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DESIGN AND *IN VITRO* EVALUATION OF MOUTH DISSOLVING TABLETS OLANZAPINE

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The purpose of this research was to design and evaluate the olanzapine fast dissolving tablets. The variable formulation of Olanzapine having challenging methodology. Olanzapine practically insoluble in water so used different polymers and superdisintigrant to make formulation. Direct compression are most desired method for preparation of mouth dissolving tablets. The tablets were evaluated for disintegration and dissolution properties of the formulation. In formulation of mouth dissolving tablet evaluate the precompression parameter and post compression parameter and after evaluation found satisfactory

INTRODUCTION

Oral route of drug administration are the most effective route and this route are mainly desired for drug administration. Oral routes of drug administration have wide acceptance up to 50-60% of total dosage forms. Solid dosage forms are popular because of easiness of administration, accurate dosage, self-medication, pain avoidance and most importantly the patient compliance. The most popular solid dosage forms are being tablets and capsules; one important drawback of this dosage forms for some patients, is the difficulty to swallow. For swallowing of oral dosage form drinking water plays an important role. Often times people experience inconvenience in swallowing conventional dosage forms such as tablet when water is not available, in the case of the motion sickness (kinetosis) and sudden episodes of coughing during the common cold, allergic condition and bronchitis. For these reason, tablets that can rapidly dissolve or disintegrate in the oral cavity have involved a great deal of responsiveness. Mouth dissolving tablet is mainly for those who heaving problem in swallowing but also effective or ideal for active people[1].

Preparation of Mouth dissolving tablet:

Mouth dissolving tablet using different active and excipients such as Olanzapine, Sodium Starch Glycollate, Cross Caramellose Sodium, crosspovidone,Talc, Aspartame.Orange flavor. Shift the material using 60# and others. Purified water are used as binding agent in formulation. After completed binding stage dried the granules. Lubricants are added in granules and mixed the all lubricants except magnesium stearatefor 5 min and after that mix magnesium stearate for 2 min after lubrication collect the granules & using compression machine compressed the granules directly and make the mouth dissolving tablets.

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Precompresssion Parameter:

Angle of repose (θ)

It is defined as the maximum angle possible between the surface of a pile of powder and the horizontal plane.

Bulk Density

It is the ratio of total mass of powder (M) to the bulk volume (Vb). Apparent bulk density was determined by pouring presieved drug excipient blend into a graduated cylinder and measuring the volume and weight.

Tapped Density:

It is the ratio of total mass of powder to the taped volume of powder.

Carr's compressibility Index:-

It indicate the flow property of the powder. It is expressed in percentage.

Hausner Ratio:

It is an indirect index of ease of powder flow. Hausner found and showed that powders with low inter particle friction. Such as coarse sphere, have ratios of approximately 1.2 where as more cohesive, less free flowing powders such as flakes have Hausner's ratio greater than 1.6.

Post compression Parameter

Shape and Colour of tablets

Uncoated tablets were examined under a lens for the shape of the tablet and colour was observed by keeping the tablets in light.

Weight variation

The tablets were selected randomly from each batch and weighed individually to check weight variation. The U.S Pharmacopoeia allows a little variation in the weight of a tablet.

Hardness

Tablet crushing strength the critical parameter was controlled as tablet capping its depend on hardness of the tablet.

Thickness

Thickness is also important parameter for tablet as it affects other parameters.

Wetting time

Water absorption ratio gives insight into disintegration properties of the tablets.

***In- vitro* disintegration time**

Disintegration test is an important parameter of mouth dissolving tablets. It is mainly important of absorption of solid dosage form after oral administration. Disintegration time mainly affected of particle size. Tablet compaction force and hardness of tablet mainly affected the tablet disintegration time.

Dissolution profile

Dissolution testing is widely used in pharmaceutical industry for optimization of formulation and quality control.

Table 1: Formulation of olanzapine tablets

Ingredient	F1	F2	F3	F4	F5	F6	F7	F8	F9
Olanzapine	15	15	15	15	15	15	15	15	15
Lactose	45	40	45	40	45	40	35	35	35
Sodium Starch Glycollate	5	10	-	-	-	-	-	15	-
Cross Caramellose Sodium	-	-	5	10	-	-	15	-	-
Crosspovidone	-	-	-	-	5	10	-	-	15
Magnesium stearate	2	2	2	2	2	2	2	2	2
Talc	2	2	2	2	2	2	2	2	2
Aspartame	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Orange flavour	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Water	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s
Total weight	70	70	70	70	70	70	70	70	70

Table 2: Result of precompression evaluation

Formulation code	**Angle of Repose (θ)**	**Bulk Density (g/ml)**	**Tapped Density (g/ml)**	**Carr's Index (%)**	**Hausner Ratio**
F1	22.84	0.467	0.592	14.10	1.15
F2	26.45	0.498	0.536	12.68	1.13
F3	20.44	0.416	0.554	12.33	1.12
F4	23.43	0.482	0.592	13.41	1.15
F5	24.76	0.434	0.547	12.73	1.13
F6	22.56	0.466	0.556	13.86	1.16
F7	21.11	0.482	0.517	14.09	1.17
F8	23.33	0.411	0.519	13.72	1.19
F9	25.34	0.568	0.528	14.11	1.13

Table 3: Result of post compression evaluation

Formula–tion code	Appear – ance	Thickness (mm)	Hardness (Kg/cm^2)	Friability %	Weight variation (mg)	Wetting time (Sec)	Disintegration Time (sec)	Dissolution (%)	Drug content (%)
F1	OK	2.58	3.0	0.22	74	16	56	82.26	96.52
F2	OK	2.56	3.5	0.32	75	24	120	89.74	96.32
F3	OK	2.57	3.5	0.29	74	28	72	88.56	96.54
F4	OK	2.64	2.0	0.33	76	30	62	96.62	97.63
F5	OK	2.57	2.0	0.26	73	25	59	96.72	97.76
F6	OK	2.57	3.5	0.40	74	31	72	96.41	97.12
F7	OK	2.59	3.5	0.39	75	28	150	96.11	96.44
F8	OK	2.62	3.5	0.29	76	27	144	93.23	96.56
F9	OK	2.63	3.0	0.31	75	24	204	91.12	96.51

CONCLUSION

OLZ is atypical antipsychotic agent and used for preparation of mouth dissolving tablets. Disintigration studies confirmed using sodium starch glycollate and observed faster disintegration rate.Dissolution study confirmed with using cross carmellose sodium, crosspovidone and shows the better n dissolution rate.Formulation F4 and Formulation F5 give the best result as per mouth dissolving tablets. Addition of crosspovidone in formulation give the minimum disintegration time and also shows better dissolution result.Which type of formulation shows that lower hardness heaving that better disintegration rate and also dissolution rate. In prepared formulation F4 And F5 formulation are those which heaving lower hardness and shows good disintegration and dissolution result.

REFERENCES

1. Reddy LH, Ghosh B and Rajneesh. Fast dissolving drug delivery system: A review of literature. Indian J Pharm Sci 2002; 64 (4): 331-336.
2. Sharma S, *et al*new generation of tablets; Fast dissolving tablet. Pharmainfo.net.
3. Pandina GJ et al, Risperidone improves behavioral symptoms in children with autism in a randomized, double- blind, placebocontrolled tria. J Autism Dev Disord 2007, 37: 367- 373.
4. Koizumi K, Watanabe Y, Morita K, Utoguchi N and Matsumoto M: New method of preparing high porosity rapidly saliva soluble compressed tablets using mannitol with camphor, a subliming material. Int J Pharm. 1997; 152:127-131.
5. Chang R, Gua X, Burnside B and Couch R: A Review of Fast Dissolving Tablets. Pharmaceutical technology.(North America);June 2000:52-58.
6. Bi Y, Sunada H, Yonezawa Y, Dayo K, Otsuka A and Iida K. Preparation and evaluation of a compressed tablet rapidly disintegrating in oral cavity. *Chem. Pharm. Bull.* (1996) 44**:** 2121-27.
7. Burton, Michael E.; Shaw, Leslie M.; Schentag, Jerome J.; Evans, William E. (May 1, 2005). Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring (4th ed.). Lippincott Williams & Wilkins. p. 815.
8. McGlashan TH, Zipursky RB, Perkins D, Addington J, Miller T, Woods SW, Hawkins KA, et al. Randomized, double-blind trial of olanzapine versus placebo in patients prodromally symptomatic for psychosis. Am J Psychiatry. 2006;163(5):790-799.
9. Kaushik D, Dureja H, Saini TR. Mouth dissolving tablets: A review. Indian Drugs 2004; 41: 187-193.
10. C. Narendra, M.S. Srinath and B. Prakash: Development of Three Layered Buccal Compact Containing Metoprolol Tartrate By Statistical Optimization Technique. International Journal of Pharmaceutics; 304, 2005: 102-114.
11. Allen LV and Wang B. Particulate support matrix for making rapidly dissolving tablets. US Patent 1997; No. 5,595,761.

12. Chavan BS, Sidana A, Singh GP. Olanzapine induced mania: A case report. Indian J Psychiatry 2003, 45(I), 56-57.
13. Habib W, Khankari R, Hontz J. Fast-dissolving drug delivery systems, critical review in therapeutics. Drug Carrier Systems 2000; 17(1): 61-72.

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