



## International Journal of Medicine and Pharmaceutical Research

Home Page: <https://pharmaresearchlibrary.org/journals/index.php/ijmpr>

CODEN (USA): IJCPNH | ISSN: 2321-2624 | Publisher: Pharma Research Library

DOI: <https://doi.org/10.30904/j.ijmpr.2025.4882>

Int. J. Med. Pharm. Res., 2025, 13(2): 130-135



## Formulation, Evaluation and Optimization of Fast Dissolving Tablet of Zaltoprofen

Akunuri Maheswari\*<sup>1</sup>, T. Ramchander<sup>2</sup>, P. Aravinda Reddy<sup>3</sup>

<sup>1</sup>Department of Pharmaceutics, Mother Teresa College of Pharmacy, NFC Nagar Ghatkesar, Telangana, India-501301.

<sup>2</sup>Associate Professor, Mother Teresa College of Pharmacy, NFC Nagar Ghatkesar, Telangana, India-501301.

<sup>3</sup>Principal and Professor, Mother Teresa College of Pharmacy, NFC Nagar Ghatkesar, Telangana, India-501301.

### ABSTRACT

This study aimed at developing and evaluating fast oral disintegrating tablets of Zaltoprofen, supported by a validated UV spectrophotometric analysis for drug quantification. The method showed strong linearity in the concentration range of 2 to 10 µg/ml at an absorption peak of 257nm in 0.1 N HCl, ensuring precise and reliable detection. Pre-compression characterizations exhibited favorable powder flow and compressibility, indicated by consistent bulk and tapped densities, Carr's index, Hausner ratio, and angle of repose values, facilitating smooth tablet manufacturing by direct compression. Post-compression evaluation confirmed that the tablets met quality control benchmarks including uniform hardness, low friability, consistent drug content, and appropriate thickness. The formulations demonstrated rapid disintegration and wetting times, essential for effective oral delivery. In vitro dissolution studies revealed efficient release profiles, with the optimal formulation achieving nearly complete drug release within 30 minutes. Further kinetic analyses confirmed a controlled drug release mechanism, fitting zero and first-order models. FTIR studies indicated no interaction between the drug and excipients, assuring formulation stability. Overall, the research successfully produced high-quality Zaltoprofen oral disintegrating tablets with rapid onset potential and stable composition, enhancing patient compliance and therapeutic efficiency.

**Keywords:** Zaltoprofen, oral disintegrating tablets, UV spectrophotometry, drug release, kinetic modeling.

### ARTICLE INFO

#### Corresponding Author

Akunuri Maheswari  
Department of Pharmaceutics  
Mother Teresa College of Pharmacy  
NFC Nagar Ghatkesar, Telangana India- 501301.

#### Article History

Received 18 July 2025  
Revised 10 Aug 2025  
Accepted 11 Sep 2025  
Published 15 Oct 2025

**Copyright© 2025** The Contribution will be made Open Access under the terms of the Creative Commons Attribution-NonCommercial License (CC BY-NC) (<http://creativecommons.org/licenses/by-nc/4.0>) which permits use, distribution and reproduction in any medium, provided that the Contribution is properly cited and is not used for commercial purposes.

**Citation:** Akunuri Maheswari, et al. Formulation, Evaluation and Optimization of Fast Dissolving Tablet of Zaltoprofen. Int. J. Med. Pharm. Res., 2025;13(2): 130-135.

### CONTENTS

1. Introduction . . . . .	130
2. Materials and Methods . . . . .	131
3. Results and discussion. . . . .	132
4. Conclusion. . . . .	133
5. References. . . . .	134

### 1. Introduction

#### Oral Drug Delivery Systems

The oral route is the most preferred and convenient route for drug administration due to its ease, cost-effectiveness, patient compliance, and flexibility in dosage design. Among the different oral dosage forms, tablets are the most commonly used. However, conventional tablets may be challenging for patients who have difficulty swallowing, such as pediatric, geriatric, and dysphagic patients. In recent years, Fast Dissolving Tablets (FDTs) have emerged

as a significant innovation to address these challenges and enhance the onset of therapeutic action.

#### Fast Dissolving Tablets: Concept and Benefits

Fast Dissolving Tablets (FDTs), also known as orally disintegrating tablets (ODTs) or mouth-dissolving tablets (MDTs), are designed to disintegrate or dissolve rapidly in the mouth, usually within 30 seconds to 3 minutes, without the need for water or chewing.

#### Advantages of FDTs:

- Easy administration without water
- Enhanced patient compliance, especially in elderly and pediatric patients
- Rapid onset of action due to pre-gastric absorption
- Useful in emergency conditions like migraine, allergies, and pain
- Avoidance of first-pass metabolism in some cases

### Zaltoprofen: A Novel NSAID

Zaltoprofen is a non-steroidal anti-inflammatory drug (NSAID) belonging to the arylpropionic acid class. It exhibits anti-inflammatory, analgesic, and antipyretic activities, primarily through inhibition of prostaglandin synthesis by selectively inhibiting COX-2 enzymes.

#### Key Characteristics:

- **Chemical Name:** 2-(10,11-dihydro-10-oxo-dibenzo [b,f] thiepin-2-yl)propanoic acid
- **Molecular Formula:** C<sub>17</sub>H<sub>14</sub>O<sub>3</sub>S
- **Molecular Weight:** 298.36 g/mol
- **Class:** BCS Class II (low solubility, high permeability)
- **Onset:** Requires rapid release in acute pain or inflammation
- **Drawback:** Poor aqueous solubility leads to slow onset when administered as a conventional tablet

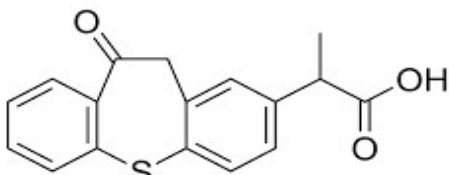


Fig.1: Zaltoprofen

**Molecular Formula:** C<sub>17</sub>H<sub>14</sub>O<sub>3</sub>S

**Molecular Weight:** 298.36 g/mol

**IUPAC Name:** 2-(10,11-dihydro-10-oxo-dibenzo [b,f] thiepin-2-yl) propanoic acid

**Chem Spider ID:** 10482169

**Density:** ~1.3 ± 0.1 g/cm<sup>3</sup>

**Boiling Point:** ~500.5 ± 50.0 °C at 760 mmHg

**Vapour Pressure:** ~0.0 ± 1.3 mmHg at 25 °C

**Flash Point:** ~256.5 ± 30.1 °C

**Refractive Index:** ~1.656

**Polar Surface Area:** ~79.67 Å<sup>2</sup>

**LogP (Octanol/Water):** ~3.68

**Generic Name:** Zaltoprofen

**Brand Names:** Soleton, CN100

**Drug Category:** NSAID (preferential COX-2 inhibitor)

**Indications:** Used for the treatment of inflammation and pain, particularly in arthritis and musculoskeletal disorders

**Pharmacology:** Inhibits prostaglandin synthesis by selectively targeting COX-2; also inhibits bradykinin-induced pain without binding to bradykinin receptors<sup>2</sup>

**Potency:** Comparable or superior to other NSAIDs in preclinical pain models

**Tolerability:** Generally well tolerated with fewer gastric side effects than traditional NSAIDs

**Contraindications:** Hypersensitivity to NSAIDs, active peptic ulcer, severe hepatic or renal impairment

**Adverse Effects:** May include gastrointestinal discomfort, dizziness, rash, or elevated liver enzymes

**Availability:** Available in tablet form in select countries, particularly in Asia

## 2. Materials and Methods

Table.1: List of Materials Used

Name of the Material	Source
Zaltoprofen	Supplied by pharma Train
Sodium starch glycolate	SD fine chemicals, Mumbai
Crospovidone	Nihal pharma, Hyd
Croscarmellose sodium	SD fine chemicals, Mumbai
Mannitol	SD fine chemicals, Mumbai
Lactose	SD fine chemicals, Mumbai
Avicel ph102	SD fine chemicals, Mumbai
Aspartame	SD fine chemicals, Mumbai
Peppermint flavour	Nihal pharma, Hyd
Magnesium stearate	SD fine chemicals, Mumbai
Talc	SD fine chemicals, Mumbai

Table.2: List of Equipment's used

Name of the Equipment	Manufacturer
Electronic weighing balance	Wensar
Friabilator	Franz
Compression machine	Labindia, Mumbai, India
Tablet hardness tester	Labindia, Mumbai, India
UV	Per kin Elmer, United States of America.
Dissolution apparatus	Labman scientific instruments

### Analytical Method Development

- **Preparation of 0.1 N Hydrochloric Acid (pH 1.2)**  
8.5 ml of concentrate hydrochloric acid was taken and diluted with distilled water up to 1000 ml.
  - **Determination of  $\lambda_{\max}$  of Zaltoprofen in 0.1N HCL:**  
**Procedure:**  
**Working standard:** 100mg of Zaltoprofen was weighed and dissolved in 10ml methanol and then make up to a volume of 100ml with 0.1N HCL it give 1000µg/ml concentrated stock solution.  
**Dilution 1:** From the working standard solution 10ml was diluted to 100ml with 0.1N HCL it will give 100µg/ml concentrated solution.  
**Dilution 2:** From the dilution-1 10ml was diluted to 100ml with 0.1N HCL it will give 10µg/ml concentrated solution. This solution was scanned at range of 200-400nm wavelength light corresponding scan spectrum curve was noted. the corresponding wavelength having highest absorbance is noted as  $\lambda_{\max}$ .
- II. Construction of calibration curve of Zaltoprofen in 0.1N HCL:**

**Working standard:** 100mg of Zaltoprfen was weighed and dissolved in 10ml methanol and then make up to a volume of 100ml with 0.1N HCL it give 1000µg/ml concentrated stock solution.

**Dilution 1:** From the working standard solution 10ml was diluted to 100ml with 0.1N HCL it will give 100µg/ml concentrated solution.

From dilution 1, take 0.2, 0.4, 0.6, 0.8 and 1ml of solution and was diluted up to mark in 10ml volumetric flask to obtain 2, 4, 6, 8 and 10 µg/ml concentrated solutions. This solutions absorbance was noted at  $\lambda_{max}=257$

**Preparation of Oral Disintegrating Tablets**

**Direct compression method:**

Mouth disintegrating tablets of Zaltoprfen were prepared by direct compression method. All the ingredients were powdered separately and passed through # 40 mesh sieve separately. The drug and directly compressible excipient were mixed by adding small portion of each at a time and blending it to get a uniform mixture and kept aside. Then the other ingredients were mixed in geometrical order, in an inflated polyethylene pouch magnesium stearate and talc were added last and mixed for further two minutes and the tablets were compressed using 6 mm flat round punches to get tablets of 100 mg weight.

**Assay Procedure:** Ten tablets were weighed and powdered, a quantity of powder equivalent to 100 mg of Zaltoprfen was transferred to a 100 ml volumetric flask and 10 ml methanol is added. The drug is extracted in methanol by vigorously shaking the stoppered flask for 15 minutes. Then the volume is adjusted to the mark with 0.1N HCL and the liquid is filtered. From prepared solution take 0.1ml solution in 10ml volumetric flask and make up to mark with 0.1 N HCL. The Zaltoprfen content was determined by measuring the absorbance at 257 nm after appropriate dilution. The drug content was calculated using the standard calibration curve. The mean percent drug content was calculated as an average of three determinations.

Calculate the quantity in mg of drug in the portion taken by the formula

**Assay** = test absorbance/standard absorbance\*standard concentration/sample concentration\*purity of drug/100\*100

**In vitro Dissolution Study:**

900 ml of 0.1N HCL was placed in the vessel and the USP-II apparatus (Paddle method) was assembled. The medium was allowed to equilibrate to temperature of 37°C±0.5°C. A tablet was placed in the vessel and was covered; the apparatus was operated up to 30mins at 50 rpm. At definite time intervals, 5 ml of dissolution medium was withdrawn; filtered and again replaced with 5 ml of fresh medium to maintain sink conditions. Suitable dilutions were done with dissolution medium, were analyzed spectrophotometrically at  $\lambda_{max}=257$  nm using a UV-spectrophotometer (Lab India).

**Table.3:** Dissolution Parameters

Parameter	Details
Dissolution apparatus	USP -Type II (paddle)
Medium	0.1N HCL
Volume	900 ml
Speed	50rpm
Temperature	37± 0.5 °C

Sample volume withdrawn	5ml
Time points	2, 4, 6, 8, 10, 15, 20 and 30mins
Analytical method	Ultraviolet Visible Spectroscopy
$\lambda_{max}$	257 nm

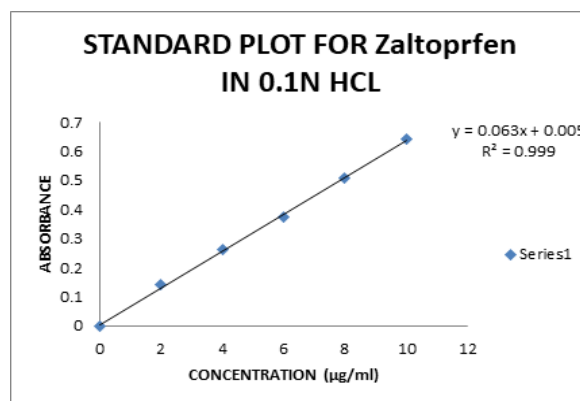
**3. Results and Discussion**

**Construction of Standard Calibration Curve of Zaltoprfen in 0.1 N HCL:** The absorbance of the solution was measured at 257nm, using UV spectrometer with 0.1N HCL as blank. The values are shown in table. A graph of absorbance Vs Concentration was plotted which indicated in compliance to Beer’s law in the concentration range 2 to 10 µg/ml

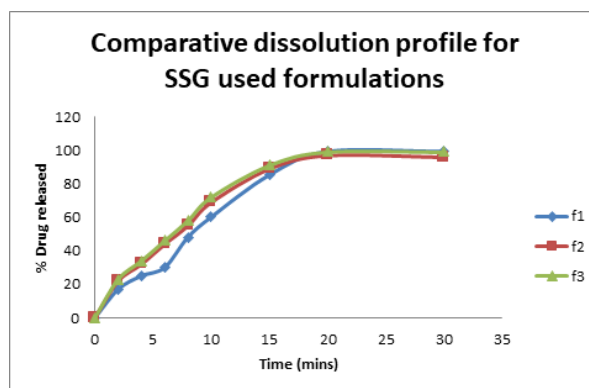
**Table.4:** Standard Calibration Graph Values of Zaltoprfen in 0.1 N HCL

Concentration (µg/ml)	Absorbance
0	0
2	0.141
4	0.26
6	0.372
8	0.507
10	0.64

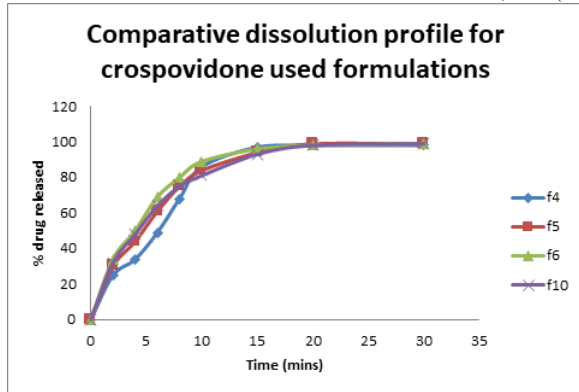
Standard plot of Zaltoprfen by taking absorbance on Y – axis and concentration (µg/ml) on X–axis, the plot is shown fig.



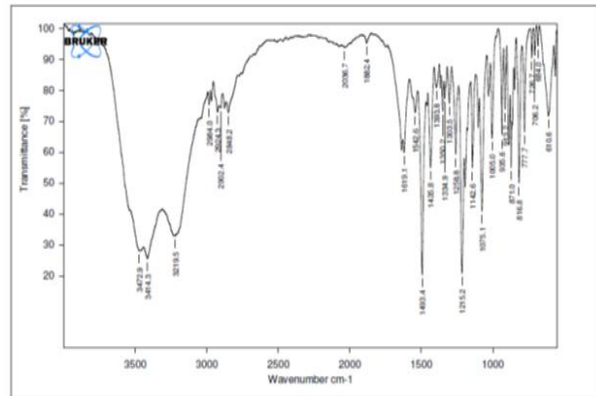
**Fig.2:** Standard Calibration Curve of Zaltoprfen in 0.1N HCL



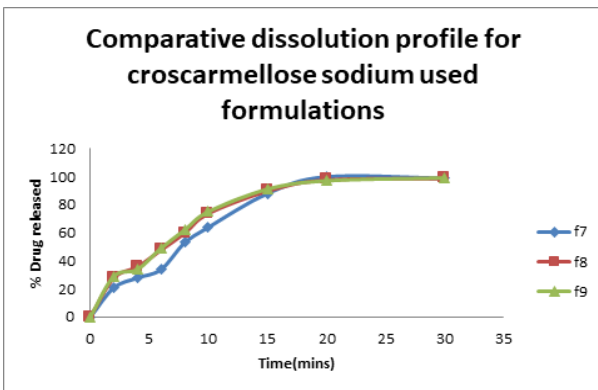
**Fig.3:** Comparative dissolution profiles for SSG used Formulations



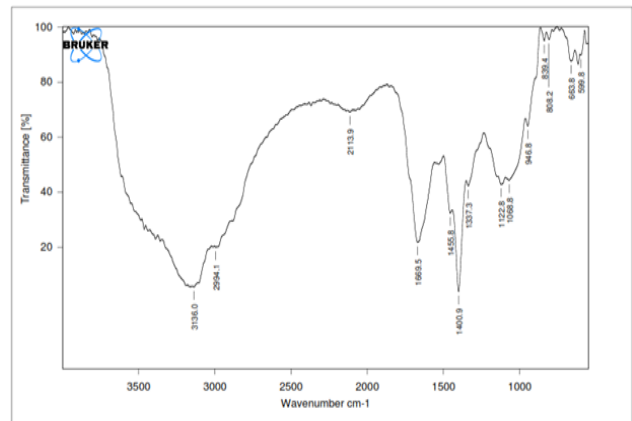
**Fig.4:** Comparative dissolution profiles for Crospovidone used Formulations



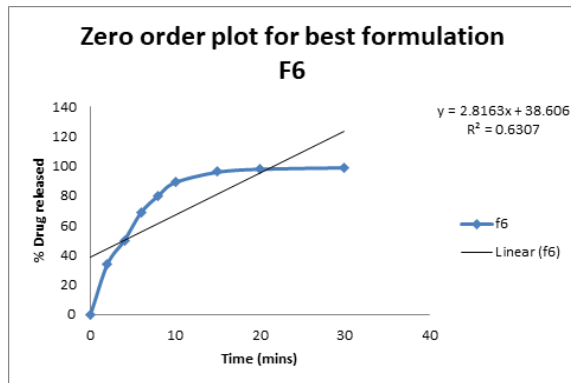
**Fig.8:** FTIR graph for Zaltoprfen



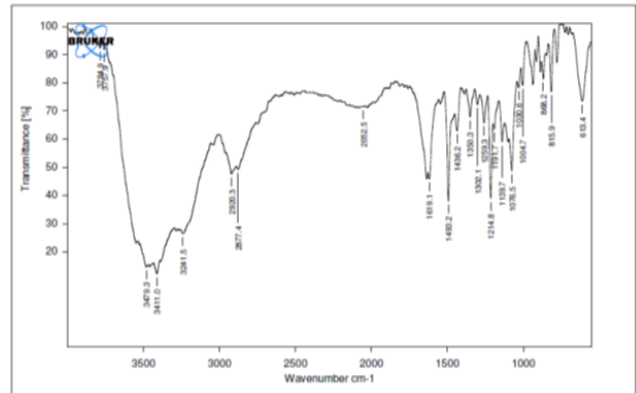
**Fig.5:** Comparative dissolution profiles for Croscarmellose sodium used Formulations



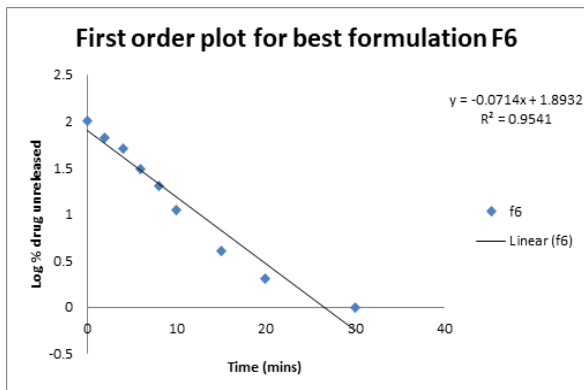
**Fig.9:** FTIR graph for Crospovidone



**Fig.6:** Zero order plot for best formulation F6



**Fig.10:** FTIR graph for Zaltoprfen best formulation



**Fig.7:** First order plot for best formulation F6

#### 4. Conclusion

A UV spectrophotometric method was developed for Zaltoprfen quantification, utilizing 0.1 N HCl as the solvent and measuring absorbance at 257 nm. The constructed calibration curve showed excellent linearity between 2 and 10 µg/ml, confirming compliance with Beer’s law and highlighting strong analytical accuracy. This validated method provides a reliable approach for routine drug estimation in formulations. Pre-compression evaluations of the Zaltoprfen tablet blends revealed good flow and compressibility properties, as evident from consistent bulk and tapped densities, favorable Carr’s index, Hausner ratio, and acceptable angles of repose. These attributes indicate that the powder blends are well-

suitable for the direct compression manufacturing process. Post-compression tests further demonstrated that the formulated tablets met all critical quality parameters including hardness, friability, drug content, thickness, weight uniformity, and moisture absorption, ensuring robust and precise dosage forms. The tablets exhibited rapid disintegration and wetting times, key for effective oral disintegrating formulations. In vitro dissolution testing displayed efficient and consistent drug release profiles across all formulations, with the F6 batch showing the most optimal performance by releasing nearly 99% of the drug

within 30 minutes. Kinetic analysis revealed that the drug release from the tablets follows a controlled mechanism, fitting well with zero-order and first-order models, which support predictable and sustained therapeutic effects. FTIR analysis confirmed compatibility between Zaltoprofen and excipients, ensuring stability of the final formulation. Overall, this study successfully formulated Zaltoprofen oral disintegrating tablets with consistent quality, rapid drug release, and validated analytical support. These attributes suggest promising potential for enhanced patient compliance and therapeutic efficacy in clinical use.

**Table.5:** Pre Compression Studies Of Zaltoprofen Oral Disintegrating Tablets

Formulation code	Bulk density (Kg/cm <sup>3</sup> )	Tapped density (Kg/cm <sup>3</sup> )	Cars index	Hausners ratio	Angle of repose (°)
F1	0.40	0.48	16	1.2	32.73
F2	0.39	0.48	18	1.23	34.96
F3	0.50	0.58	13	1.16	28.58
F4	0.44	0.50	12	1.1	27.92
F5	0.37	0.41	9.75	1.1	25.35
F6	0.37	0.41	9.75	1.1	33.14
F7	0.36	0.39	7.6	1.0	27.03
F8	0.41	0.45	8.8	1.0	31.85
F9	0.39	0.48	18	1.23	28.96
F10	0.41	0.45	8.8	1.0	27.85

**Table.6:** Post Compression Studies for Oral Disintegrating Tablets of Zaltoprofen

Batch	Hardness (kg/cm <sup>2</sup> )	Friability (%)	Drug Content (%)	Thickness (mm)	Disintegration Time (sec)	Wetting Time (sec)	In vitro dispersion time	Weight variation	Water absorpti on ratio
F1	3.1	0.45	99.12	2.5	30	45	29	pass	61.3
F2	2.9	0.62	100.73	2.8	25	42	34	pass	69.8
F3	3.3	0.71	99.74	2.6	20	35	25	pass	73.4
F4	2.5	0.32	98.98	2.5	31	31	32	pass	86.2
F5	2.8	0.51	99.67	2.6	27	36	31	pass	84.12
F6	2.8	0.52	99.83	2.8	25	43	33	pass	93.4
F7	2.9	0.38	101.32	2.8	31	41	36	pass	64.3
F8	3.2	0.48	100.87	2.5	26	36	33	pass	74.8
F9	3.5	0.63	99.74	2.7	24	48	39	pass	76.1
F10	3.0	0.54	99.86	2.6	32	39	28	pass	82.3

**Table.7:** Dissolution Data of Oral Disintegrating Tablets of Zaltoprofen

Time points (mins)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
0	0	0	0	0	0	0	0	0	0	0
2	17	22	23	25	30	34	21	28	29	32
4	25	32	34	34	44	50	28	36	34	48
6	30	44	46	49	61	69	34	48	49	64
8	48	55	58	68	75	80	53	60	62	75
10	60	69	72	86	84	89	64	74	75	81
15	85	89	91	97	94	96	88	90	91	93
20	99	97	99	98	99	98	100	98	97	98
30	99	96	99	98	99	99	99	99	99	99

## 5. Bibliography

- [1] Chatap, Vivekanand K., et al. "Formulation and evaluation of zaltoprofen fast disintegrating tablet." *J. Pharma Sci Tech.* 2013; 3(1): 20.
- [2] Kukadiya, Chetan G., Kesha Desai, and S. M. Swamy. "Formulation, evaluation and optimization of press coated pulsatile tablet of Zaltoprofen for

the treatment of rheumatoid arthritis. *Pharma Sci Monit.* 2014; 5(2): 153-179.

- [3] Poreddy Srikanth Reddy, V. Alagarsamy, P. Subhash Chandra Bose, Damineni Sarita, Vuppula Sruthi, G. Ravi. Formulation and Evaluation of Zaltoprofen Immediate Release Tablets using Superdisintegrants. *Research J. Pharm. and Tech.* 2020; 13(3): 1152-1156
- [4] Patel, Kunal N., Formulation and Optimization of Pellets Containing Zaltoprofen by Extrusion Spheronization Technique. *Nirma University Journal of Pharmaceutical Sciences.* 2024; 11(1); 11-32.
- [5] Alayadan, P., Kumar, A., Prakash, S. S., Bashir, B., Bhagya, V., Murthy, S. N., & Shivakumar, H. N. Development, in vitro and in vivo evaluation of film forming solutions for transdermal drug delivery of Zaltoprofen. *Journal of Biomaterials Science, Polymer Edition*, 2025; 36(9):1265–1288.
- [6] K. Anju, Sneha Priya, D. S. Sandeep, Prashant Nayak, Pankaj Kumar, Abhishek Kumar, Cynthia Lizzie Lobo and S. P. Krithi. Formulation and Optimization of Zaltoprofen Loaded Ethosomal Gel by using 23 Full Factorial Designs”, *Journal of Pharmaceutical Research International.* 2021; 33(24B): 30–44
- [7] Mishra, Ratnesh, Kedar S. Prabhavalkar, and Lokesh Kumar Bhatt. "Preparation, optimization, and evaluation of Zaltoprofen-loaded microemulsion and microemulsion-based gel for transdermal delivery. *Journal of liposome research.* 2016; 26(4): 297-306.
- [8] Kalamkar, Rajan, and Shailesh Wadher. Formulation and pharmacokinetic evaluation of phosal based zaltoprofen solid self-nanoemulsifying drug delivery system. *Pharmaceutical nanotechnology.* 2019; 7(4): 328-338.
- [9] Patel, Jaymin, Rucha V. Divekar, and Vaishali Y. Londhe. Formulation, characterization, and in-vivo evaluation of Zaltoprofen self-microemulsifying drug delivery system. *International Journal of Polymeric Materials and Polymeric Biomaterials.* 71.10 (2022): 777-782.
- [10] A Patel, Mehul B Vyas, Dr. Rahil Bhura, Dr. Samir K Shah, Abhishek Raj and Dr. Vijay Parmar. Design and development of bilayer tablets containing Zaltoprofen (sustained release) and hibiscus *Rosa sinensis* leaf powdered Nano crystals (immediate release) for arthritis. *International Journal of Pharmacognosy and Pharmaceutical Sciences.* 2022; 4(1): 71-77