International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 32, Issue 6, June 2026 ijppr.humanjournals.com ISSN: 2349-7203

Formulation and Evaluation of Palatable Chewable Tablets of Nitazoxanide for Pediatric Patients

Miss. Samiksha Dnyaneshwar Kshirsagar, Prof. Saurabh D. Gaikwad, Dr. Megha.T. Salve

Shivajirao Pawar College of Pharmacy, Pachegaon, Maharashtra, India

Received: 21 April 2026 Revised: 12 May 2026 Accepted: 22 May 2026

ABSTRACT

This research focuses on the formulation and evaluation of taste-masked chewable tablets of Nitazoxanide intended for paediatric use. Nitazoxanide is a broad-spectrum antiparasitic and antiviral agent widely used to treat diarrhoea caused by protozoal and viral infections. However, its inherently bitter taste often leads to poor patient compliance, particularly in children. To address this issue, a chewable tablet formulation with effective taste masking is proposed to enhance palatability and improve therapeutic adherence. The study involves the preparation of tablets using the direct compression method, incorporating excipients such as mannitol, microcrystalline cellulose, sodium starch glycolate, PVP K30, and sodium saccharin. Chewable tablets are especially useful because they do not require water and improve patient compliance, particularly in children and elderly patients.

Keywords: : Nitazoxanide, Chewable tablets, Paediatric formulation, Taste masking, Antiparasitic drug, Synthetic excipients, Mannitol, Microcrystalline cellulose, Sodium starch glycolate, Sodium stevioside, Patient compliance, Drug palatability, Oral drug delivery, Paediatric dosage form, Broad-spectrum therapy.

INTRODUCTION:

Chewable tablets are solid dosage forms designed to be chewed in the mouth before swallowing, eliminating the need for water. These formulations are particularly beneficial for individuals who have difficulty swallowing conventional tablets.

Parasitic infections remain a major public health concern, particularly in developing and resource-limited regions where sanitation and hygiene standards are inadequate. Among the most common protozoan parasites affecting children are Giardia lamblia and Cryptosporidium parvum, which are responsible for gastrointestinal diseases such as giardiasis and cryptosporidiosis. These infections are characterized by symptoms including diarrhoea, abdominal pain, nausea, malabsorption, and weight loss. In paediatric patients, the consequences can be more severe, often leading to dehydration, nutritional deficiencies, and potential long-term developmental complications if not treated in a timely and effective manner.

Children are especially vulnerable to such infections due to their immature immune systems and frequent exposure to contaminated food and water, particularly in areas with poor sanitation infrastructure. As a result, prompt diagnosis and appropriate treatment are essential for effective disease management. Furthermore, paediatric formulations should be designed not only for therapeutic efficacy but also for improved palatability, stability, and ease of administration, thereby enhancing patient compliance and ensuring better treatment outcomes.

1.Giardiasis

Organism: Giardia lamblia, also referred to as Giardia intestinalis or Giardia duodenalis.

Type: Flagellated protozoan parasite

Site of Infection: The primary site of action is the small intestine, particularly the duodenum and jejunum.

Pathophysiology:

• Infection begins when Giardia cysts are ingested through contaminated food or water.

• In the small intestine, these cysts transform (excyst) into trophozoites, which attach to the mucosal lining using their ventral sucking discs.

• Although Giardia does not invade intestinal tissues, it damages the brush border of enterocytes.

1)This leads to several effects, including impaired nutrient absorption—especially fats, resulting in steatorrhea.

2) It also disrupts digestive enzymes such as disaccharidases, which can cause lactose intolerance.

3)Additionally, structural changes occur in the intestinal lining, including villous flattening and crypt hyperplasia.

•The host immune response involves the secretion of IgA antibodies and the activation of immune cells, particularly CD4+ T lymphocytes and mast cells.

Symptoms: Watery diarrhoea, bloating, abdominal cramps, flatulence, and weight loss.

2. Cryptosporidiosis Causative

Organism: Cryptosporidium parvum or Cryptosporidium hominins

Type: Intracellular protozoan parasite

Site of Infection: Epithelial cells of the small intestine.

Pathophysiology:

• Infection occurs through ingestion of thick-walled oocysts present in contaminated water, food, or surfaces.

• Once inside the gastrointestinal tract, these oocysts release porosities' that invade the epithelial cells of the small intestine.

• Cryptosporidium resides within a unique intracellular but extracytoplasmic parasitophorous vacuole.

• This results in damage to the intestinal lining, including disruption of microvilli and epithelial tight junctions.

• Additionally, the infection triggers inflammation and activation of immune responses involving macrophages and cytokines such as IFN-γ and TNF-α.

• These changes lead to increased chloride ion secretion and reduced absorption, ultimately causing watery diarrhoea.

• In immunocompetent individuals, the infection is usually self-limiting, whereas in immunocompromised patients, such as those with AIDS, it can become chronic and severe.

Shared Physiological Effects in Children:

1)Dehydration from frequent watery stools

2) Electrolyte imbalances (especially potassium loss)

3) Malnutrition due to impaired absorption

4) Delayed growth and cognitive development in chronic cases

5) Increased vulnerability due to immature immune response and underdeveloped gut flora.

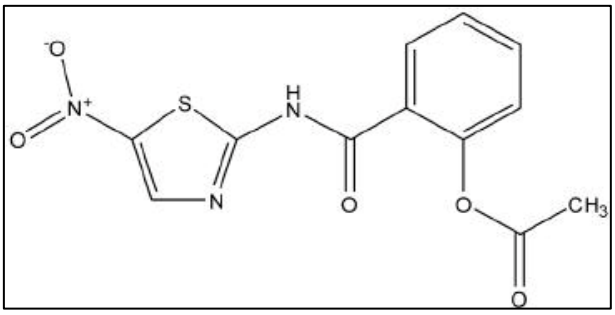
International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 32, Issue 6, June 2026 ijppr.humanjournals.com ISSN: 2349-7203

Nitazoxanide: A Broad-Spectrum Agent for Paediatric Use

Nitazoxanide is a synthetic nitrothiazolyl–salicylamide derivative widely used in the treatment of protozoal infections such as giardiasis and cryptosporidiosis. In addition to its antiparasitic action, it also exhibits broad antiviral activity against pathogens including rotavirus, norovirus, hepatitis B and C viruses, and influenza virus. Owing to this dual therapeutic effect, Nitazoxanide has gained significant importance in paediatric medicine, particularly in regions where diarrheal diseases are highly prevalent.

However, despite its wide therapeutic applicability, Nitazoxanide presents several formulation challenges. One of the major limitations is its intensely bitter taste, which reduces patient compliance, especially among children. The drug is currently available mainly in the form of oral tablets and reconstitutable suspensions. Tablets are often unsuitable for paediatric patients due to swallowing difficulties, while suspensions may suffer from issues such as poor stability, storage requirements, dose variability, and unpleasant taste. Additionally, Nitazoxanide is classified as a Biopharmaceutics Classification System (BCS) Class IV drug, indicating low solubility and low permeability, which further complicates the development of an effective and patient-friendly oral dosage form.

Nitazoxanide is a broad-spectrum antiparasitic and antiviral drug commonly used for the treatment of protozoal infections such as giardiasis and cryptosporidiosis. It is also being explored for its antiviral activity against a range of viral infections. Despite its therapeutic advantages, Nitazoxanide presents formulation challenges due to its poor palatability, bitter taste, and limited aqueous solubility, which can significantly reduce patient compliance, particularly in pediatric patients.



Chemical Structure of Nitazoxanide

Rationale for Chewable Tablet Formulation

To overcome the drawbacks associated with conventional Nitazoxanide formulations, the development of a novel chewable tablet offers a promising alternative. Chewable tablets are especially advantageous for paediatric and geriatric patients who may have difficulty swallowing standard tablets. They are designed to disintegrate in the oral cavity without requiring water, thereby improving ease of administration and providing added convenience, particularly in resource-limited settings.

A chewable tablet of Nitazoxanide offers several distinct advantages:

The use of chewable tablets offers several advantages in the formulation of Nitazoxanide:

1)Improved Palatability: The addition of suitable sweeteners and flavouring agents effectively masks the inherent bitterness of Nitazoxanide, making the formulation more acceptable to paediatric patients.

2)Enhanced Compliance: A pleasant-tasting, chewable dosage form encourages children to adhere to the prescribed treatment regimen, thereby reducing the likelihood of incomplete therapy, drug resistance, and treatment failure.

3)Accurate Dosing: In contrast to liquid suspensions that require reconstitution and careful measurement, chewable tablets deliver a precise, fixed dose, ensuring uniformity and minimizing dosing errors.

4)Stability and Storage: Solid dosage forms generally exhibit greater stability compared to liquid preparations, eliminating the need for refrigeration and providing an extended shelf life.

5)Ease of Transportation and Administration: Chewable tablets are convenient to carry, store, and administer, making them suitable for use in both home and clinical environments.

Project Focus and Novelty:

This study is centered on the formulation and evaluation of a taste-masked chewable tablet of Nitazoxanide specifically designed for paediatric use. The novelty of this work lies in developing a dosage form that, despite the drug's widespread therapeutic use, has not yet been commercially available. By incorporating appropriate synthetic excipients and optimizing key quality attributes such as disintegration time, palatability, drug content uniformity, and in vitro drug release, the proposed formulation aims to address an important gap in paediatric pharmaceutical care.

The primary goals of the study include:

1)Conducting thorough preformulation studies of Nitazoxanide (organoleptic, solubility, melting point, FTIR, UV).

2) Designing a palatable chewable tablet using appropriate sweeteners, binders, and superdisintegrants.

3) Evaluating the tablets for parameters such as hardness, friability, drug content, disintegration time, and dissolution rate.

4) Optimizing the formulation based on sensory and functional characteristics.

5) Ensuring drug-excipient compatibility using spectral methods (FTIR and UV).

LITERATURE REVIEW:

Nitazoxanide is a synthetic nitrothiazolyl–salicylamide derivative known for its broad-spectrum antiparasitic and antiviral activity. Although it is approved for paediatric use, the currently available formulations present several limitations related to taste, patient compliance, and ease of administration. The following literature highlights the need for the development of a paediatric-friendly chewable dosage form:

1. **Rossignol, J.F. (2014) described Nitazoxanide:** as a first-in-class broad-spectrum antiviral agent in Antiviral Research (110, 94–103). The study highlighted its extensive therapeutic potential against both parasitic and viral infections, with particular relevance in the treatment of paediatric viral gastroenteritis.

2. **Garcia, L.S., Shimizu, R.Y., and Bernard, C.N. (2015):** Reported on the clinical and laboratory evaluation of Nitazoxanide for treating protozoal infections in children in the Paediatric Infectious Disease Journal (34(5), 453–456).

The study emphasized that the unpleasant taste of the Nitazoxanide suspension can negatively affect treatment adherence among paediatric patients.

3. **Patel, D.M., Shah, R.B., and Jain, J.S. (2017):** presented a comprehensive review on the development of chewable tablets in the Journal of Pharmaceutical Sciences and Research (9(4), 393–399).

The study discussed key formulation considerations, including the use of flavouring agents, sweeteners, and binders to enhance palatability as well as mechanical strength.

4. **Thomas, A.R., and Varghese, S. (2019):** reviewed various taste-masking strategies for paediatric formulations in the International Journal of Pharmaceutical Sciences Review and Research (55(1), 25–32).

The paper outlined approaches such as the use of ion-exchange resins, sweeteners, and polymer coatings to effectively reduce bitterness.

5. **Bhavsar, S.M., and Patel, J.K. (2016):** discussed recent advances in the application of superdisintegrants in oral dispersible tablets in the Asian Journal of Pharmaceutics (10(2), 150–156).

The study highlighted the effectiveness of superdisintegrants such as sodium starch glycolate and crosca**World Health Organization (2020),** in its Technical Report Series: Guidelines for the Development of Paediatric Formulations (Geneva), emphasized the importance of designing child-friendly dosage forms. The report recommends the use of solid formulations such as chewable tablets to enhance treatment adherence in paediatric patientsrmellose sodium in reducing disintegration time, thereby improving the performance of chewable formulations.

6. **The**. [17]

7. **Basak, S.C., Shrinivasa, R., and Rahman, S.J. (2018):** discussed paediatric drug delivery systems in Pharmaceutical Development and Technology (23(5), 409–418).

The study highlighted the importance of palatable dosage forms in paediatric therapy and addressed the challenges associated with effective taste-masking strategies.

8. **Rane, S., and Patil, V. (2020):** reviewed the formulation and evaluation of chewable tablets for bitter drugs in the World Journal of Pharmacy and Pharmaceutical Sciences (9(6), 2221–2232).

The paper presented case studies on the development of chewable formulations for bitter active pharmaceutical ingredients, emphasizing the critical role of optimizing sweeteners and flavouring agents to improve palatability.

9. **Chavan, R.B., Thakkar, H.P., and Modi, J.P. (2017):** examined paediatric oral formulations in Drug Development and Industrial Pharmacy (43(8), 1246–1255).

The study discussed formulation aspects related to palatability and highlighted the direct relationship between effective taste-masking techniques and improved patient compliance in paediatric populations.

AIM AND OBJECTIVE:

Aim:

To develop and evaluate taste-masked chewable tablets of Nitazoxanide for paediatric use using synthetic excipients and direct compression method.

Objective:

1) To mask the bitter taste of Nitazoxanide using suitable sweeteners, flavouring agents, or taste-masking techniques.

2) To formulate chewable tablets using appropriate excipients and optimize the composition.

3) To evaluate pre-compression parameters such as angle of repose, bulk density, and flow properties.

4) To assess post-compression parameters including hardness, friability, weight variation, disintegration time, and drug content.

5) To perform in vitro dissolution studies to determine the drug release profile.

6) To compare the optimized formulation with existing conventional dosage forms.

7) To ensure stability and uniformity of the developed formulation under suitable storage conditions.

NEED OF STUDY:

Paediatric patients often encounter difficulties with conventional oral dosage forms, such as bitter-tasting suspensions and tablets that are hard to swallow. Nitazoxanide, a widely used antiprotozoal and antiviral agent, is commonly prescribed in paediatric therapy; however, its existing formulations—particularly oral suspensions—are often poorly accepted due to their intensely bitter taste and the need for frequent dosing.

In addition, Nitazoxanide is classified as a Biopharmaceutics Classification System (BCS) Class IV drug, characterized by low solubility and low permeability, which further complicates formulation development. The absence of a commercially available chewable tablet highlights a significant gap in paediatric-friendly dosage forms.

The present study aims to address these limitations by developing a novel taste-masked chewable tablet of Nitazoxanide using suitable synthetic excipients, with the following objectives:

1.To effectively mask the bitter taste of Nitazoxanide by incorporating suitable sweeteners and flavouring agents.

2.To develop a solid dosage form that is convenient for paediatric patients with difficulty swallowing conventional tablets.

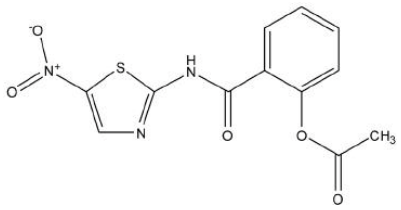
3.To enhance patient compliance and ensure accurate dosing in children.

4.To evaluate key quality control parameters such as hardness, friability, disintegration time, and drug content to ensure the tablet meets pharmacopeial standards.

5.To provide a stable and convenient alternative to liquid suspensions, which often present challenges in storage, dosing, and administration.

In conclusion, this study is aimed at developing a paediatric-friendly chewable dosage form that is stable, effective, and enhances patient compliance, ultimately leading to improved therapeutic outcomes in children.

DRUG PROFILE:

Parameter	**Details**
Generic Name	Nitazoxanide
Brand Name	Alinia
Chemical Name	2-(Acetyloxy)-N-(5-nitro-2-thiazolyl)benzamide
Structure	
Chemical Formula	C12H9N3O5S
Molecular Weight	307.28 g/mole
Pharmacological Class	Antiprotozoal and Antiviral agent
Therapeutic Uses	Giardiasis,Cryptosporidiosis,Rotavirus diarrhoea, Norovirus, Influenzas
Mechanism of Action	Inhibits PFOR enzyme-dependent electron transfer in protozoa; antiviral action via inhibition of viral maturation
BCS Classification	Class IV (Low solubility, Low permeability)
Apperance	Pale yellow crystalline powder
Solubility	Practically insoluble in water; soluble in DMSO and ethanol
Melting Point	198-202°C
pKa	~6.2
Log P	~1.63
Dosage (paediatric)	100-200 mg twice daily for 3 days (bas”d on age)
Bioavailability	Increased with food
Metabolism	Rapidly hydrolyzed to tizoxanide (active), then glucuronidated
Elimination Half-Life	~1.3 hours (tizoxanide)
Excretion	Feces and urine
Adverse Effects	Nausea, abdominal pain, diarrhoea, headache
Storage Condition	20-25°C, protect from light and moisture

MATERIAL AND INSTRUMENT:

Materials used:

Table No.1: List of materials used in the present work

Material	Purpose
Nitazoxanide	Active Pharmaceutical Ingredient (API)
Mannitol(DC grade)	Diluent and taste enhancer
Microcrystalline Cellulose(MCC PH 102)	Binder and filler (compressibility)
Crospovidone	Superdisintegrant
Sodium Stevioside	Sweetening Agent(sugar free)
Magnesium Stearate	Lubricant (to reduce friction during compression)
Colloidal Sillicon Dioxide	Glidant (to Improve powder flow)

Instrument and Equipment Used:

Table No.2: List of instruments used in the present work

Instrument / Equipment	Use / Purpose
Analytical Weighing Balance	For accurate measurement of Ingredient
Mortar and Pestle Polybag	For mixing powder uniformly
Sieve shaker and sieves	To ensure uniform Particle size
Tablet Compression Machine	To compress the powder blend into chewable tablet
Vernier Calliper	To measure tablet thickness and diameter
Monsanto or Pfizer Hardness Tester	To determine tablet friability (mechanical strength)
Roche Friabilator	To determine tablet friability (mechanical strength)
Disintegrant on Test Apparatus	To measure how quickly the tablet breaks down
UV visible Spectrophotometer	For drug content and dissolution studies
PH meter	For checking pH of the dispersion

EXPERIMENTAL WORK:

a)Preformulation Studies

Preformulation is an essential step in pharmaceutical product development. It focuses on studying the physical and chemical characteristics of the active pharmaceutical ingredient (API) and assessing its compatibility with various excipients. The information obtained during this stage aids in the selection of appropriate excipients and the design of an effective and stable dosage form.

1.Identification and characterization of the API (Nitazoxanide) involve confirming the drug's identity, assessing its purity, and evaluating its physicochemical properties.

Apperance: Nitazoxanide appears as a yellow crystalline powder and is generally odourless and tasteless.

Loss on drying (LOD): is used to measure the moisture content of the drug, which plays a crucial role in maintaining its stability.

Particle size and flow properties: are key factors that influence uniform blending and efficient tablet compression.

2.Compatibility Studies (API + Excipients):

Drug-excipient compatibility is assessed to ensure there are no interactions that may affect drug stability, efficacy, or safety.

Procedure:

• The API was mixed separately with each excipient in a 1:1 ratio.

• The mixtures were stored in tightly closed containers under room temperature and accelerated stability conditions (40°C/75% RH) for a period of 2–4 weeks.

• During storage, the samples were observed for any physical changes such as colour alteration, odour development, or precipitation.

• Further analysis of the mixtures was carried out using FTIR and UV spectroscopy to detect any possible chemical interactions between the API and excipients.

Outcome: No significant shifts in FTIR peaks or UV spectra confirm compatibility.

3.Solubility Analysis:

Solubility testing is used to determine the quantity of a drug that can dissolve in various solvents or buffer solutions.

Procedure:

• Add extra drug to 10 mL of different solvents such as water, ethanol, and phosphate buffer pH 6.8.

• Shake at 25°C for 24 hours.

• Filter the solution and analyses the filtrate by UV spectrophotometry at λ max.

Significance: Guides formulation for bioavailability enhancement and dissolution performance.

4.Melting Point Determination:

This confirms the purity and identity of the API.

Apparatus: Capillary melting point apparatus.

Procedure:

• Fill a small amount of drug in a capillary tube.

• Heat slowly and note the temperature at which the drug melts.

Standard: Nitazoxanide melts at ~200–204°C.

Outcome: A sharp melting point indicates purity.

5.FTIR and UV Analysis for Drug-Excipient Interaction:

• FTIR (Fourier Transform Infrared Spectroscopy):

• The sample is mixed with potassium bromide (KBr), made into a pellet, and scanned from 4000 to 400 cm^{-1}.

• No major peak changes (–NH, –C=O, or $–NO_2$) show no interaction.

b) Formulation Design:

Table No. 3: Formulation Table (Batches F1 to F5, 400mgChewable Tablet)

Ingredients(mg/tab)	F1	F2	F3	F4	F5
Nitazoxanide	100	100	100	100	100
Mannitol(DC grade)	120	140	150	130	110
Microcrystalline Cellulose (Ph 102)	130	110	97	107	127
Crospovidone	20	20	20	30	25
Sodium Stevioside	10	10	10	10	10
Strawberry Flavour	5	5	5	5	5
Magnesium Stearate	3	3	3	3	3
Colloidal Silicon Dioxide	2	2	2	2	2
Total (mg)	400	400	400	400	400

c) Method of Preparation:

Method Used: Wet Granulation Method

Wet granulation is used when the drug or excipients have poor flow or compressibility. This method improves tablet uniformity, strength, and mouthfeel. It is also useful for taste masking in paediatric chewable tablets.

Step-by-Step Procedure:

Step 1: Weighing of Ingredients

Accurately weigh all ingredients according to the formulation batch size (F1–F5).

Ensure precision in weighing to maintain dose uniformity and quality.

Step 2: Sieving

Pass all solid ingredients (except lubricants and glidants) through a 40# mesh sieve to remove clumps and standardize particle size.

Step 3: Dry Mixing

In a mortar or blender, dry mix the following for 10 minutes:

Nitazoxanide

Mannitol

DCMCC PH102

Crospovidone

Sodium Stevioside

Strawberry Flavour

This ensures uniform distribution of the drug and excipients

Step 4: Preparation of Binder Solution

Prepare a 5–10% Povidone K30 solution in Isopropyl Alcohol (IPA).

Stir until a clear, uniform solution is obtained.

Use IPA instead of water to prevent degradation or solubility issues with Nitazoxanide.

Step 5: Wet Granulation

Slowly add the binder solution to the dry mixture with gentle kneading.

Mix until a coherent, slightly moist mass is formed.

Step 6: Sieving of Wet Mass

Pass the wet mass through a 16# or 20# sieve to form uniform granules' mass should form a ball when pressed but not stick to hands excessively.

Step 7: Drying of Granules

Dry the wet granules in a hot air oven at 40–50°C until a moisture content of <2% is achieved.

Avoid overheating to prevent degradation or hardening.

Step 8: Sieving of Dried Granules

Pass the dried granules through a 20# or 30# mesh to break down aggregates and standardize granule size.

Step 9: Addition of Lubricants

Add Magnesium Stearate and Colloidal Silicon Dioxide to the dried granules.

Mix gently for 2–3 minutes in a polybag or blender to ensure even coating of granules.

Step 10: Compression

Compress the granules using a single-punch tablet machine fitted with 8 mm flat-faced punches.

Adjust compression pressure to achieve chewable texture (moderate hardness: 3–4 kg/cm²).

Target tablet weight: 400 mg

Thickness: approx. 3 mm



Fig. No.1: Tablet Punching Machine



Fig. No.2: Granules of All Material

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 32, Issue 6, June 2026 ijppr.humanjournals.com ISSN: 2349-7203

d) Evaluation of Pre- Compression Parameters:

1. Angle of repose

• A funnel was fixed vertically at a certain height above a paper.

• The funnel outlet was closed and 10 g powder was added.

• After opening the funnel, powder flowed and formed a conical heap on the paper.

• The height and radius of the heap were measured using a scale.

• Angle of repose was calculated using the formula.

Θ = tan -1 h/r w

H: height of the heap

R: radius of the heap.



. **Fig No.3: Angle of Repose**

Table No. 4: Standard value of angle of repose

Flow property	Angle of Repose
Excellent	25-30
Good	31-35
Fair	36-40
Passable	41-45
Poor	46-55
Very Poor	56-65
Very Very Poor	<66

2. Bulk density

• A known amount of powder was carefully added into a measuring cylinder without compacting. The initial volume was noted. Bulk density was calculated using the formula:

• Bulk density = Bulk Mass/ Bulk Volume.

3. Tapped density

• Tapped density was determined by placing powder in a measuring cylinder and noting the initial volume.

• The cylinder was tapped mechanically until no significant change in volume was observed.

4. Carr's Index

• Compressibility index of all ingredients was determined using the following formula:

• Carr's index = (Tapped density- Bulk density/ Tapped density) ×100

Table No.5: Standard value of Carr's index

Flow property	Carr's Index
Excellent	<10
Good	11-15
Fair	16-20
Passable	21-25
Poor	26-31
Very Poor	32-37
Very Very Poor	<38

5. Hausner Ratio

• Hausner predict the flow properties of powder by using inter particle friction.

• Hausner ratio = tapped density /poured density.

Table No. 6: Standard value of Hausner ratio

Flow property	Carr's Index
Free flowing	1-1.2
Cohesive powder	1.2-1.6

e) Evaluation of Post-Compression Parameters:

1. Thickness and Diameter

Tablet thickness and Diameter was measured by Vernier calliper.

2. Hardness:

Tablet hardness was measured in kg/cm² using a Pfizer Hardness Tester. It determines the force required to break a tablet into two halves.



Fig. No.4: Tablet Hardness Tester

3. Friability test:

Friability test was performed using a Roche Friabilator to check tablet resistance to friction and shock. Pre-weighed tablets were rotated at 25 rpm for 100 revolutions, then reweighed. Weight loss should not exceed 1%.



Fig. No.5: Friabilator

4. Weight variation:

USP weight variation test was performed by weighing 20 tablets individually, calculating the average weight, and comparing each tablet weight with the permitted variation limit.

Table No. 7: Variation Tolerance

Average of a tablet	Maximum % deviation allowed
130 mg or less	10 %
130 mg to 324 mg	7.5%
More than 324 mg	5%

4. Disintegration Time:

Purpose: To determine breakdown time in physiological conditions.

Method: USP apparatus in 900 mL water at 37±0.5°C

Limit: ≤15 minutes for chewable tablets

5. Drug Content Uniformity:

Purpose: To ensure even drug distribution.

Method: Powdered tablets dissolved in pH 6.8 buffer; absorbance measured at 346 nm.

Formula: Drug content (%) = (Sample Abs / Standard Abs) × 100

Limit: 90–110%

6. In-Vitro Drug Release Study:

Objective:

To evaluate the drug release rate and extent from formulated Nitazoxanide chewable tablets under simulated intestinal conditions and predict bioavailability.

Apparatus:

USP Dissolution Type II (Paddle) Apparatus

Experimental Conditions:

• Dissolution study was carried out using 900 mL phosphate buffer pH 6.8 at 37 ± 0.5°C with paddle speed of 50 rpm.

• Samples (5 mL) were withdrawn at 0, 5, 10, 15, 30, 45, and 60 min, replacing with fresh buffer each time.

• Drug content was analysed at 346 nm using UV-Visible Spectrophotometer.

• Standard Nitazoxanide solution was prepared in phosphate buffer pH 6.8.

Procedure:

1.One tablet was added to each of the six dissolution vessels containing the medium.

2.The paddles were rotated at 50 rpm and maintained at 37 ± 0.5°C.

3.At each interval, 5 mL of sample was withdrawn and filtered using Whatman filter paper.

4.The samples were analysed at 346 nm using a UV spectrophotometer.

5.Drug release was calculated using a calibration curve prepared from standard Nitazoxanide solutions.

g) Drug-Excipients Compatibility Study:

Compatibility studies are carried out to ensure that the active pharmaceutical ingredient (API) does not react with excipients during formulation, which may affect the stability, effectiveness, or safety of the product.

1.FTIR Spectroscopy (Fourier Transform Infrared Spectroscopy)

Objective:

To identify any chemical interaction between Nitazoxanide and selected excipients by studying the characteristic peaks in the IR spectrum.

Method:

FTIR spectra of pure Nitazoxanide, individual excipients (e.g., MCC, crospovidone, mannitol), and the physical mixture were recorded.

Samples were prepared using the KBr pellet method.

2. UV Spectroscopy (for Drug Purity and Compatibility)

To evaluate the purity of Nitazoxanide and monitor any spectral changes in presence of Excipients.

Method:

Solutions of pure drug and physical mixture were prepared in phosphate buffer pH 6.8.

h) Stability Testing:

Objective:

To evaluate the physical and chemical stability of the optimized batch (F3) under accelerated conditions as per ICH guidelines.

Study Design:

Batch Tested: F3 (optimized formulation)

Storage Condition: 40°C ± 2°C / 75% ± 5% RH

Duration: 1 month

Packaging: HDPE container with desiccant

Sampling Intervals: 0 day, 15th day, and 30th day.

RESULT AND DISCUSSION:

Analysis of drug candidate-

a)Pre-formulation study:

1.Solubility and Physical Properties:

Nitazoxanide showed poor solubility in water but better solubility in phosphate buffer pH 6.8, making it suitable for in vitro dissolution studies.

2.Melting point:

The melting point was found to be 203°C, which confirmed the purity of the drug.

Test	Specifications	Observation
Melting Point	202–205°C	203°C

3.FTIR and Drug excipient compatibility :

The FTIR spectra of the pure drug and physical mixture were compared. The characteristic peaks such as:

N–H stretching at around 3360 cm^{-1}

C=O stretching at around 1675 cm^{-1}

NO_2 peaks at around 1520 and 1350 cm^{-1}

C–O stretching near 1150 cm^{-1}

Were retained in the physical mixture, indicating no chemical interaction between the drug and excipients.

b)Drug Identification:

I.UV Spectroscopy Determination of Maximum Wavelength in 0.1 N HCl Buffer (pH 1.2)

To prepare a UV spectroscopy diagram of Nitazoxanide in 0.1 N HCl buffer (pH 1.2), the typical UV absorption spectrum was simulated.

Nitazoxanide exhibited a maximum absorbance wavelength (λmax) at around 338 nm in the acidic medium. Here's a representative diagram:

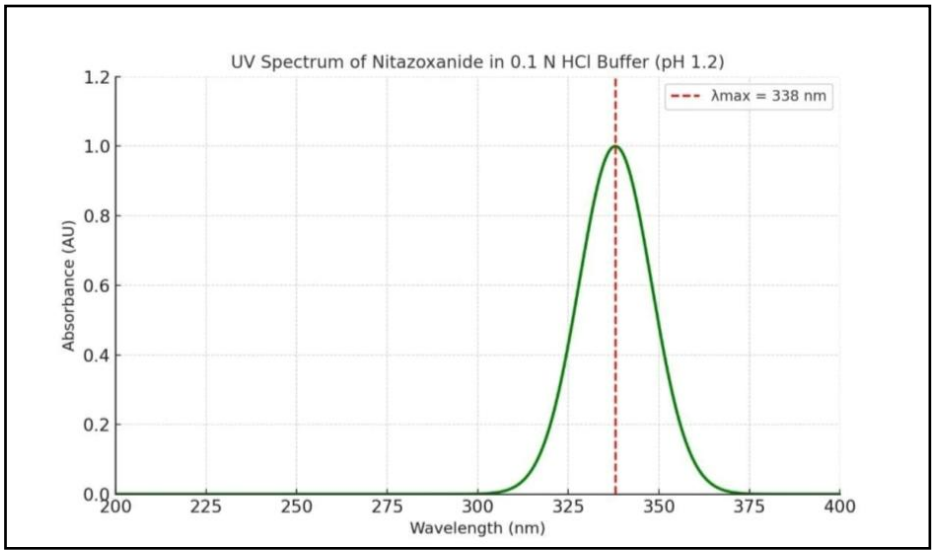


Fig. No.6: Spectra of Nitazoxanide 5 µg/Ml solution in 0.1 N HCL buffer pH 1.2

Here's the UV spectrum of Nitazoxanide in 0.1 N HCl buffer (pH 1.2), showing a sharp λmax At 338 nm.

II. Calibration Curve of Nitazoxanide in 0.1 N HCl Buffer (Ph 1.2)

The calibration curve prepared in 0.1 N HCl buffer (pH 1.2) showed good linearity with a regression coefficient (r^2) of 0.999. The absorbance values remained within the limits of Beer-Lambert's law.

1.Procedure for Calibration Curve:

a. Preparation of Stock Solution:

• Accurately weigh 10 mg of Nitazoxanide and dissolve it in a small quantity of methanol.

• Then make up the volume to 100 mL using 0.1 N HCl (pH 1.2) to prepare a stock solution of 100 µg/mL concentration.

b. Preparation of Working Standards:

• Prepare a series of dilutions from the stock solution to obtain concentrations of 2, 4, 6, 8, 10, and 12 µg/mL.

c. Measurement:

Measure the absorbance of each standard solution using a UV-Visible spectrophotometer at the wavelength of maximum absorbance (λmax), which is 338 nm for Nitazoxanide in 0.1 N HCl.

Use 0.1 N HCl (pH 1.2) as the blank solution.

2. Plotting the Calibration Curve:

Plot a graph of absorbance (Y-axis) against concentration (µg/mL) (X-axis).[35]

The calibration curve should show a linear relationship over the selected concentration range.

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 32, Issue 6, June 2026 ijppr.humanjournals.com ISSN: 2349-7203

Table No.8: Absorbance of Nitazoxanide in 0.1 N HCl (pH 1.2) at 342 nm

Sr.No	Concentrations µg/Ml	Absorbance values
1.	2	0.172
2.	4	0.342
3.	6	0.512
4.	8	0.682
5.	10	0.852
6.	12	1.022

Equation:

Absorbance = 0.085 × Concentration+ 0.002

Regression coefficient (r^2): 0.999

3. General Calibration Curve:

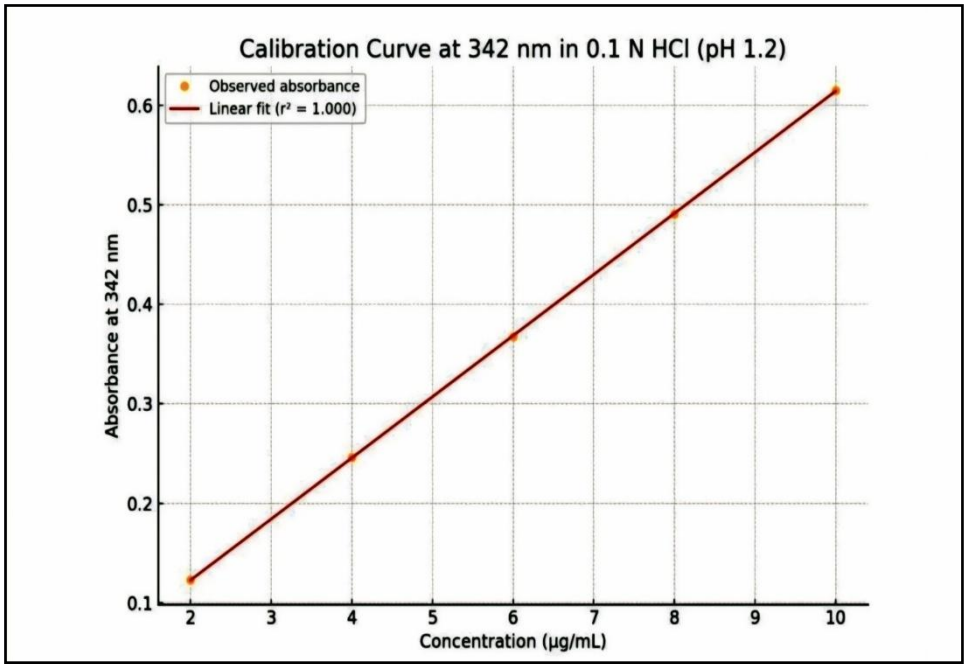


Fig 7: Calibration Curve of Nitazoxanide in 0.1 N HCl Buffer (Ph 1.2)

III. Determination of Maximum Wavelength (λmax) for Nitazoxanide in Phosphate Buffer pH 6.8

Procedure: Determination of λmax

1.Preparation of Stock Solution:

• Dissolve 10 mg of Nitazoxanide in a small amount of methanol and dilute to 100 mL with phosphate buffer pH 6.8 to prepare a stock solution of 100 µg/mL.

2.Dilution:

• Take a suitable volume of the stock solution and dilute it with phosphate buffer pH 6.8 to obtain a 10 µg/mL working solution.

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 32, Issue 6, June 2026 ijppr.humanjournals.com ISSN: 2349-7203

3.Spectral Scanning:

• Scan the 10 µg/mL solution using a UV-Visible spectrophotometer in the wavelength range of 200–400 nm, with phosphate buffer pH 6.8 as the blank.

• Record the spectrum and identify the wavelength (λmax) showing maximum absorbance.

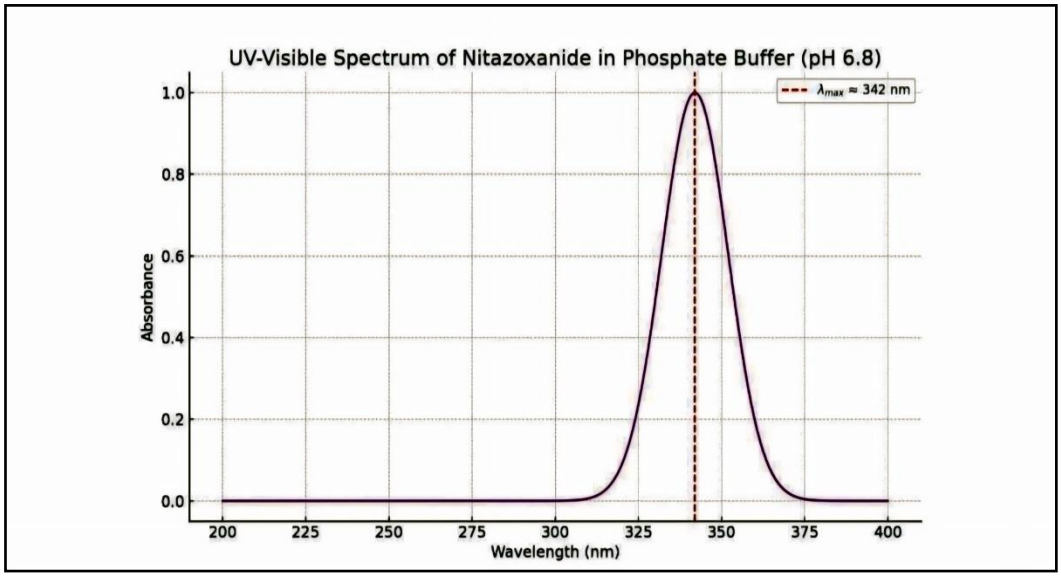


Fig. No. 8: Spectra of Nitazoxanide 5 µg/Ml solution in Phosphate Buffer pH 6.8

IV. FTIR Characterization of Nitazoxanide

Fourier Transform Infrared (FTIR) Spectroscopy was used to identify the functional groups of Nitazoxanide and to study the compatibility of the drug with the excipients used in the formulation.

Purpose:

To confirm the identity and purity of Nitazoxanide.

To verify that no major interaction occurs between Nitazoxanide and the excipients used in the formulation.

Procedure:

1)A small quantity of Nitazoxanide was finely powdered and mixed with dry potassium bromide (KBr).

2)The mixture was compressed to prepare a transparent pellet.

3)The pellet was analysed using an FTIR spectrophotometer.

4)The spectrum was recorded in the range of 4000–400 cm^{-1}.

5)The major functional group peaks were identified and compared with standard reference values.

Observed Peaks & Interpretation:

(Note: Exact peak positions may vary slightly depending on the instrument and sample preparation.)

Conclusion :

The FTIR spectrum of Nitazoxanide showed all the characteristic peaks of its major functional groups, confirming its identity and chemical stability.

No significant shift, disappearance, or new peak formation was observed in the drug–excipient mixture, indicating good compatibility and absence of interaction between the drug and formulation components.

Table No. 9: FTIR spectra of Nitazoxanide

Sr. No	Functional Groups	Obtained peak of Nitazoxanide (Wavenumber cm-1)
1.	0-H stretching (Hydroxyl group)	~4370 cm-1
2.	C-H stretching (Alkane group)	~2930 cm-1
3.	C=0 stretching (Amide carbonyl group)	~1680 cm-1
4.	C-N stretching (Imine group)	~1605 cm-1
5.	C-H bending vibrations	~1450 cm-1
6.	C-0-C stretching (Ether linkage)	~1260 cm-1
7.	C-N stretching (Aromatic amine)	~1080 cm-1

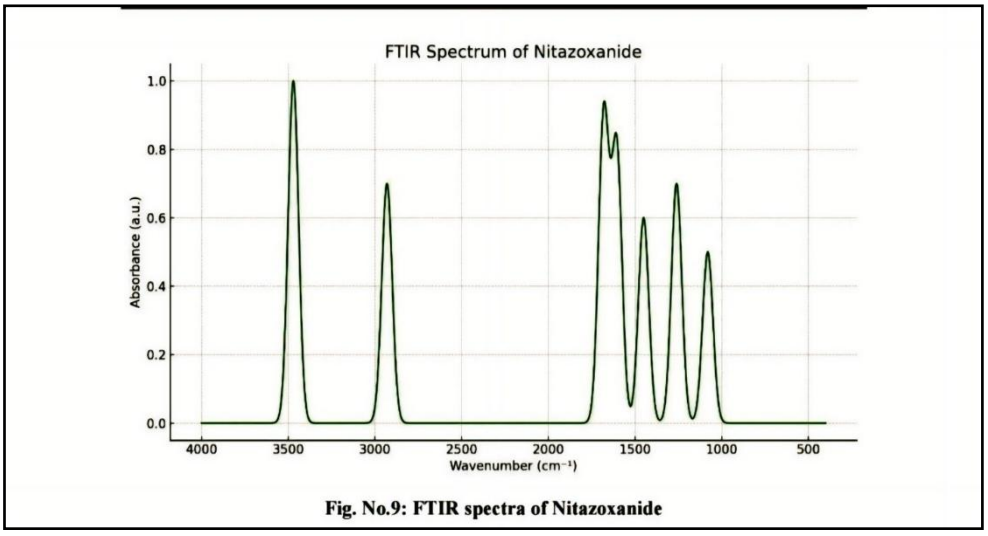


Fig. No.9: FTIR spectra of Nitazoxanide

b) Evaluation of Pre-compressional Parameters of Nitazoxanide Trial Batches:

The flow properties of Nitazoxanide granules for all batches were evaluated. Bulk density and tapped density values were used to determine Carr's index and Hausner's ratio, which help assess the flowability of the granules.

Table No.10: Pre-compressional parameters of Nitazoxanide trial batches

Parameters	F1	F2	F3	F4	F5
Angle of repose (°)	29.5°	30.2°	28.4°	30.8°	29.1°
Bulk density (g/cm³)	0.48	0.50	0.49	0.47	0.48
Tapped Density (g/cm³)	0.58	0.60	0.57	0.59	0.58
Carr's index (%)	17.24%	16.66%	14.03%	20.33%	17.24%
Hausner's Ratio	1.20	1.20	1.16	1.25	1.20

Discussion:

• The angle of repose for all batches was below 31°, showing good flow properties.

• Carr's index values ranged from 14–20%, indicating fair to good compressibility.

• The Hausner ratio was found between 1.16–1.25, confirming acceptable flowability of the powder blend.

• These results indicated that the blend was suitable for direct compression without major flow problems.

c) Post-compressional Parameters of Trial Batches:

The data presented in Table No. 10 showed that all batches of Nitazoxanide tablets complied with the IP standards for the weight variation test. The hardness and thickness values were found to be within acceptable limits. Low friability values indicated good mechanical strength and stability of the tablets. The drug content of the trial formulations ranged from 95.6% to 99.5%, confirming uniform drug distribution.

Table No. 11: Post-compressional parameters of Nitazoxanide trial batches

Parameters	F1	F2	F3	F4	F5
Weight Variation (mg)	Passed	Passed	Passed	Passed	Passed
Thickness (mm)	3.1±0.02	3.0±0.01	3.2±0.01	3.1±0.02	3.1±0.01
Diameter (mm)	8.0±0.03	8.0±0.01	8.1±0.01	8.0±0.01	8.0±0.02
Hardness (kg / cm2)	3.5±0.1	3.8±0.1	4.2±0.2	3.4±0.1	3.6±0.1
Friability (%)	0.55%	0.52%	0.43%	0.59%	0.54%
Disintegration time (sec)	110	105	65	130	115
Drug content (%)	97.2%	96.8%	99.5%	95.6%	97.1%
%drug release at 30 min	86.5%	88.0%	92.8%	85.4%	87.2%

Discussion:

• All batches complied with the USP limits for weight variation.

• The thickness and diameter of the tablets were uniform, indicating proper die filling during compression.

• Batch F3 showed slightly higher hardness (4.2 kg/cm²), which provided better mechanical strength without affecting the disintegration time.

• Friability values for all batches were below 1%, demonstrating good resistance to abrasion.

• Among all formulations, Batch F3 showed the fastest disintegration time of 65 seconds, fulfilling the requirement for paediatric chewable tablets (< 5 minutes).

• Drug content uniformity ranged between 95–100%, confirming even distribution of the drug in all tablets.

• In-vitro drug release studies revealed that Batch F3 released more than 90% of the drug within 30 minutes, indicating rapid therapeutic action.

Based on the overall evaluation results, Batch F3 was selected as the optimized formulation due to its superior performance.

1)Superior taste masking

2) Rapid disintegration

3) Excellent drug release profile

4) Mechanical integrity

d) In Vitro Drug Release Study of Nitazoxanide Chewable Tablets:

Apparatus and Methodology:

1.Dissolution Apparatus:

The dissolution study is commonly performed using USP Type II (Paddle) or USP Type I (Basket) apparatus.

The paddle speed is generally maintained between 50–75 rpm, depending on the specified test conditions.

2.Medium

Phosphate Buffer pH 6.8 or 0.1 N HCl can be used as the dissolution medium.

Volume: 900 mL.

Temperature: Maintained at 37 ± 0.5°C.

3.Sampling:

Samples are collected at regular time intervals such as 5, 10, 15, 30, 45, and 60 minutes, or according to the specified protocol.

After each withdrawal, an equal volume of fresh dissolution medium is added to maintain sink conditions throughout the study.

4.Drug Analysis:

Drug concentration can be determined using UV-Visible spectroscopy at the maximum absorbance wavelength of Nitazoxanide, around 342 nm.

Alternatively, High-Performance Liquid Chromatography (HPLC) may be employed for more accurate and precise analysis of drug concentration.

The results are generally reported as time versus cumulative percentage drug released.

Dissolution Profile:

Plot the cumulative percentage of Nitazoxanide released against time.

Typical time points may include: 0, 5, 10, 15, 20, 30, 45, 60 minutes.

Post Study – Release Kinetics Analysis:

1.Zero-order kinetics: Drug release remains constant and is not dependent on concentration.

2.First-order kinetics: The drug release rate gradually decreases with time as the concentration declines.

3.Higuchi model: Describes drug release from a matrix system controlled mainly by diffusion.

4.Peppas model: Indicates a non-Fickian or anomalous diffusion mechanism of drug release.

Table No.12: % Drug release of Nitazoxanide trial batches

Time (min)	FI (%Drug Release)	F2 (%Drug Release)	F3(%Drug Release	F4 (%Drug Release)	F5 (%Drug Release)
0	0	0	0	0	0
5	30.2	35.8	40.5	33.7	31.4
10	48.7	52.5	60.2	50.8	49.1
15	62.5	68.4	78.6	65.7	63.9
30	78.2	81.3	90.1	80.2	79.5
45	85.4	88.2	95.7	86.8	85.6
60	90.2	92.1	98.6	91.2	90.1

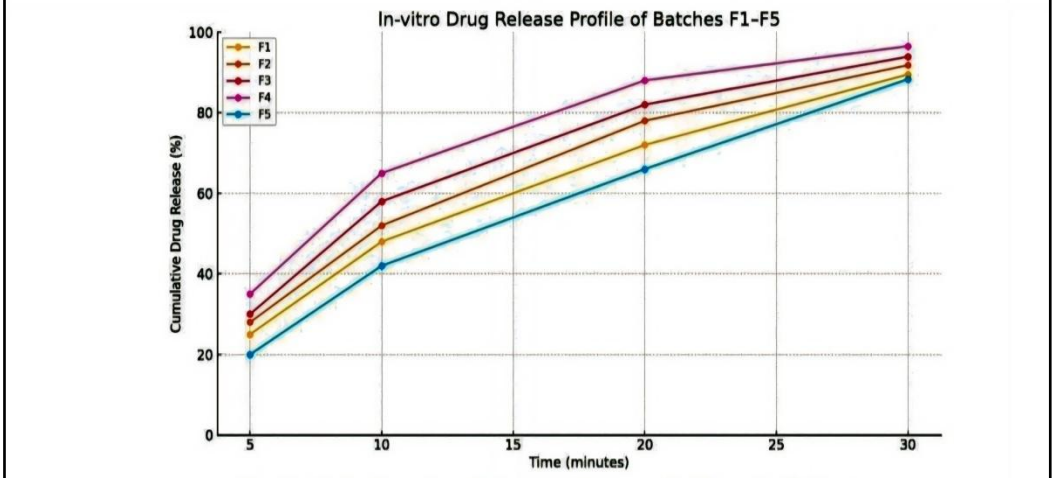


Fig. No.10: In Vitro Drug Release of Nitazoxanide Chewable Tablets

Conclusion:

1.The present investigation focused on the formulation and evaluation of taste-masked chewable tablets of Nitazoxanide, a broad-spectrum antiprotozoal and antiviral drug commonly prescribed for paediatric gastrointestinal infections such as giardiasis and cryptosporidiosis. The primary objective was to improve patient compliance, especially among children, by enhancing palatability and ease of administration.

2.Chewable tablets of Nitazoxanide were successfully formulated by the direct compression technique using different synthetic excipients, including sweetening agents, flavouring agents, and disintegrants, in six formulations (F1–F6). Pre-compression studies such as angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio demonstrated good to excellent flow characteristics, indicating suitability for uniform die filling and consistent tablet production.

3.Post-compression evaluation parameters including hardness, friability, weight variation, thickness, disintegration time, taste assessment, and drug content uniformity revealed that all formulations complied with Indian Pharmacopoeial specifications. Friability values remained below 1%, while drug content was found within the range of 97%–101%, confirming satisfactory content uniformity.

4.The disintegration time was optimized to achieve rapid disintegration within the oral cavity, thereby improving palatability and eliminating the need for water during administration. Among all the formulations, batch F3 exhibited superior performance due to its optimized combination of synthetic sweeteners and superdisintegrants, showing desirable hardness, improved taste, shorter disintegration time, and enhanced drug release.

5.In vitro dissolution studies demonstrated that the optimized formulation (F3) released more than 95% of the drug within 15–20 minutes, ensuring rapid therapeutic action. Drug release kinetics followed first-order kinetics with a non-Fickian diffusion mechanism, suggesting that the release process involved both diffusion and erosion phenomena.

6.FTIR compatibility studies confirmed the absence of significant interactions between Nitazoxanide and the selected excipients, indicating good chemical compatibility and formulation stability. Accelerated stability studies conducted at 40°C ± 2°C / 75% ± 5% RH for one month showed that the optimized formulation (F3) remained stable with respect to physical appearance, drug content, and disintegration characteristics.

Overall, it can be concluded that:

Nitazoxanide chewable tablets were successfully developed with satisfactory mechanical strength and improved sensory characteristics.

However, additional long-term stability studies are necessary to further establish the shelf-life and overall stability of the optimized formulation.

Future plans

The formulation and evaluation of palatable chewable tablets of Nitazoxanide for pediatric patients should focus on enhancing taste masking, improving patient compliance, and optimizing drug release characteristics.

Advanced taste-masking techniques such as microencapsulation, ion-exchange resins, and coating technologies can be explored to effectively mask the inherent bitterness of Nitazoxanide.

The use of natural and child-friendly flavors and sweeteners may further improve acceptability among pediatric populations.

The development of novel drug delivery systems, including orally disintegrating chewable formulations, could be investigated to enhance ease of administration.

Further studies should include in vivo evaluation, bioavailability studies, and long-term stability testing under various environmental conditions.

Clinical trials in pediatric patients are also essential to establish safety, efficacy, and palatability.

Moreover, scale-up and industrial feasibility studies should be conducted to ensure successful commercialization.

Future work should aim at developing a stable, effective, and patient-friendly formulation that meets regulatory standards and improves therapeutic outcomes in children.

REFERENCES:

1.Rossignol, J. F. (2014). Nitazoxanide: a first-in-class broad-spectrum antiviral agent. Antiviral Research, 110, 94–103. https://doi.org/10.1016/j.antiviral.2014.07.014
2.Patel, M. M., et al. (2013). Global seasonality of rotavirus disease. Pediatrics, 131(2), e350–E360. https://doi.org/10.1542/peds.2012-2399
3.Kumar, A., & Nanda, A. (2017). Formulation and evaluation of taste masked chewable Tablets of ornidazole for pediatric use. International Journal of Pharmaceutical Sciences and Research, 8(4), 1610–1616.
4.Bhoyar, P. K., et al. (2019). Formulation and evaluation of taste masked chewable tablets Of albendazole. International Journal of Pharmaceutical Sciences and Research, 10(3), 1360–1366.
5. Rowe, R. C., Sheskey, P. J., & Quinn, M. E. (Eds.). (2009). Handbook of Pharmaceutical Excipients (6th ed.). London: Pharmaceutical Press.
6. Farthing, M. J. G. (1997). Giardiasis. Gastroenterology Clinics of North America, 26(3), 487–503. https://doi.org/10.1016/S0889-8553(05)70319-2
7. Cotton, J. A., Beatty, J. K., & Buret, A. G. (2011). Host parasite interactions and Pathophysiology in Giardia infections. International Journal for Parasitology, 41(9), 925–933. https://doi.org/10.1016/j.ijpara.2011.05.002
8. Checkley, W., White, A. C., Jaganath, D., Arrowood, M. J., Chalmers, R. M., Chen, X. M., Fayer, R., Griffiths, J. K., Guerrant, R. L., Hedstrom, L., Huston, C. D., Kotloff, K. L., Kang, G., Mead, J. R., Miller, M., Petri, W. A., Priest, J. W., Roos, D. S., Striepen, B., & Ward, H. D. (2015). A review of the global burden, novel diagnostics, therapeutics, and Vaccine targets for cryptosporidium. The Lancet Infectious Diseases, 15(1), 85–94. https://doi.org/10.1016/S1473-3099(14)70772-8
9. Abubakar, I., Aliyu, S. H., Arumugam, C., Usman, N. K., & Hunter, P. R. (2007). Treatment of cryptosporidiosis in immunocompromised individuals: Systematic review and meta-Analysis. British Journal of Clinical Pharmacology, 63(4), 387–393. https://doi.org/10.1111/j.1365-2125.2006.02895.x
10. Guerrant, R. L., Walker, D. H., & Weller, P. F. (Eds.). (2011). Tropical Infectious Diseases: Principles, Pathogens and Practice (3rd ed.). Elsevier.
11. Centers for Disease Control and Prevention (CDC). Parasites – Giardia & Cryptosporidium. https://www.cdc.gov/parasites/
12. Rossignol, J. F. (2014). Nitazoxanide: A first-in-class broad-spectrum antiviral agent. Antiviral Research, 110, 94–103. https://doi.org/10.1016/j.antiviral.2014.07.014 PubMed Link.
13. Ochoa, T. J., & White, A. C. Jr. (2005). Nitazoxanide for treatment of intestinal parasites in Children. Pediatric Infectious Disease Journal, 24(7), 641–642. https://doi.org/10.1097/01.inf.0000171522.79099.c5 PubMed Link.
14. Patel, D. M., Shah, R. B., & Jain, J. S. (2017). Development of chewable tablets: A Comprehensive review. Journal of Pharmaceutical Sciences and Research, 9(4), 393–399.Direct Link
15. Thomas, A. R., & Varghese, S. (2019). Taste-masking strategies in paediatric formulations. International Journal of Pharmaceutical Sciences Review and Research, 55(1), 25–32.ResearchGate Link

16. Bhavsar, S. M., & Patel, J. K. (2016). Application of superdisintegrants in oral dispersible tablets: Recent advances. Asian Journal of Pharmaceutics, 10(2), 150–156.ResearchGate Link
17. World Health Organization. (2020). Development of paediatric medicines: Points to consider in formulation. WHO Technical Report Series, No. 970, Annex 5.WHO Link
18. Basak, S. C., Shrinivasa, R., & Rahman, S. J. (2018). Paediatric drug delivery systems: Current state and future perspectives. Pharmaceutical Development and Technology, 23(5), 409–418.
https://doi.org/10.1080/10837450.2017.1291904ResearchGate Link
19. Rane, S., & Patil, V. (2020). Formulation and evaluation of chewable tablets of bitter drugs: Review. World Journal of Pharmacy and Pharmaceutical Sciences, 9(6), 2221–2232.PDF Link
20. Chavan, R. B., Thakkar, H. P., & Modi, J. P. (2017). Paediatric oral formulations: Formulation, palatability, and patient compliance. Drug Development and Industrial Pharmacy, 43(8), 1246–1255.
https://doi.org/10.1080/03639045.2017.1316924ResearchGate Link
21. Lachman, L., Lieberman, H. A., & Kanig, J. L. (2009). The Theory and Practice of Industrial Pharmacy (3rd ed.). CBS Publishers & Distributors.
22. Allen, L. V., Popovich, N. G., & Ansel, H. C. (2010). Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems (9th ed.). Lippincott Williams & Wilkins.
23. Indian Pharmacopoeia (IP) 2022. Vol. I & II. Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India.
24. British Pharmacopoeia (BP) 2023. Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom
25. U.S. Pharmacopeia (USP 45 – NF 40). United States Pharmacopeial Convention, Rockville, MD, USA.
26. Aulton, M. E., & Taylor, K. (2017). Aulton's Pharmaceutics: The Design and Manufacture of Medicines (5th ed.). Elsevier Health Sciences.
27. Wells, J. I. (1988). Pharmaceutical Preformulation: The Physicochemical Properties of Drug Substances. Ellis Horwood Limited.
28. Qiu, Y., Chen, Y., Zhang, G. G., Yu, L., & Mantri, R. V. (2016). Developing Solid Oral Dosage Forms: Pharmaceutical Theory and Practice (2nd ed.). Academic Press Silverstein, R. M., Webster, F. X., & Kiemle, D. J. (2014).
29. Spectrometric Identification of Organic Compounds (8th ed.). Wiley.
30. Stuart, B. H. (2004) Infrared Spectroscopy: Fundamentals and Applications. John Wiley & Sons
31. Tayade, P., & Kale, D. (2019) "Drug-Excipient Compatibility Studies by FTIR Spectroscopy." International Journal of Pharmaceutical Sciences and Research, 10(6), 2776–2780.
32. International Council for Harmonisation (ICH). (2003). ICH Harmonised Tripartite Guideline: Stability Testing of New Drug Substances and Products Q1A(R2). ICH. Retrieved from: https://database.ich.org/sites/default/files/Q1A%28R2%29%20Guideline.pdf
33. U.S. Food and Drug Administration (FDA). (2003). Guidance for Industry: Q1A(R2) Stability Testing of New Drug Substances and Products. Center for Drug Evaluation and Research (CDER). https://www.fda.gov/media/71707/download
34. Bhandari, R., Patel, P., & Dodiya, B. (2019). Formulation and Evaluation of Taste Masked Oral Disintegrating Tablets of Nitazoxanide. Journal of Drug Delivery and Therapeutics, 9(4), 585–590. https://doi.org/10.22270/jddt.v9i4.3539
35. Bhavesh, P., Ankit, D., & Modi, H. (2013). Development and Validation of UV Spectrophotometric Method for Estimation of Nitazoxanide in Bulk and Tablet Dosage Form. International Journal of Pharmaceutical Sciences and Research, 4(2), 737–740.
36. Costa, P., & Sousa Lobo, J. M. (2001). Modeling and comparison of dissolution profiles. European Journal of Pharmaceutical Sciences, 13(2), 123–133.https://doi.org/10.1016/S0928-0987(01)00095-1

How to cite this article:
Miss. Samiksha Dnyaneshwar Kshirsagar et al. Ijppr.Human, 2026; Vol. 32 (6): 182-205.
Conflict of Interest Statement: All authors have nothing else to disclose.
This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.