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FORMULATION, DEVELOPMENT AND EVALUATION OF FAST DISSOLVING TABLET OFACECLOFENACBY USING NATURAL SUPERDISINTEGRANT (BANANA POWDER)

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***Abstract*—The requests for quick dissolving tablets have gotten truly expanding step by step during the last 10 years. In the present projected study, the impact of normal Superdisintegrants was contrasted and manufactured Superdisintegrants and customary Superdisintegrants in the of quick dissolving tablet detailing of Aceclofenac. Aceclofenac NSAID is utilized for the treatment of gentle to direct agony in different circumstances like (e.g., dental torment, osteoarthritis) and to diminish agony and blood misfortune during feminine periods. It is additionally utilized for different medicines like decreasing agony, expanding, and joint solidness caused with rheumatoid joint inflammation. In the current work 9 details of FDT (Quick dissolving tablet) of Aceclofenac were ready by utilizing Superdisintegrants was assessed and orders with the authority boundaries and determinations. Different details were arranged utilizing four unique superdisintegrsnts specifically regular super disintegrats Banana Powder, sodium starch glycolate , cross carmelose sodium with three fixations (2% , 4% , 6%) by direct pressure strategy.**

The mix was assessed for pre-pressure boundaries like Point of rest , mass thickness , tapped thickness , and afterward tablet assessed with different post-pressure boundaries like thickness , drug content , hardness , weight variety , wetting time , friability , deterioration time , disintegration time, drug discharge study. Definition F2 showed the most reduced deterioration time and in-vitro disintegration concentrates on recorded that detailing F2 showed 98.55% medication discharge toward the finish of 3 minutes. The best details among these were likewise observed to be steady and upgraded plans were exposed to the security concentrates according to ICH rule.

***Keywords*--Fast dissolving tablet, Natural Super disintegrants, menstrual periods, Aceclofenac, sodium starch glycolate, Banana powder, direct compression, dissolution time.**

I. INTRODUCTION

The tablet is most broadly involved measurement for due to its comfort in term of self-organization, smallness, precise dose and simplicity in assembling. Over this one disadvantage of these customary tablets is hardships in gulping by pediatric and geriatric patients.[1-2]

To beat these issues the researchers have created novel medication conveyance framework that known as quick dissolving tablet. The quick dissolving tablets that dissolving in couple of moments in the mouth when they accompany contact saline without necessity of extra water. The benefit of FDT (Quick dissolving tablet) is beginning of activity, higher patient acknowledgment, and expanded bioavailability.[3]

Aceclofenac is the sodium salt type of strong NSAID Aceclofenac, an anthranilic corrosive and non-steroidal calming drug (NSAID) with mitigating, antipyretic and pain relieving activities. Aceclofenac acts repressing the action of the compounds cyclo-oxygenase I and II, which diminished the arrangement of forerunners of prostaglandins and thromboxanes. Aceclofenac is likewise utilized for the treatment of essential dysmenorrheal (excruciating feminine periods) and for the treatment of idiopathic weighty feminine blood misfortune.

It goes through quick first-pass digestion in the liver (roughly 95% of a portion). This prompts lower bioavailability of Aceclofenac. Such medications shows first-pass digestion impact, so the medication is chosen for quick dissolving tablet.[5-10]

II. MATERIAL AND METHOD

MATERIAL

Aceclofenac was gotten as gift test by Genius Lab Showcasing Pvt. Ltd., Delhi, Magnesium stearate utilized were secured from Figure creature medical care, Jaipur ,Banana powder was gifted by Ayursatva, Madhya-Pradesh, Asparteme utilized was obtained from Sugar India, Delhi, and different reagents and synthetics utilized were of insightful grade.

III. METHOD

Quick dissolving tablet of Aceclofenac were ready by direct pressure technique. Unadulterated medication and excipients were gone through # 60 No. network,

Required measure of medication and excipients were taken for each definition (Table No. 1). The powdered medication, Mannitol and Lactose were blended consistently with ceaseless pulverizing utilizing mortar and pestle. Then, at that point, gauged amount of super crumbles and aspartame taken for every plan and appropriately blended, at last magnesium stearate and powder were added and blended well. The blended mix of medication and excipients were compacted utilizing 10 station tablet punching machine. (Shakti drugs). A Bunch of 50 tablets of every detailing was ready for all the planned tablet definitions. Prior to the tablet planning/punch the combination mix of all planned definitions were exposed to similarity studies (IR) and pre-pressure boundaries like-Point of rest, Mass thickness, Tapped thickness, compressibility record, Hauser's proportion.[11-12]

Pre-formulation studies:-

Angle of Repose (θ):

Point of rest is characterized as, the most extreme conceivable point between the outer layer of the heap of the powder and the level plane of the powder. At the point when greater amount of the powder is added to the heap, it slides down, until the shared erosion of the particles creating a surface point θ, is harmony with the gravitational force.13

The point of not entirely set in stone by the pipe strategy proposed by researcher Newman. Point of not entirely set in stone by the accompanying recipe

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

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

Bulk Density:

Density characterized as weight per unit volume. Mass thickness can be characterized as the mass of the powder is separated by the mass volume of powder and is communicated as gm/cm3.The mass thickness of any powder principally relies upon its different boundaries such molecule shape, molecule size, dissemination and the propensity of particles to stick together. There are two kinds of mass density.14

Low mass density

The particles are pack in such a manner to leave enormous holes between their surfaces coming about up in light powder of low mass tdensity

High mass density

Here the more modest particles shift between the huge particles bringing about weighty powder of high mass density

Tapped Density (Dt):

It was the index representing the ratio of the powder's total mass to its tapped volume. If there was a difference of less than 2% between these two volumes, the tapped volume was recorded and the powder was tapped 500 times to report the volume. If the difference was greater than 2%, 750 taps were made, and the volume of each tap was recorded. Until the

volume difference in the bulk density apparatus was less than 2%, tapping was kept up. It was stated as follows, with an expression in g/ml.
Dt= M/Vt

Where, M is the mass of powder, Vt is the tapped volume of the powder.[15-17]

Carr's index (or) % compressibility:

Carr's index indicates powder flow properties. It is expressed bypercentage and is given by:

I=Dt−Db/Dt×100 \

Where, Dt denotes the tapped density of the powder, And Db is the bulk density of the powder.[18-19]

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)[20]

EVALUATATION OF TABLET:-

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

WEIGHT VARIATION:-

Twenty tablets of Aceclofenac formulation were selected randomly from each of the formulation and weighted individually using Citizen Digital Balance for their weight data. The average weight of the tablets calculated was found in standard range.[21]

HARDNESS:-

Hardness of theAceclofenac tablet was measured with the tablet hardness testing apparatus known as Monsanto tablet harness tester.[22]

THICKNESS:-

The thickness of the tablet was measured in mm by the Vernier Calipers for all the designed formulation batches.[23]

FRIABILITY:-

The friability of the Aceclofenac tablet, a sample of twenty tablets was measured using USP type Roche fraibilator. The tablets reweighed and percentage weight-loss was calculated, was found in standard range.[24]

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

Water absorption ratio:

A piece of tissue paper (12 cm X 10.75 cm) folded twice was placed in small Petri-plate (ID = 6.5 cm) containing 10 ml of water. A tablet of every batch was placed on the paper and time for complete wetting of the tablet was measured in seconds. Three random trials for each batch were performed and the standard deviation was also determined. The wetted tablet was weighed and water absorption ratio R, was determined by following equation

$$\mathbf{R = \{(Wa - Wb) / Wa\} \times 100}$$

Where, Wa and W_b were weights of the tablets after and before study.[25-27]

Wetting Time

A piece of tissue paper (12cmX10.75cm) folded twice was placed in a small Petri dish (ID = 9 cm) containing 6ml pH 6.8 phosphate buffer, A tablet was placed on the paper and the time taken for complete wetting was noted. Three tablets from each formulation were randomly selected and than the average wetting time was noted.[28-29]

DISINTEGRATION STUDY:-

Disintegration time study was carried out by selecting6 tablets of Aceclofenacand performed disintegration test using 900ml distilled water at temperature ($37^0C \pm 2^0C$)[30]

DISSOLUTION STUDY:-

The USP (United States Pharmacopoeia) dissolution test apparatus type 2, also known as the paddle dissolution apparatus, was used to conduct the in-vitro dissolution study. Phosphate buffer was used as the dissolution medium; 900 ml of PH 6.8 was placed in the vessel, and the temperature was kept at 37±0.50C in accordance with standard protocols. After setting the dissolving apparatus paddle's speed to 50 revolutions per minute, 5 millilitres of the dissolution medium were removed, and the same volume of new medium was added back in. The absorbance basis was used to compute the concentration. Three duplicates of the medication formulation were released at a time. [31-32]

Table I

Formulation of fast dissolving tablet of Aceclofenac

Ingredients(mg)	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
Meclofenamate	100	100	100	100	100	100	100	100	100
Banana Powder	3	6	9	-	-	-	-	-	-
Sodium Starch Glycolate	-	-	-	3	6	9	-	-	-
Cross carmellose Sodium	-	-	-	-	-	-	3	6	9
Aspartame	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Flavour	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
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	20	17	14	20	17	14	20	17	14
Lactose	21	21	21	21	21	21	21	21	21
TOTAL	**150**	**150**	**150**	**150**	**150**	**150**	**150**	**150**	**150**

Table II

Pre-compression parameters of Aceclofenac FDTs

Parameters / Formulation		Bulk Density (mg/ml)	Tapped Density (mg/ml)	Hausners Ratio	Compressibility Index (%)	Angle of Repose
F_1		0.500± 0.011	0.576±0.011	1.103±0.051	13.19± 0.15	24.77± 1.38
F_2		0.471± 0.022	0.538±0.019	1.177±0.090	12.00± 0.03	23.96± 1.35
F_3		0.517± 0.019	0.576±0.014	1.121±0.019	12.66± 0.18	23.19± 1.40
F_4		0.391 ± 0.09	0. 455± 0.02	1.151 ± 0.02	13.11± 0.60	31.14 ± 1.20
F_5		0.365 ± 0.15	0.421± 0.03	1.162 ± 0.04	15.22± 0.75	30.08 ± 1.55
F_6		0.410 ± 0.02	0.481± 0.02	1.171 ± 0.01	14.12± 1.23	35.12 ± 1.42
F_7		0.521± 0.16	0.621± 0.11	1.161± 0.07	15.01± 0.22	30.20± 0.16
F_8		0.582± 0.04	0.482± 0.14	1.141±1.00	16.19± 0.56	28.28± 0.23
F_9		0.495± 0.10	0.572± 0.19	1.103±1.11	17.27± 1.58	29.31± 1.15

Table III

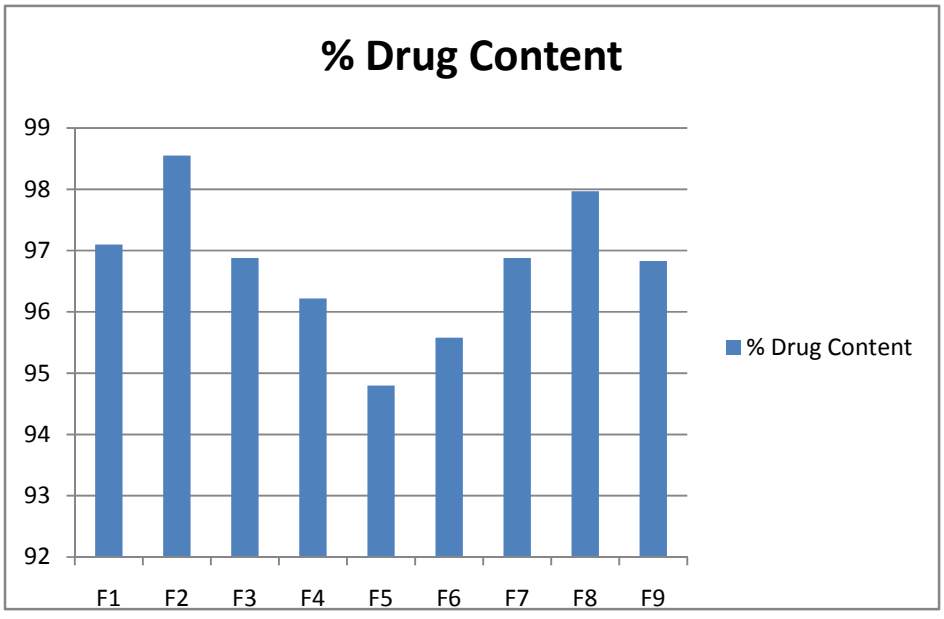
Post-Compression parameters of Aceclofenac FDTs:

Parameters / Formulation	Diameter (mm)	Thickness (mm)	Weight (mg)	Hardness (Kg/cm^2)	Friability (%)	Disintegration Time(Sec)	Swelling Time (Sec)
F_1	4	3	145.05±0.55	3.15±0.15	0.60±0.84	44±1.44	15±1
F_2	4	3	147.57±0.78	3.09±0.01	0.62±0.25	39±1.14	14±2
F_3	4	3	146.01±0.11	3.24±0.09	0.59±0.17	45±1.46	16±1
F_4	4	3	138.02±0.25	3.18±0.12	0.61±0.16	48±1.25	21±1
F_5	4	3	140.01±0.11	3.28±0.01	0.60±0.12	40±1.52	22±2
F_6	4	3	142.05±0.15	3.22±0.10	0.62±0.32	46±1.36	18±2
F_7	4	3	141.01±0.15	3.32±0.05	0.65±0.13	41±1.01	19±2
F_8	4	3	143.50±0.04	3.50±0.09	0.62±0.23	42±1.59	22±2
F_9	4	3	142.02±0.22	3.41±0.18	0.68±0.19	43±1.58	17±1

Table IV

Drug Content in the Fast Dissolving Tablet of Aceclofenac

Parameters **Formulation**	**Drug Content** (mg per Tablet)	**% Drug Content**
F_1	145.66±0.015	97.10
F_2	147.83±0.031	98.55
F_3	145.32±0.115	96.88
F_4	144.33±0.010	96.22
F_5	142.20±0.085	94.80
F_6	143.37±0.151	95.58
F_7	145.33±0.158	96.88
F_8	146.96±0.085	97.97
F_9	145.25±0.150	96.83



III RESULTS AND DISCUSSION

The powder blend's bulk density and tapped density have been assessed. It was discovered that the angle of repose for the mix of all formulas fell between 23.19 and 35.12°. Angle of repose values < 24.77o were observed in formulations including Natural Superdisintegrants (Banana Powder) (F1-F3) as determined to be 12.0% to 17.27%. Every formulation exhibited acceptable flow characteristics. The range of 1.103 to 1.177 for Hausner's ratio suggested that all formulations had satisfactory flow characteristics.

Batches with lower hardness (3.09) and greater hardness (3.50). Friability is higher in F9 and lower (0.59%) in F3. Weight fluctuation, thickness, and disintegration time (sec) are all a disintegrat. The formulations comprising sodium starch glycolate (F4-F6) and sodium carmelose (F7-F9) revealed angle of repose values ≤35.12o and ≤30.20o, respectively, suggesting only a fair flow quality of the powder mix. The range of the compressibility index w

within the acceptable range for all metrics. Every formulation was put through a dissolving process. Based on the aforementioned findings, it was determined that formulation F3, which contains 4% of banana powder, has a faster dissolve rate than formulation F2. However, formulation F3, which also contains 4% of banana powder, has a maximum percentage drug release of 98.55%.

IV.CONCLUSION

The entire investigation leads to the conclusion that the medication Aceclofenac comes in fast-dissolving tablet form. Oral medication distribution can make use of natural superdisintegrants as pharmaceutical excipients. Therefore, natural superdisintegrants, such as banana powder, demonstrated quicker drug dissolution, improving bioavailability, therapeutic ratio (effectiveness of therapy), patient compliance, and meeting all requirements for a fast-dissolving tablet. The greatest percentage of drug release for formulation F3, using banana powder, was determined to be 98.55%.

According to the study, natural superdisintegrants, such as banana powder, had superior dissolving properties compared to synthetic superdisintegrants, such as sodium starch glycolate (SSG) and cross-carmelose sodium (CCS).

Because banana powder is non-toxic, inexpensive, biodegradable, and biocompatible, it may thus be utilised at larger concentrations.

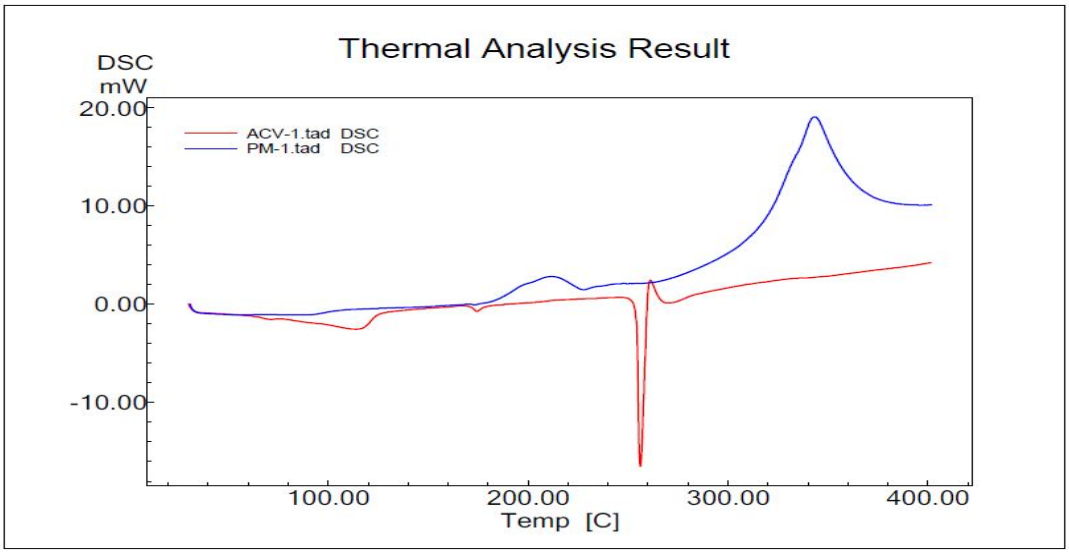


Fig. 2DSC Thermogram of Aceclofenac

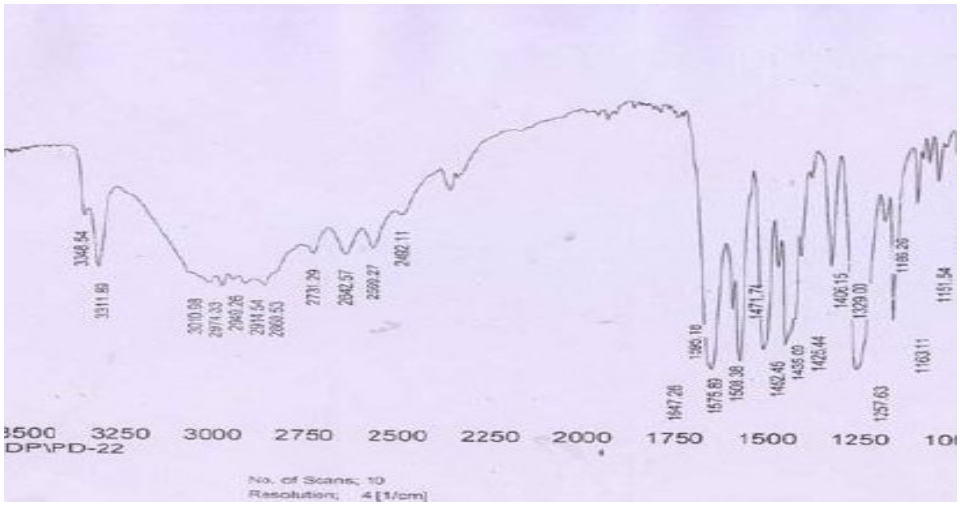


Fig 3. IR spectra of Aceclofenac

Conflict of Interest

No conflict of interest to all authors.

REFERENCES:

[1] Fu Y, Yang S, Jeong SH, Kimura S, Park K., Orally Fast Disintegrating Tablets

Developments, Technologies, Taste- Masking and Clinical Studies, Crit. Rev. Ther. Drug Carrier Sys. 2004; 21:433- 476.

[2] Sharma S, Gupta GD., Formulation and Characterization of Fast Dissolving Tablet of Promethazine Theoclate, Asian J Pharmaceutics, 2008: 70-72.

[3] Venkateswarw SS, Nyshdham JR Josef AF, Recent technological Advances in Oral Drug Delivery –A Review PST, Today 2000, edition - 3, page- 138-145.

[4] Sharma AK, Nareda M, Aziz S, Sharma D, Garg S, Fentanyl - A Potent Opioid Analgesic: A Review. J Dev Drugs 5:162. doi: 10.4172/2329-6631.1000162.

[5] Sultan A., Park J. B.,Mefenamic acid taste-masked oral disintegrating tablets with enhanced solubility via molecular interaction produced by hot melt extrusion technology, Journal of Drug Delivery Science and Technology, 2015; Jun 1; 27: 18–27.

[6] Wagstaff AJ and Bryson HM, Aceclofenac: A review of its pharmacology, clinical efficacy and tolerability in the management of spasticity associated with pain and dental pain. Drugs, 1997; 53: 435-452.

[7] Moffat AC, Clark's isolation and identification of drugs. London: Pharmaceutical Press; 2006; 691.

[8] Acorda Therapeutics, Inc. Meclovate (Aceclofenac) Tablets and Capsules Prescribing Information. Hawthorne: Acorda Therapeutics; 2006.

[9] Moffat AC. Clark's Isolation and Identification of Drugs. London: Pharmaceutical Press; 2006. Page-691.

[10] Setty CM, Prasad DVK, Gupta VRM, Development of fast dispersible aceclofenactablets:Effect of functionality of superdisintegrants; IJPS, 2008; 70: 180–185.

[11] Jacob S, Shirwarkar AA, Joseph A, Srinivasan KK. Novel Co-Processed Excipients of Mannitol and Microcrystalline Cellulose for Preparing Fast Dissolving Tablets of Glipizide. Indian J Pharm Sci 2007; 69(5): 633-9.

[12] Akihiko I, Masayasu S. Development of oral dosage form for elderly patient: use of agar as base of rapidly disintegrating oral tablets; Chem Pharm Bull 2005; 44 suppl 11:2132-36.

[13] Carr R.L. Evaluating Flow Properties of Solids. Chem. Eng 1965; 72:163–168.

[14] Martin A, Micromeretics. In: Martin A, ed. Physical Pharmacy; Baltimores, MD: Lippincott Williams and Wilkins; 2001. p. 423-54.

[15] Government of India Ministry of Health & Family Welfare. Indian Pharmacopoeia. Delhi: Controller of Publications; 2007. p. 1689-90.

[16] Kakade SM, Mannur VS, Ramani KB, Dhada AA, Naval CV, Bhagavat A. Formulation and evaluation of mouth dissolving tablets of losartan potassium by direct compression techniques; Int J. Res. Pharm. Sci; 2010;1(3):290-5.

[17] Chang RK, Guo X, Burnside BA, Cough RA, Fast dissolving tablets. Pharm Tech. 2000; 24:52–8.

[18] Nareda M, Sharma AK, Nareda S, Ghadge M, Garg DS, Sharma DP, World J Pharm Pharm Sci; 7 (2), 631-642.

[19] Indian Pharmacopoeia Committee; India. Ministry of Health; Family Welfare (1985). Pharmacopoeia of India. Controller of Publications.

[20] Rockville, M.D. (2007) United States of Pharmacopeia-National Formulary. USP 30 – NF 25, Vol 1, (PP. 634-645). The Unit States Pharmacopeial Convention.

[21] Shankya K, Agrawal D, Sharma AK, Aman S, Goyal RK, Khandelwal M, World J Pharmacy and Pharm Sci; 10 (3); 1749-1762.

[22] Kuchekar, B.S., Badhan, A.C., Mahajan, H.S, Mouth Dissolving Tablets: A Novel Drug Delivery System; Pharma Times; 2003;

[23] Sharma AK, Sharma V, Soni SL, Pareek R, Goyal RK, Khandelwal M, World J Pharmacy and Pharm Sci; 7 (2); 643-653.

[24] Remington "The science and Practice of Pharmacy", Edition-21, volume- I , Publication- Lippincott Williams and Wilkins, Pg. 1181-1192.

[25] Bandari, S., Mittapalli, R.K., Gannu, R., Rao, Y.M., Orodispersible tablets: An overview, Asian Journal of Pharmaceutics; 2008; Jan.; 2-11.

[26] Sharma AK, Nareda M, Rathore R, Soni SL, Sharma M., Khandelwal M, Formulation, Development and In-vitro Evaluation of Fast Dissolving Tablet of Aceclofenac using co-processed Superdisintegrant by Direct Compression Method; Int. J. Pharm. Sci. Rev. Res., 54(2), January - February 2019; Article No. 12, Pages: 67-72.

[27] Sunada H, Bi Y. Preparation, evaluation and optimization of rapidly disintegrating tablets. Powder Technology. 2002; 122: 188–198. doi:10.1016/S0032-5910(01)00415-6.

[28] Vijaya KS, Mishra DN. Rapidly disintegrating oral tablets of meloxicam. Ind Drugs. 2006; 43(2): 117-21.

[29] Bhupendra GP and Patel SN. Formulation, evaluation and optimization of orally disintegrating tablet of cinnarizinee-Journal of Science & Technology, 2010; 5(5):9-21.

[30] Aly AM, Semreen M, Qato MK. Superdisintegrants for solid dispersion to produce rapidly disintegrating tenoxicam tablets via camphor sublimation. Pharma Tech. 2005; 68-78.

[31] 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.

[32] Bai, G., Armenante, P. M., "Hydrodynamics, Mass transfer and Dissolution Effects Induced by Tablet Location during Dissolution Testing," Journal of Pharmaceutical Sciences;2009; Volume 98, Issue 4, Pages 1511-1531.