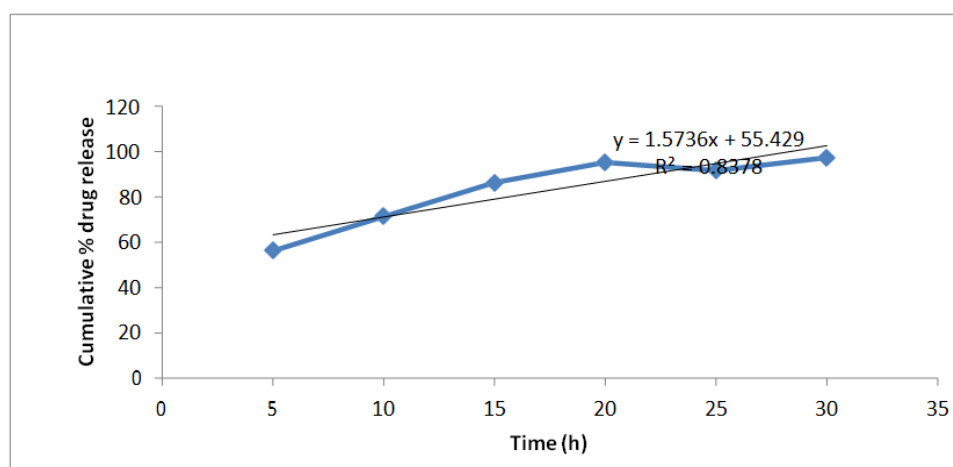
S.No.	Ingredients(mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1.	Almotriptan	5	5	5	5	5	5	5	5	5
2.	Sodium Starch Glycolate	4	6	8	-	-	-	-	-	-
3.	Crosspovidone	-	-	-	4	6	8	-	-	-
4.	Kyron314	-	-	-	-	-	-	4	6	8
5.	Mannitol	20	20	20	20	20	20	20	20	20
6.	Microcrystallinecell ulose(MCC)	162	160	158	162	160	158	162	160	158
7.	MagnesiumSt earate	4	4	4	4	4	4	4	4	4
8.	Talc	5	5	5	5	5	5	5	5	5
	Total	200	200	200	200	200	200	200	200	200

Table 2 Evaluation Parameters of different formulation

Formulation Code	Weight variation(mg)	Thickne ss(m m)	Hardness (kg/Cm ²)	Friability (%)
F1	194.29±0.47	2.20±0.14	2.4±0.21	0.23±0.02
F2	194.45±0.68	1.97±0.02	2.2±0.21	0.27±0.08
F3	199.75±0.56	2.03±0.02	2.6±0.28	0.33±0.06
F4	201.02±0.38	2.20±0.14	2.2±0.35	0.23±0.14
F5	203.57±0.94	1.98±0.04	2.5±0.14	0.43±0.28
F6	200.20±0.77	2.17±0.02	2.6±0.28	0.46±0.42
F7	197.85±0.51	2.23±0.02	2.3±0.28	0.48±0.42
F8	202.59±0.47	2.13±0.03	2.7±0.28	0.44±0.67
F9	204.32±0.19	1.97±0.28	2.3±0.28	0.44±0.35

Table3 Release kinetics of different formulations

Formulation Code	Zero-order	First-order	Higuchi	KorseMeyer-Peppas		Hixon-Crowell
	r ²	r ²	r ²	r ²	N	r ²
F1	0.9633	0.9151	0.8871	0.9639	0.2864	0.9473
F2	0.8431	0.8846	0.6878	0.955	0.1731	0.8418
F3	0.9435	0.9583	0.8407	0.9707	0.2978	0.9688
F4	0.8962	0.9885	0.7585	0.9732	0.2373	0.9681
F5	0.8921	0.9904	0.7536	0.9728	0.2085	0.9720
F6	0.8655	0.559	0.7216	0.9582	0.2055	0.5584
F7	0.903	0.9783	0.7687	0.9733	0.2916	0.6187
F8	0.8378	0.8873	0.6908	0.9486	0.1679	0.8875
F9	0.9309	0.9822	0.8064	0.9857	0.2679	0.9914

**Figure 1.** Zero order plot of optimized formulations (F8)

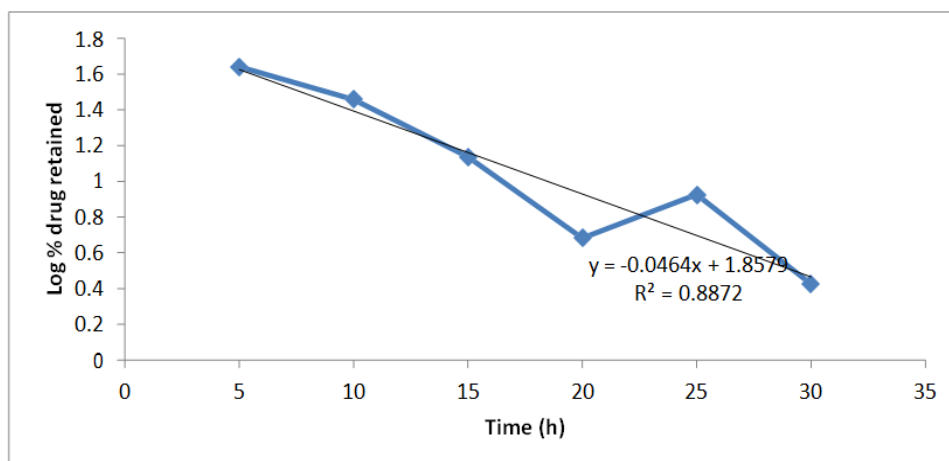


Figure 2 First order plot of optimized formulations (F8)

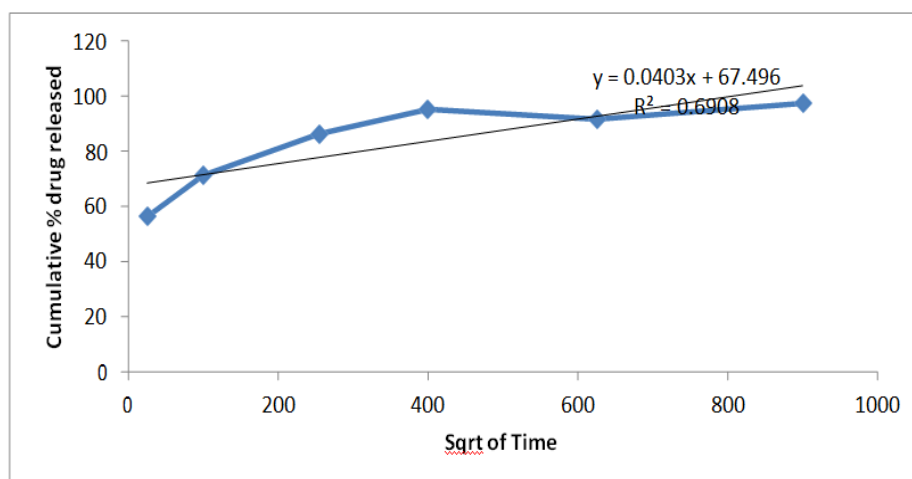


Figure 3 Higuchi plot of optimized formulations (F8)

2. RESULTS AND DISCUSSION:

Thickness

The thickness of all the formulation was measured and was found in the range between 1.97 ± 0.02 mm (F2) to 2.135 ± 0.03 mm (F8) and there were no significant difference among the batches with respect to thickness.

Weight Variation

The Weight Variation of all the formulation was measured and were found in the range between 194.29 ± 1.470782 (F1) to 204.325 ± 1.19501 mg (F9). The weight variation of the formulations (in mm) is shown in table and graphically represented in fig. [Dr. Ganesh Kumar *et al.* 2017] prepared orodispersible tablets of Levetiracetam using Sodium Starch Glycollate and Crosspovidone in which they found weight variation 375 ± 0.12 to

375 ± 0.43 mg.

Hardness

The hardness of the tablets was measured and the value were found in the range between 2.2 ± 0.21 (F2) to 2.45 ± 0.21 (F1) kg/cm^2 . The hardness of the formulation (in kg/cm^2) is shown in table and graphically represented in fig. Sudarshan Singh and Dhaval Shah *et al.*, (2012) prepared mouth dissolving tablet of Almotriptan using Crospovidone and Sodium Starch Glycolate in which they found hardness 3.04 ± 0.21 to 3.64 ± 0.12 kg/cm^2 .

Friability

The % friability of all the formulation was found to be less than 1% this is in the acceptable limit. The % friability values of all the formulation were

measured and the value was found in the range 0.4 ± 0.0424 (F7) to 0.445 ± 0.0353 (F9) % and there were no significant difference among the batches with respect to friability.

Disintegration Time

The Porous structure of the tablet is responsible for faster water uptake resulting in fast disintegration. The disintegration time for each formulation were found to be in the range of 25 ± 2.121 (F1) sec to 43 ± 2.828 (F3) sec.

Drug content assay

The drug content of the tablets was measured and the values were found in the range between 89.20 ± 0.91 (F3) to 98.88 ± 0.63 (F8). The drug content of the formulation (in %) is shown in table and graphically represented in figure. [Abbas Ibrahim et al. 2017] prepared taste masked orally disintegrating tablets of Almotriptan using (Eudragit E100; X1) and croscarmellose sodium (CCS; X2) in which they found drug content 96.9 to 103 %. In comparison of that the drug content of our formulation was found in 98.88 % (F8).

3. CONCLUSION:

Oral disintegrating tablets of Almotriptan were formulated by direct compression method using, KyronT314, Sodium Starch Glycolate and Crospovidone as superdisintegrant, Magnesium stearate as lubricant, Mannitol as filler and Microcrystalline cellulose (MCC) as binder. This indicates that the drug is compatible with the formulation components. The blends were analysed for parameters such as Bulk density, Tapped density, Compressibility index and Hausner's ratio and the results were found to be within limits. Bulk density and tapped density values were found to be within limits. Compressibility index has been proposed as an indirect measure of bulk density, size and shape, surface area and cohesiveness of material. The powdered blend has required flow property. After compression, all the tablets were dried at 60°C for 30 min and were evaluated for various parameters like weight variation, hardness, thickness, friability, disintegration, and in-vitro drug release.

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