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Formulation and Evaluation of Orally Disintegrating Tablets of Nimesulide

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ABSTRACT

The objective of the current study is to evolved nimesulide ODT or quickly dissolving tablet preparations by direct compression method applying sodium starch glycolate as super disintegrating agent is to provide better bioavailability with a maximum half-life period. The average weight of the tablets 251.1 ± 0.25mg to 264.6 ± 029 mg. The hardness was determined 4.25± 0.11to 6.25± 0.17 kg/cm^2 during compression and friability for all the formulation varies from 0.47 ±0.06 to 0.30 ±0.05 %. Water absorption of all preparations was noted to be 48±1.65% to 72±1.53%. Wetting time was acknowledging to be 50±0.12 to 60±0.15 sec. The disintegration time were found to be 15±0.01 sec to 11±0.04 sec. In F3 formulation the most drug release of 97.30% in 30min. Good preparation F3 exhibits an r^2 value of 0.980.

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INTRODUCTION

To develop various batch formulations of ODTs of nimesulide by direct compression technique. The ODTs satisfy the patient's demands that are difficult in the consumption of the conventional tablets. Next benefit of ODTs it doesn't need water or chewing prior to swallowing [1]. Some ODTs are prepared to soluble within a few seconds are commonly called as true oral disintegrating tablets. The performance of ODTs based on the manufacturing automation and the most required property of such a dosage form is the capability to quickly disintegrating and dispersing or soluble in the saliva, thereby preventing the requirement for water intake [2]. ODTs should represent some absolute properties to differ them from traditional conventional dosage forms. Nimesulide, a majorly advised anti-inflammatory analgesic drug having greater dissolution rate is a primary factor in its formulation evolution mainly solid dosage forms like tablets and nimesulide BCS class II drug having high permeability hence used as ODT formulation so it can easily be absorbed from salivary and mucosal tissues [3].

MATERIALS AND METHODS

Nimesulide became purchased free of charge sample from B.M.R Chemicals, Hyderabad; Microcrystalline cellulose, Dried Microcrystalline cellulose, Cross carmellose sodium, cross Povidone, Sodium starch glycolate, Talc, Magnesium stearate used to be a present sample of Hi-media laboratory. Mumbai and other ingredients victimized in with Analytical grade.

Methodology

Compatibility Studies

Compatibility study with excipients was performed by FTIR. The unmixed drug and its preparations

along with excipients were exposed to FTIR studies. In the current study, the potassium bromide disc (pellet) method was applied [4].

Preparation of Nimesulide Oral Disintegrating Tablets

Different Nimesulide oral dispersible tablet preparations were synthesized by direct compression method. The concentration of disintegrates was evolved as an ideal concentration under experimental formula and states of a formulation. A total of 4 preparations were produced. All the products be permitted to while away through 60 mesh sieve individually and gathered [5]. The drug and Avicel pH 101 were combined in a little proportion of both and single time mixed to get a uniform powder in a geometrical sequence [Table 1]. The tablets were then compress with the help of 10 mm size punches to get a tablet of 100 mg Nimesulide using a hydraulic press with the apt standard punches and placed in a well-closed container till consumed. In the primary set 3 batches of Nimesulide rapid dispersible tablets were produced by using various concentrations of sodium starch glycolate and supplementary super disintegrants.

Evaluation Parameters

Pre Compression Parameters

The blended mixture was analyzed for flow characteristics as follows.

Angle of repose: $\theta = \tan^{-1}$ (h/r)

Bulk density = Weight of powder/ Bulk volume

Tapped density = Weight of powder/ Tapped volume

Carr's Index (I) = (Tapped Density - Bulk Density)/ (Tapped Density) x100

Hausner's ratio = Tapped density/ Bulk density [Table 2] [6].

Post Compression Parameters

Weight Variation

This test transmit by balancing 20 tablets separately [7], together with the help of digital balance estimating the average weight, and in respective to the each tablet weight to the average weight.

Tablet Thickness

Tablet thickness was determined by keeping a tablet in between two arms [8] the Vernier calipers. 5 tablets were considered and their thickness was determined.

Hardness and Friability

The hardness of the tablet may be determined with the help of Monsanto hardness test [9]. Friability was determined by first weighing 20 tablets after dusting and then placing them in a Roche Friabilator, which was rotated for 4 min at 25 rpm. After dusting, the total remaining mass of the tablets was recorded and the percent friability calculated using following equation

$$\%Friability = 100(W_o - W_f)/W_o$$

Where W_o-W_f is the weights of tablet before and after test for friability respectively.

Wetting Time And Water Absorption Ratio

The wetting time can be measured using a piece of tissue paper folded twice was placed in a small Petri dish (internal diameter of 5 cm) containing 6 ml of water. A tablet was placed on the paper and the time required for complete wetting was measured. The wetted tablet is then weighed and the water absorption ratio was calculated using following equation

$$R = 100\ (W_a - W_b)\ /\ W_b$$

where, W_b and W_a are the weights of tablet before and after water absorption respectively.

Moisture Uptake

The ODT should be directed to analyze the stability of the preparation. The 10 tablets from single preparation were placed in a desiccator above the calcium chloride at 37^{o}C for 24h. Then the tablets were considered their weight and allowed to 75% relative humidity, at room temperature for two weeks [10].

***In-vitro* Disintegration**

It was evaluated in three human volunteers by placing a tablet on the tongue and immediately after the last noticeable mass had disintegrated, the time was recorded [11].

***In-vitro* Dissolution**

The dissolution using USP type II paddle apparatus in 6.8 PH phosphate buffer (900 ml) at 37^{o}C$\pm$0.5^{o}C at speed 50$\pm$5 rpm. At specified time intervals, 5 ml samples were collected and immediately replaced with an equal volume of fresh medium. Samples were suitably diluted and analyzed by using UV spectrophotometer and cumulative % drug released was calculated [12].

Kinetic Treatment

The data acquired from the in vitro dissolution tests obtain the kinetic track record analysis [13].

Zero-order kinetics: $Q_t = Q_o + K_o t$

First-order kinetics: $Q_t = \log Q_o + K_1 t/2.303$

Higuchi model: $Q_t = K_H \cdot t^{1/2}$

Korsmeyer-Peppas release model: $Mt / M_\infty = K \cdot t^n$

Table 1: Composition of different formulations of Nimesulide ODTs

S.No.	Ingredients(mg)	F1	F2	F3
1.	Nimesulide	100	100	100
2.	Sodium starch glycolate	10	20	25
3.	MCC	50	50	50
4.	Mg.stearate	4	4	4
5.	Talc	6	6	6
6.	D-Mannitol	30	20	15

Table 2: Pre-Compression Parameters of Nimesulide ODTs

Code	Angle of repose(θ)	Bulk density (g/cm^3)	Tapped density (gm/cm^3)	Hausner ratio (H)	Carr's index (I)
F-1	27.528±0.235°	0.561±0.032	0.634±0.043	1.230	18.04
F-2	24.512±0.290°	0.567± 0.045	0.660 ±0.057	1.164	17.40
F-3	27.210±0.352°	0.574± 0.058	0.652±0.083	1.235	19.87

Table 3: Physicochemical Characterization of Nimesulide ODTs

Formulation code	Uniformity of weight(mg)	Hardness (kg/cm^2)	Friability (%)	Wetting Time (sec)	Water Absorption Ratio (%)	Disintigration time (sec)
F1	251.1±0.25	4.25±0.11	0.47±0.06	60±0.15	48±1.65	15±0.01
F2	261.5±0.20	5.00±0.77	0.34±0.09	56±0.35	63±2.40	12±0.06
F3	264.6±0.29	6.25±0.17	0.30±0.05	50±0.12	72±1.53	11±0.04

Table 4: *In-vitro* dissolution studies of Nimesulide ODTsF1-F3

Time (Mints)	F1	F2	F3
0	0	0	0
5	21.04	21.014	251.01
10	44.14	44.16	44.15
15	59.7	59.2	59.5
20	65.4	65.8	65.7
25	68.25	78.25	84.25
30	79.30	84.30	97.30

Table 5: Release order kinetics of Nimesulide ODTs

Formulation	r^2 values Zero order	First order	Higuchi	Korsmeyer - Peppas	n values Korsmeyer-Peppas (n)
F3	0.980	0.782	0.953	0.924	1.146

RESULTS AND DISCUSSION

Compatibility Studies

From drug excipient compatibility trend analysis, we referred to the absence of interactions between pure drug and excipients as depicted in Figures 1 and 2.

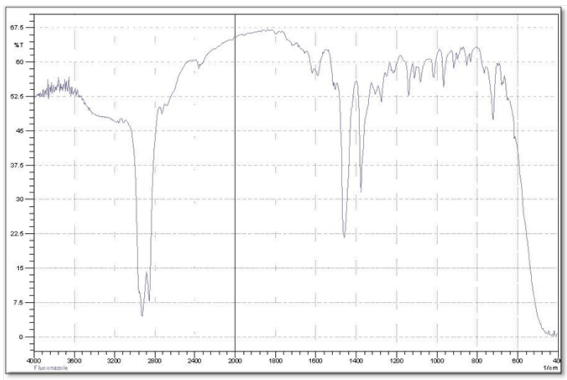

Figure 1: FTIR Image of pure Nimesulide

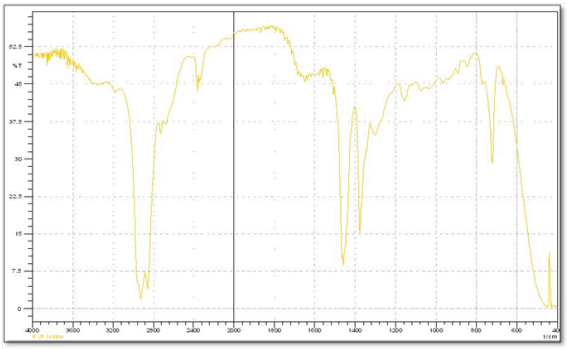

Figure 2: FTIR Image of Nimesulide and Excipients

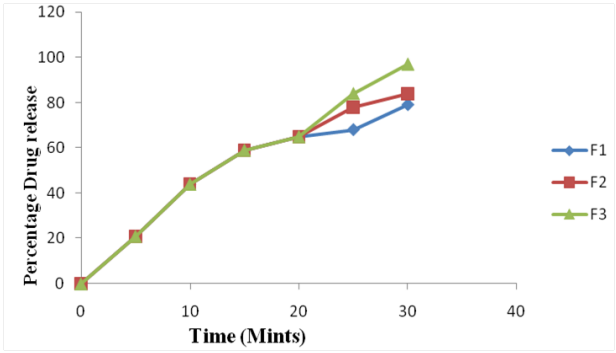

Figure 3: *In Vitro* Drug Release Profiles of Nimesulide ODTs F1 and F3

Characterization of Drug

Weight variation

The average weight of the tablets 251.1 ± 0.25mg to 264.6 ± 029 mg [Table 3].

Hardness and Friability

The hardness was determined 4.25± 0.11to 6.25± 0.17 kg/cm^2 during compression and friability for all the formulation [Table 3] varies from 0.47 ±0.06 to 0.30 ±0.05 %.

Water Absorption & Wetting Time

Water absorption of all preparations was noted to be 48±1.65% to 72±1.53%. Wetting time was acknowledging [Table 3] to be 50±0.12to 60±0.15 sec.

Disintegration Time

All formulations were found to be 15±0.01 sec to 11±0.04 sec [Table 3].

In-vitro Dissolution Studies

In F3 formulation the most drug release of 97.30% in 30min. The dynamic in drug release varied polymer levels in all three preparations [Table 4 & Figure 3].

Kinetic Studies

The best formulation F3 performed with release order kinetics [Table 5]. The best formulation F3 exhibits an r^2 value of 0.980.

CONCLUSION

Finally i concluded that pre formulation and post formulation parameters of nimesulide ODTs are acceptable range. The in-vitro drug release data from the most satisfactory formulation F3 was suitable to different kinetic equations and the method of drug release was studied. The best formulation of F3 exhibited a highest drug release of 96.3% in 30min.

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Conflict of interest

The authors declare no conflict of interest, financial or otherwise.

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REFERENCES

[1] Manoj M Nitalikar and Dinesh M Sakarkar. Formulation development and characterization of fast disintegrating tablets of Nimesulide. *Stamford Journal of Pharmaceutical Sciences*, 4(2):25–28, 2011.

[2] Y Ramesh, V Raghu Murthy, S Nagarjuna, M Viswanath Reddy, M Sudheer, and M Manikanta. Development and In-vitro Evaluation of Fast dissolving Tablets of Imipramine. *International Journal of Research in Pharmaceutical Sciences*, 2(3):344–347, 2011.

[3] B Aparna, B Kumar, K Gnanaprakash, M Gobinath, and Y Ramesh. Development and Evaluation of Sublingual Tablets of Aripiprazole. *International Journal of Biopharmaceutics*, 5(4):251–257, 2014.

[4] R Raghuveer and V Gopal. Comparison of Polyherbal Tablets to Treat Type II Diabetes. *Future Journal of Pharmaceuticals and Health Sciences*, 1(2):8–11, 2021.

[5] S Das, P J Ghule, and G D Karle. Formulation and Evaluation of Nimesulide Sublimated Mouth Dissolving Tablets. *International Journal of Contemporary Research and Review*, 1(3):1–5, 2010.

[6] M Pradeep Kumar, G S N Murthy, and S Neelima. Formulation and In-Vitro Evaluation of Eplerenone Fast Disintegrating Tablets by Solid Dispersion Technique. *Future Journal of Pharmaceuticals and Health Sciences*, 1(2):1–7, 2021.

[7] Goparaju Suryanarayana Murthy. Formulation and In-Vitro Evaluation of immediate-release pellets of Candesartan Cilexetil. *Future Journal of Pharmaceuticals and Health Sciences*, 1(1):11–20, 2021.

[8] Yerikala Ramesh, Abhilash Kaki Rohan, Balasaradhi Koorapati, and P Sudarsanam. Formulation and evaluation of almotriptan controlled-release pellets. *Journal of Drug Delivery and Therapeutics*, 9(1-s):312–318, 2019.

[9] R A Shoukri, I S Ahmed, and R N Shamma. In vitro and in vivo evaluation of nimesulide lyophilized orally disintegrating tablets. *European Journal of Pharmaceutical Biopharmaceutics*, 73(1):162–171, 2009.

[10] Y Ramesh and Pudi Venkata Prasad. Formulation and evaluation of fast dissolving tablets of ketorolac tromethamine. *Creative Journal of Pharmaceutical Research*, 2(1):12–18, 2016.

[11] M Sudheer, Y Ramesh, V Raghu Murthy, M Viswanatha Reddy, and K Jhansi Reddy. Formulation and Evaluation of Gastroretentive Pioglitazone Floating Tablets. *Journal of Pharmacy Research*, 4(8):2468–2470, 2011.

[12] G Kavitha, M Balakrishnan, Y Ramesh, and J Parkavi. Formulation And Evaluation of Gastroretentive Floating Drug Delivery System of Amlodipine. *International Journal of Pharmacometrics and Integrated Biosciences*, 1(2):49–59, 2016.

[13] K Gnanaprakash, K Mallikarjuna Rao, KB Chandra Sekhar, K Chetty, M Alagusundaram, and S Ramkanth. Formulation and evaluation of fast dissolving tablets of valdecoxib. *International Journal of PharmTech Research*, 1(4):1387–1393, 2009.

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