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Original Research Article

DESIGN AND EVALUATION OF FAST DISSOLVING TABLET OF BECLOFEN BY USING NATURAL (FENUGREEK POWDER) SUPERDISINTEGRANT

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Abstract

The demands of new drug delivery system fast dissolving tablets have ever increased day by day during the last two/three decade. In the proposed research study, the effect of natural Superdisintegrants was compared with synthetic Superdisintegrants and other conventional Superdisintegrants in the formulation of fast dissolving tablet drug delivery system and formulation of Beclofen. Baclofen is a GABA agonist NSAID is used as a skeletal muscle relaxant and also used for the relief of painful and uncomfortable muscle spasms, joint stiffness caused with rheumatoid arthritis. In the present work 6 formulations of Fast dissolving tablet of Beclofen were prepared by using different type of Superdisintegrants was evaluated and compiles with the official parameters. Various formulations were prepared using four different- different superdisintegrsnts namely natural super disintegrats Fenugreek Powder, crespovidone, cross carmelose sodium with three effective concentrations (3%, 6%, and 9%) by direct compression method. Formulation F8 results the lowest disintegration time and in-vitro dissolution studies observed that formulation F8 showed 97.06% drug release at the end of 3 minutes.

Keywords: Fast dissolving tablet, GABA, Muscle spasm, Beclofen, Crospovidone, Fenugreek powder, dissolution time.

INTRODUCTION

The tablet dosage form is generally used solid dosage form because of its convenience in term of self-administration, easy to manufacturing and effective dose accuracy. Over these advantages one drawback of these conventional tablets is difficulties in swallowing by pediatric, geriatric and unconscious patients. The fast dissolving tablets which dissolving within few seconds in the mouth when they come in contact of mouth saliva without requirement of any additional water. The advantage of FDT (Fast dissolving tablet) is onset of action, higher patient acceptance, and increased bioavailability during emergencies and other required conditions. Beclofen is the potent non-steroidal anti-inflammatory drug (NSAID) with anti-inflammatory, antipyretic and analgesic actions. Beclofen is a GABA agonist NSAID used in the treatment of rheumatoid arthritis, osteoarthritis, back pain, chronic low back pain, acute gout and muscle spasm.[1-5]

MATERIAL AND METHOD: -

MATERIAL: -

Beclofen was received as gift sample by Intas Pharmaceuticals Ltd. Mumbai. Fenugreek powder was gifted by Ayursatva, MP, Asparteme used was procured from Sweetener India, Delhi, and other all the reagents and chemicals used were of analytical grade.

METHOD: -

FDT of Beclofen were prepared by using direct compression method. Pure drug and excipients were passed through # 60 No. mesh, the powdered drug; Mannitol and Lactose were mixed uniformly with continuous trituration using mortar and pestle. Then weighed quantity of super disintegrates and aspartame taken for each formulation and properly mixed, finally magnesium stearate and talc powder were added and mixed well. The mixed blend of drug and excipients were compressed using 10 station tablet punching machine. All designed formulations were subjected to compatibility studies (IR) and pre-compression parameters like- Angle of repose, Bulk density, Cars index, Tapped density, compressibility index, Hauser's ratio.[1-2]

Pre-formulation studies: -

Angle of Repose (θ):

The angle of repose is determined by the funnel method suggested by scientist Newman. Angle of repose is determined by the following formula

$\text{Tan } \theta = h/r$

$\theta = \text{Tan}^{-1} h/r$

Where θ = Angle of repose, r = Radius of the cone, h = height of the cone

Bulk Density:

Density defined as weight per unit volume. Bulk density can be defined as the mass of the powder is divided by the bulk volume of powder and is expressed as gm/ cm^3. There are two types of bulk density.[7]

Tapped Density (Dt):

Volume was reported by tapping the powder for 500 times and the tapped volume was recorded, if the difference between these two volumes was less than 2%. It was expressed in g/ml and was given as following,

$Dt = M/Vt$

Where, M is the mass of powder, Vt is the tapped volume of the powder.[1-2]

Carr's index (or) % compressibility:

Carr's index results powder flow properties. It is expressed by percentage and is given by:

$I = Dt - Db/Dt \times 100$

Where, Dt denotes the tapped density of the powder, And Db is the bulk density of the powder.[7]

Hausner ratio:

Hausner ratio is an indirect index of ease of powder flow properties. It is calculated by the following formula:

Hausner ratio=Dt/Db Where, Dt show the tapped density, Db is the bulk density.

Lower hausner ratio (<1.25) indicates better flow properties than higher ones (>1.25). [8]

EVALUATATION OF TABLET: -

All prepared tablets of Beclofen were evaluated for the following parameters as per IP guideline; all the calculations are represented in the table No.3

Weight Variation: -

The average weight of the tablets calculated was found in standard range.[9]

Hardness: -

Hardness of the Beclofen tablet was measured with the tablet hardness testing apparatus known as Monsanto tablet harness tester.[10]

Thickness: -

The thickness of the tablet was measured in mm by the Vernier Calipers for all the designed formulation batches.[11]

Friability: -

The tablets weighted and reweighed after fraibilator process, percentage weight-loss was calculated, was found in standard range.[16-17]

Formula use for calculation of Friability

%Friability= Initial Weight−Final Weight * 100/ Initial Weight

DISINTEGRATION STUDY: -

Disintegration time study was carried out by selecting 6 tablets of Beclofen and performed disintegration test using 900 ml distilled water at temperature ($37^0C \pm 2^0C$)

DISSOLUTION STUDY: -

Dissolution test apparatus type 2 known as Paddle dissolution apparatus, used phosphate buffer as dissolution medium as 900 ml containing PH 6.8 was taken in vessel and the temperature maintained at 37 ± 0.5^0C as per standard ICH guidelines.[13-15]

Table No. 1: Formulation of fast dissolving tablet of Beclofen:

Ingredients(mg)	FDB1	FDB2	FDB3	FDB4	FDB5	FDB6	FDB7	FDB8	FDB9
Beclofen	10	10	10	10	10	10	10	10	10
Croscarmellose sodium	3	6	9	-	-	-	-	-	-
Crospovidone	-	-	-	3	6	9	-	-	-
Fenugreek Powder	-	-	-	-	-	-	3	6	9
Aspartame	1	1	1	1	1	1	1	1	1
Flavour	1	1	1	1	1	1	1	1	1
Talc	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Magnesium Stearate	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Mannitol	25	25	25	25	25	25	25	25	25
Lactose	30	30	30	30	30	30	30	30	30
Sorbitol	27	24	21	27	24	21	27	24	21
TOTAL	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**

RESULT AND DISCUSSION: -

Table No. 2: Pre-compression parameters of Beclofen FDTs

Parameters / Formulation	Bulk Density (mg/ml)	Tapped Density (mg/ml)	Hausners Ratio	Compressibility Index (%)	Angle of Repose
FDB1	0.388± 0.01	0.514±0.02	1.32±0.02	24.60± 0.02	20.21± 0.01
FDB2	0.391 ± 0.02	0.505± 0.01	1.29±0.01	22.57± 0.01	22.72± 0.01
FDB3	0.395± 0.01	0.512±0.01	1.29±0.01	22.85± 0.01	20.66± 0.02
FDB4	0.395± 0.03	0.521±0.03	1.31±0.03	24.18± 0.01	20.44± 0.02
FDB5	0.412 ± 0.15	0.502±0.03	1.21±0.04	17.92± 0.02	21.77 ± 0.01
FDB6	0.414 ± 0.10	0.492±0.02	1.18±0.02	15.85± 0.03	23.09± 0.03
FDB7	0.419 ± 0.04	0.488± 0.01	1.16±0.03	14.13± 0.02	24.35± 0.02
FDB8	0.392± 0.02	0.521±0.01	1.32±0.02	24.76± 0.03	20.44± 0.01
FDB9	0.391 ± 0.02	0.505± 0.01	1.29±0.01	22.57± 0.01	22.72± 0.01

Table No. 3: Post-Compression parameters of Beclofen FDTs:

Parameters / Formulation	Thickness (mm)	Weight (mg)	Hardness (Kg/cm^2)	Friability (%)	Disintegration Time (Sec)	Swelling Time (Sec)
FDB1	4	96.25±0.55	3.12±0.10	0.52±0.06	55±0.01	20±1
FDB2	4	97.55±0.78	3.15±0.11	0.58±0.11	45±0.02	17±2
FDB3	4	98.16±0.11	3.25±0.06	0.55±0.12	48±0.01	18±1
FDB4	4	98.22±0.25	3.23±0.03	0.62±0.11	50±0.02	21±1
FDB5	4	99.29±0.11	3.21±0.08	0.64±0.09	48±0.03	22±2
FDB6	4	101.05±0.15	3.18±0.11	0.66±0.02	42±0.01	18±2
FDB7	4	101.18±0.15	3.10±0.08	0.64±0.03	44±0.02	19±2
FDB8	4	100.05±0.04	3.05±0.02	0.62±0.05	40±0.03	14±2
FDB9	4	101.02±0.22	3.08±0.11	0.66±0.09	42±.0.4	16±1

Table No. 4: Drug Content in the Fast-Dissolving Tablet of Beclofen

Parameters / Formulation	Drug Content (mg per Tablet)	% Drug Content
FDB1	95.22±0.010	95.22
FDB2	94.84±0.011	94.84
FDB3	95.21±0.012	95.21
FDB4	95.33±0.013	95.33
FDB5	96.32±0.005	96.32
FDB6	96.55±0.011	96.55
FDB7	96.12±0.008	96.12
FDB8	97.06±0.005	97.06
FDB9	96.55±0.016	96.55

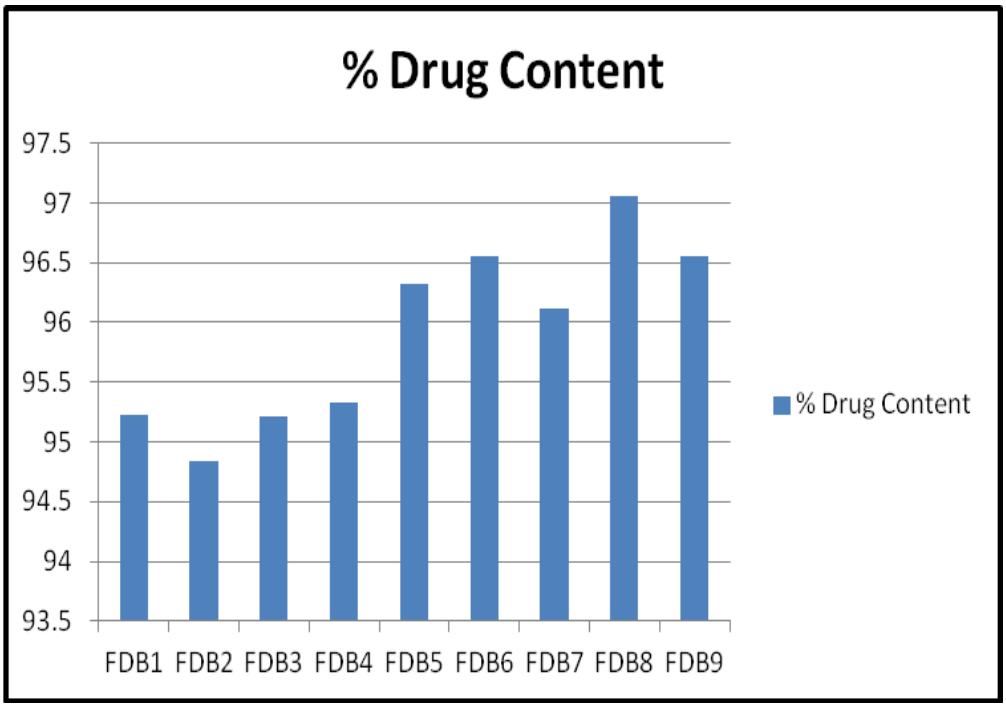


Figure:1: Drug Content in the Fast Dissolving Tablet of Beclofen

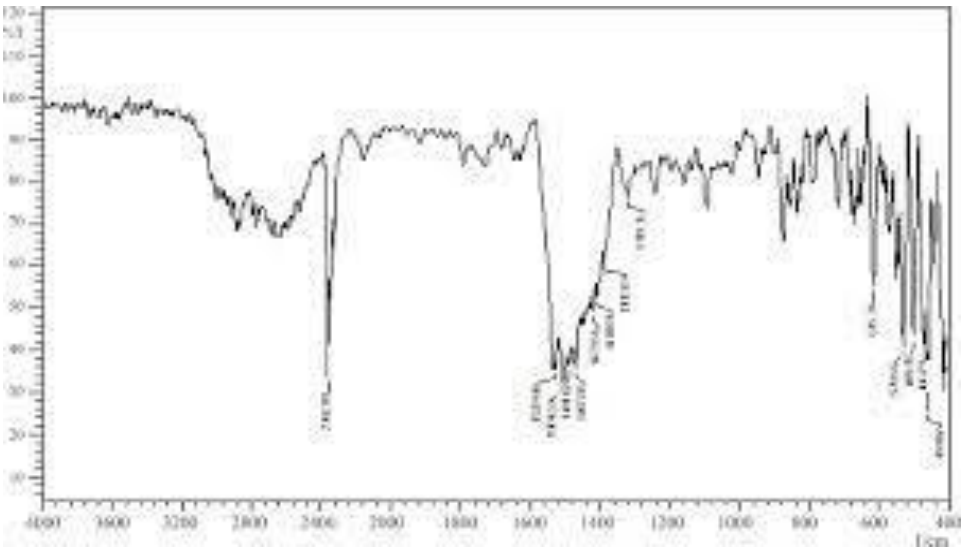
RESULTS AND DISCUSSION:

The angle of repose for the entire formulations blend was found to be in the range. All formulations showed good flow properties. Hausner's ratio was found to be in the range as per IP, and that indicated that all formulation has good flow properties. All parameters show weight variation, thickness, Disintegration time (sec) within standard limit. From all the

above observations it was concluded that the formulation F8contain Fenugreek powder 6% found to be better formulation in terms of rapid dissolution and but maximum percentage drug release was found 97.06% of formulation F8, with Fenugreek Powder (6%).

CONCLUSION:

It concluded from the present study that fast dissolving tablets of Beclofen drug can be possible with effective bioavailability. Natural Superdisintegrants can be used as pharmaceutical excipients for oral drug delivery. It was concluded formulation F8 maximum percentage drug release was found 97.06%, with Fenugreek Powder conc. 6 %. Hence the Fenugreek Powder can be used at higher concentration at it has advantage of being non-toxic, low cost, biodegradable and biocompatible with no side effect.



IR spectra of Beclofen

REFERENCES:

1. Venkateswarw SS, Nyshdham JR Josef AF, Recent technological Advances in Oral Drug Delivery –A Review PST, Today 2000, edition -3, page- 138-145.
2. Sharma AK, Nareda M, Aziz S, Sharma D, Garg S, Fentanyl - A Potent Opioid Analgesic: A Review. J Dev Drugs 5:162.
3. Abdelkader H, Youssef O, Abdulla and Sale H: Formulation of controlled-release Baclofen matrix tablets: Some hydrophilic polymers on the release rate and in-vitro evaluation. 2007; 156-167.
4. Moffat AC, Clark's isolation and identification of drugs. London: Pharmaceutical Press; 2006; 691.
5. Shankar KR, Madhan K and Swetha G: Formulation and evaluation of sustained release matrix tablets of Baclofen. Int J Pharm Sci & Res 2018; 9(10): 4402-09.
6. Sanders-Bush E, Mayer SE. 5-hydroxytryptamine (Serotonin): Receptor agonists & antagonists. In: Brunton LL, Lazo JS, Parker KL, editors. Goodman & Gilman's The Pharmacological Basis of Therapeutics. 11th ed. New York: McGraw Hill; 2006. p. 305-9.
7. Antimigraine Drugs. In: Sweetman SC, editor. Martindale the complete drug reference. 33rd ed. London: Pharmaceutical Press; 2002. p. 445-46.
8. Nareda M, Sharma A., Design and Formulation of Fast Dissolving Tablet of Lornoxicam using Banana Powder

as Natural Superdisintegrant by Direct Compression Method. Wjpps, 2018; 7(2): 631-642.
9. Sharma AK, Sharma V, Soni SL, Pareek R, Goyal RK, Khandelwal M, Formulation and Evaluation of Fast Dissolving Tablet of Domperidone Using Fenugreek Seed Mucilage As Natural Superdisintegrant By Direct Compression Method World J Pharmacy and Pharm Sci; 7 (2); 643-653.
10. Remington "The science and Practice of Pharmacy", Edition-21, volume- I, Publication- Lippincott Williams and Wilkins, Pg. 1181-1192.
11. Bandari, S., Mittapalli, R.K., Gannu, R., Rao, Y.M. (2008) Orodispersible tablets: An overview, Asian Journal of Pharmaceutics, Jan, Pp. 2-11.
12. Bhupendra GP and Patel SN. Formulation, evaluation and optimization of orally disintegrating tablet of cinnarizinee-Journal of Science & Technology, 2010; 5(5):9-21.
13. Aly AM, Semreen M, Qato MK. Superdisintegrants for solid dispersion to produce rapidly disintegrating tenoxicam tablets via camphor sublimation. Pharma Tech. 2005; 68-78.
14. Bai, G., Wang, Y., Armenante, P. M., "Velocity profiles and shear strain rate variability in the USP Dissolution Testing Apparatus 2 at Different Impeller Agitation Speeds, " International Journal of Pharmaceutics, 403 (1-2), Pages 1–14, 2011.
15. United States Pharmacopeia 34/National Formulary 29, 2011.