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Formulation and in-vitro Evaluation of Immediate Release Tenoxicam

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KEYWORDS

Tenoxicam, NSAID, Immediate release, Sodium starch glycolate

ABSTRACT:

The aim of this research was to develop and assess immediate release tablets of Tenoxicam using the wet granulation technique and incorporating various disintegrants. This study encompassed multiple stages including pre-formulation analysis of the drug and excipients, formulation development, comprehensive evaluation, and stability assessments. In pursuit of this goal, nine distinct formulations of Tenoxicam were meticulously prepared, each containing varying concentrations of disintegrants. The selection of the optimal formulation was guided by the outcomes of the evaluation criteria applied to each variant.

Introduction

Tenoxicam is a non-steroidal anti-inflammatory drug (NSAID) known for its analgesic and anti-inflammatory properties. It is commonly used to manage conditions such as osteoarthritis, rheumatoid arthritis, and postoperative pain. The formulation of immediate release tenoxicam tablets aims to achieve rapid drug release, ensuring quick pain relief and minimizing potential side effects.

The research concerning the formulation and in-vitro evaluation of immediate release tenoxicam tablets will encompass various stages to ensure the quality, efficacy, and safety of the final product. Tablets falling within this category necessitate preliminary dissolution in a liquid medium like water or other solvents prior to administration or application.

Materials and method

Tenoxicam pure drug was procured from Aurobindo Pharma Ltd., Hyderabad, India. All the excipients procured of analytical grade.

Tenoxicam Tablets Immediate Release tablets were prepared by wet granulation method.

Table 1. Formulation of Tenoxicam Tablets

S. No	Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	Tenoxicam	10	10	10	10	10	10	10	10	10
2	Starch	54.2	59.2	64.2	54.2	59.2	64.2	54.2	52.2	64.2
3	Lactose	29.5	24.5	19.5	30	4.5	19	29	24	19
4	Methyl paraben sodium	0.18	0.18	0.18	0.18	0.18	0.18	0.18	0.18	0.18
5	Propyl paraben sodium	0.12	0.12	0.12	0.12	0.12	0.12	0.12	0.12	0.12
6	Starch for paste	4	4	4	4	4	4	4	4	4
7	Tale	1	1	1	-	-	-	1	1	1
8	Magnesium stearate	1	1	1	1	1	1	1	1	1
9	Sodium starch glycolate	-	-	-	0.5	1	1.5	0.5	1	1.5
10	Total weight (in mg)	100	100	100	100	100	100	100	100	100

Formulation of Tenoxicam Tablets:

The active components and accompanying substances undergo a filtering process through a sieve labeled as #22 and are collected into appropriate containers, then into Multi-Component Granulator, that carried out dry mixing at a low rotational speed for a duration of 15 minutes. Starch is placed within a stainless-steel vessel, then dissolved water and heated to a temperature of 100°C. This solution is then combined with another solution containing the Methyl Paraben and Propyl

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Paraben, which is heated to 60°C. The mixture is thoroughly stirred. The binder solution is added to the previously sieved materials, and the blending occurs for a span of 5-15 minutes in the Multi-Component Granulator (MCG) at a slow speed, until a desired consistency is reached. The mixture is then passed through a milling machine to achieve the desired granule type. Granules is loaded into a fluidized bed dryer for drying. The dried granules are processed through the cad mill along with Super disintegrant, lubricants, and glidants. The resulting granules are sorted by passing through a mesh labeled as 14#150, ensuring uniform size. The lubricated dry blends undergo compression using a tablet punching apparatus equipped with 6mm round punches. Each tablet has a weight of 100 milligrams. [1]

- **Thickness:**

Ensuring the physical characteristics of tablets, such as their thickness and diameter, is crucial for both consumer satisfaction and maintaining uniformity across tablets. The dimensions, expressed in millimeters, were gauged using Vernier calipers. Depending on the tablet's size, a permissible variance of around ± 5% may be tolerated.[2]

- **Hardness Test:**

For the assessment of tablet hardness, a single tablet was vertically positioned between the anvil and punch of the Strong Cobb Hardness tester. By adjusting the regulating screw until the "stop" signal illuminated, the tablet was secured, after which the button was engaged until the tablet fractured. The recorded numerical value on the scale post-fracture represented the tablet's hardness. This hardness test was conducted on six tablets.[3]

- **Weight variation test:**

To ensure the accurate drug content in each tablet, the tablet's weight was regularly measured. The USP weight variation test involved the separate weighing of 20 tablets. The average weight was computed, and individual tablet weights were compared against this average. A tablet adheres to the USP test if no more than two tablets deviate outside the specified percentage limits, and no tablet deviates by more than twice the percentage limit. [4]

- **Friability test:**

To determine the tablets' friability, the Roche friabilator was employed. In this test, 20 tablets from each specific formulation were initially weighed and then placed inside the Roche friabilator. This device rotated at a speed of 25 rotations per minute (rpm) for a duration of 4 minutes. Subsequent to this rotational period, the tablets were taken out of the friabilator, and their weight was once again measured. The extent of weight loss was then calculated and expressed as a percentage.

$$\% \text{ Friability} = \frac{(W1 - W2)}{W1} \times 100$$

Where,

W1= Weight of tablet before test

W2 = Weight of tablet after test

- **Content uniformity test:**

To analyze the tablets' composition, 20 of them were weighed and transformed into powder. An accurately measured quantity of this powder, equivalent to 10 milligrams of anhydrous Tenoxicam, was combined with 50 milliliters of 0.1M hydrochloric acid. This mixture underwent heating on a water-bath set to a temperature of 70 degrees Celsius for a duration of 15 minutes. After cooling, the solution was diluted to a total volume of 100.0 milliliters using water and then subjected to filtration.[5]

In-vitro

Dissolution

Studies:

An in vitro study to examine the release of Tenoxicam was executed using a USP dissolution apparatus Type 2, which is equipped with a paddle. In this study, a dissolution medium consisting of phosphate buffer with a pH of 1.2 was utilized. The process unfolded by filling the dissolution tester's vessels with 900 milliliters of the phosphate buffer solution at a temperature of 37±0.5 degrees Celsius while maintaining a rotation speed of 50 revolutions per minute (rpm) using the paddle.

The procedure was initiated, and as time progressed, samples were withdrawn in 5 milliliter increments. Following each withdrawal, fresh dissolution media was introduced. The collected samples underwent filtration, and the absorbance of the solution was gauged at a wavelength of 273.5 nanometers. To quantify the concentration of Tenoxicam, the slope of a calibration curve was utilized, enabling the calculation of cumulative percentage release.

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Stability studies of Formulations:

Investigation into the aging effects on a prepared immediate-release tablet formulation of Tenoxicam was conducted under controlled conditions of 25°C±60% RH and 40^0C±75%RH for a duration of 2 months.[6]

Results and Discussion

Formulations of Tenoxicam tablets undergoes a range of assessment procedures, including tests for hardness, thickness, weight variation, friability, and drug content and invitro drug release. Results shown in table 2 and 3.

Table 2. Evaluation of tablets

Formulations	Hardness	Friability	Weight variation	Content Uniformity	Thickness	Wetting Time	Disintegration Time
F1	3.7	0.69	102.3± 0.15	98.94±0.25	2.7	36	42±0.73
F2	3.9	0.71	101.2±0.66	99.46±0.24	2.7	39	51±0.58
F3	4.2	0.68	98.9±0.301	99.65±0.33	2.7	45	55±0.65
F4	3.6	0.71	100.6±0.23	99.45±0.12	2.7	38	34±0.59
F5	3.5	0.74	102.1±0.18	99.25±0.31	2.7	40	41±0.85
F6	4.1	0.72	101.3±0.26	99.52±0.06	2.8	43	45±0.71
F7	3.7	0.69	101.6±0.22	99.86±0.39	2.7	35	30±0.64
F8	3.9	0.71	99.5±0.18	99.78±0.35	2.7	39	32±0.48
F9	4.1	0.70	100.8±0.2	99.42±0.14	2.8	42	35±0.40

Table 3. *Invitro* drug release of tablets

Time (In Min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
3	33.5	30.24	31.11	**35.5**	30.24	31.11	32.46	32.24	32.18
6	55.4	62.18	63.56	**56.4**	61.18	73.56	76.11	63.18	73.56
9	75.4	79.12	79.38	**76.4**	89.12	89.38	90.18	90.12	88.56
12	91.68	88.92	89.18	**92.68**	93.92	92.18	97.34	95.92	94.24
15	97.58	92.42	93.76	**99.58**	94.42	93.76	99.1	96.26	95.16

Table 4. Stability studies: *In-vitro* dissolution of optimized (F4) Formulations

Time (Min)	25^0C±60%RH		40^0C± 75%RH	
	1 Month	2 Months	1 Month	2 Months
3	31.42	31.08	31.38	30.96
6	74.85	74.52	74.45	74.36
9	89.18	88.98	88.84	88.53
12	96.34	96.12	96.38	95.97
15	98.98	98.97	98.94	98.91

Conclusion:

This study was undertaken to create and assess immediate release tablets of Tenoxicam. The initial phase encompassed a pre-formulation analysis, which included the selection of superdisintegrants. Various formulations were then developed using sodium starch glycolate and starch as the chosen superdisintegrants. The subsequent step involved the preparation of immediate release tablets of Tenoxicam using the wet granulation method. The resulting tablets exhibited

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swift disintegration, alongside satisfactory levels of friability and hardness. In vitro testing of drug release from the tablets demonstrated a marked enhancement in drug dissolution. This observation implies that the employment of superdisintegrants in the formulation of immediate release tablets for Tenoxicam holds the potential to be highly effective, enabling rapid onset of action upon administration, particularly in cases of inflammation.

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