Available online on 15.06.2026 at http://ajprd.com

Asian Journal of Pharmaceutical Research and Development

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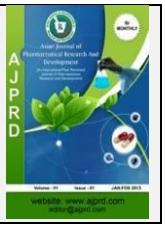

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Research Article

Formulation and Evaluation of Nicotine Polacrilex Chewable Tablets by Direct Compression

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A B S T R A C T

Nicotine polacrilex chewable tablets were developed as an effective dosage form for nicotine replacement therapy to help reduce smoking dependence. The present study focused on the formulation and evaluation of chewable tablets using suitable excipients to improve taste, stability, and drug release. Tablets were prepared by the direct compression method using ingrediaents such as mannitol, microcrystalline cellulose, sodium starch glycolate, and flavouring agents. Pre-compression studies indicated good flow properties of the powder blend, ensuring uniform tablet formation. The prepared tablets were evaluated for various parameters including weight variation, hardness, friability, thickness, disintegration time, and in-vitro drug release. All formulations complied with pharmacopeial limits, showing acceptable mechanical strength and rapid disintegration. Among the formulations, batch NT4 showed the best performance with optimum hardness, lowest friability, and faster disintegration time. In-vitro dissolution studies demonstrated effective drug release within a short period, indicating suitability for rapid nicotine delivery. Overall, the developed chewable tablets offer a convenient, patient-friendly, and effective approach for nicotine replacement therapy.

Keywords: Nicotine Polacrilex, Chewable Tablets, Direct compression, Drug release.

A R T I C L E I N F O: Received 22 Dec. 2025; Review Complete 26 March., 2026; Accepted 13 May. 2026; Available online 15 June 2026

Cite this article as:

Namannavar S, Jakaraddi SR, Patil CC, UpparAL, Formulation and Evaluation of Nicotine Polacrilex Chewable Tablets by Direct Compression, Asian Journal of Pharmaceutical Research and Development. 2026; 14(3):31-36,
DOI: http://dx.doi.org/10.22270/ajprd.v14i3.1754

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INTRODUCTION

Nicotine is a naturally occurring alkaloid predominantly present in tobacco plants and is mainly responsible for the addictive nature of tobacco consumption. It acts as a stimulant on the central nervous system by interacting with nicotinic acetylcholine receptors, leading to various pharmacological effects. Due to its addictive properties, nicotine has been extensively studied in the context of smoking cessation therapies. To help individuals overcome tobacco dependence, nicotine replacement therapy (NRT) has been developed to deliver controlled amounts of nicotine without exposing users to the harmful substances found in tobacco smoke[1].

Nicotine replacement therapy is widely used as an effective strategy to reduce withdrawal symptoms and cravings associated with quitting smoking. Different dosage forms such as transdermal patches, lozenges, chewing gums, and tablets have been designed to provide a safer and controlled delivery of nicotine. These formulations aim to gradually decrease nicotine dependence while improving patient compliance and supporting successful smoking cessation.

Among the different oral dosage forms, chewable tablets have attracted considerable attention because of their convenience, ease of administration, and improved patient compliance. Nicotine chewable tablets are intended to be chewed in the mouth, which allows the drug to be released gradually and absorbed through the oral mucosa as well as the gastrointestinal tract. This route of administration facilitates a relatively rapid onset of action and enables better regulation of nicotine delivery[2].

Chewable tablets are particularly advantageous for individuals who experience difficulty swallowing conventional tablets or capsules, including paediatric and geriatric patients. In addition, these dosage forms can be taken without the need for water, which makes them highly suitable for use during travel or in circumstances where access to water is limited.

Consequently, chewable tablets provide a patient-friendly alternative for effective drug administration.

The development of nicotine chewable tablets requires careful selection of suitable excipients to achieve desirable taste, texture, and appropriate drug release characteristics. Since nicotine has a naturally bitter taste, the application of effective taste-masking techniques is essential to enhance palatability and ensure patient acceptability. This is commonly achieved by incorporating sweeteners, flavouring agents, and appropriate fillers into the formulation.

Excipients such as mannitol, sorbitol, and other directly compressible materials are frequently used in chewable tablet formulations to improve mouthfeel and provide a pleasant chewing sensation. In addition to improving taste and texture, the proper choice of formulation components helps maintain adequate mechanical strength, ensures uniform distribution of the drug within the tablet, and allows controlled release of nicotine during the chewing process[3].

METHODS AND MATERIALS

Nicotine polacrilex was obtained as a gift sample. The superdisintegrant sodium starch glycolate was procured from Chemsworth Products Co. Ltd. Xylitol was obtained from Roquette. Other excipients such as mannitol, magnesium stearate, talc, and fruits flavour were sourced from local suppliers

Pre-formulation Studies

Preparation of Chewable Tablets

All the ingredients, including the drug and diluents, were accurately weighed and triturated individually using a mortar and pestle, and then passed through a 60 and 80 sieve to ensure uniform particle size. The sieved materials were blended thoroughly using the geometric dilution method to achieve a uniform mixture. The resulting powder blend was then lubricated with magnesium stearate and talc. Finally, the prepared blend was compressed into tablets using a multi-station rotary tablet compression machine. Different formulations were prepared by varying the composition, and the batches were designated as NT1 to NT6.

Table 1: Formulation table of Nicotine Polacrilex chewable tablet

Sr. No	Ingredients	Quantity (mg)
1.	Nicotine Polacrilex(equivalent to 2 mg nicotine)	13.5
2.	Mannitol	62
3.	Microcrystalline cellulose	28
4.	Sodium starch glycolate	15
5.	xylitol	5
6.	Fruit flavour	5
7.	Magnesium stearate	3
8.	Talc	3

Table 2: Composition of excipients used in different formulation

Ingredients	NT1	NT2	NT3	NT4	NT5	NT6
Nicotine Polacrilex (equivalent to 2 mg nicotine)	13.5	13.5	13.5	13.5	13.5	13.5
Mannitol	60	65	55	62	58	60
Microcrystalline cellulose	30	25	35	38	32	30
Sodium starch glycolate	15	15	15	15	15	15
xylitol	5	5	5	5	5	5
Fruit flavour	5	5	5	5	5	5
Magnesium stearate	3	3	3	3	3	3
Talc	3	3	3	3	3	3

Bulk Density

A calculated quantity of the drug powder was carefully introduced into a 100 mL graduated cylinder. The volume employed by the powder was recorded without applying any compaction or tapping. Bulk density was then determined by calculating the ratio of the mass of the powder to the bulk volume it occupied, using the suitable formula[4]

The bulk density of the powder was calculated using the following equation:

Bulk Density = M / V_0

Where:
M = Mass of the test sample

$\mathbf{V_0}$ = Unsettled apparent volume of the powder.

Tapped Density

A measured quantity of the drug powder was carefully moved into a 100 mL graduated cylinder. The cylinder was then repeatedly tapped using a tapped density apparatus, in which the cylinder was higher and allowed to fall under its own weight, producing a fixed drop of 14 ± 2 mm at a rate of approximately 250 taps per minute. Initially, the cylinder was tapped 1250 times, after which the tapped volume was recorded. The tapped density was then calculated using the following equation:

Tapped Density = M\V_f

Where:
M = Mass of the test sample

$\mathbf{V_f}$ = Final tapped volume after tapping

The comparison between bulk density and tapped density offers an indication of the amount of interparticle interactions within the powder. These interactions influence the flow appearances of the powder and are commonly used to assess its flow properties[5].

Compressibility Index (Carr's Index)

The compressibility index, also known as Carr's Index, is used to evaluate the flow properties of a powder. It indicates the tendency of a powder to be crushed and reflects the extent of interparticle interactions within the powder system[6]. It is calculated using the following equation:

$$\text{Carr's index} = \frac{TD-BD}{TD} \times 100$$

Where:
TD = Tapped density
BD = Bulk density

A lower Carr's Index value indicates better flow properties of the powder, whereas a higher value suggests poor flow due to stronger interparticle interactions.

Hausner's Ratio

Hausner's ratio is a parameter used to evaluate the flow properties of a powder. It indicates the relationship between tapped density and bulk density and helps in assessing the compressibility and flowability of the powder. It is calculated using the following equation:

$$\text{Hausner's Ratio} = \frac{Tapped\ Density}{Bulk\ Density}$$

A Hausner's ratio value close to 1 indicates good flow properties, whereas higher values suggest poor flow due to increased interparticle friction[7].

Angle of Repose

The angle of repose is defined as the maximum angle formed between the surface of a pile of powder and the horizontal plane. It is used to evaluate the flow properties of powders, as it reflects the frictional forces present between the particles in a loose powder or granular material. The angle of repose was determined by measuring the height and radius of the powder pile formed and calculated using the following equation:[8]

Tan θ= h\r

Where:
θ = Angle of repose

h = Height of the powder pile

r = Radius of the base of the powder pile.

Evaluation test

Weight variation test

Twenty tablets were randomly selected from each batch and individually weighed using a digital balance. The mean weight of the tablets was then calculated to determine the average weight. The weight variation test was carried out according to the guidelines of the Indian Pharmacopoeia. As per these specifications, not more than two tablets are permitted to deviate from the calculated average weight by more than ±7.5%, and none of the tablets should exceed a deviation of twice this percentage. This test ensures the uniformity of tablet weight within the batch.[9]

Thickness

Tablet thickness was evaluated by measuring 20 pre-weighed tablets from each batch using a digital vernier caliper. The thickness of each tablet was recorded in millimeters (mm), and the average thickness was calculated. The results were reported as mean ± standard deviation (SD).[10]

Hardness

Tablet hardness reflects the mechanical strength required to withstand handling, transportation, and storage. It was determined individually using a pre-calibrated digital hardness tester. The measured values were recorded, and the results were expressed as mean ± standard deviation (SD).[11]

Percentage friability

The friability test was performed to evaluate the ability of tablets to resist chipping and abrasion during handling, packaging, and transportation. For conventional tablets, a friability value of not more than 1.0% is generally considered acceptable. If the tablet weight was ≥ 650 mg, ten tablets were selected and their initial weight was recorded. The tablets were then placed in a Roche's friabilator and rotated at 25 rpm for 100 revolutions, allowing the tablets to fall from a height of approximately six inches during each rotation. After the test, the tablets were dedusted and reweighed. Tablets showing a weight loss of less than 1% were considered to comply with the friability specification[12].

The percentage friability is calculated by the formula:

$$\%\ \text{Friability} = \frac{A-B}{A} \times 100$$

Where:
A = Initial weight of the tablets before the test

B = Final weight of the tablets after 100 revolutions in the friabilator.

Disintegration Time

Disintegration time is defined as the period required for a tablet to break down into smaller particles of a specified size

under controlled experimental conditions. The test was performed using a disintegration test apparatus consisting of a basket-rack assembly containing six glass tubes, each fitted with a 10-mesh sieve at the bottom. The basket assembly was immersed in 900 mL of medium maintained at 37 ± 0.5 °C and moved vertically at a frequency of 28–32 cycles per minute. One tablet was placed in each tube, and the time taken for the complete disintegration of the tablets, allowing all fragments to pass through the sieve, was recorded as the disintegration time[13].

Preparation of Standard Curve for Nicotine Polacrilex:

A standard calibration curve for nicotine polacrilex was prepared by accurately weighing 5 mg of nicotine working standard and transferring it into a clean, dry 100 mL volumetric flask. Approximately 70 mL of methanol was added, and the solution was sonicated to ensure complete dissolution of the drug. The volume was then made up to the mark with methanol to obtain the stock solution. From this stock solution, a series of standard dilutions in the concentration range of 10–50 µg/mL were prepared using methanol. The absorbance of each solution was measured, and a calibration curve was constructed by plotting absorbance against concentration[14].

Dissolution test

The dissolution test was performed to evaluate the rate and extent of drug release from the dosage form under in-vitro conditions. It is generally expressed as the percentage of drug released into the dissolution medium over a specified period under controlled conditions. For oral solid dosage forms, disintegration alone is not sufficient for effective drug absorption; the dissolution of the drug in the surrounding medium plays a crucial role in determining its bioavailability.

The in-vitro drug release of nicotine polacrilex chewable tablets was assessed using a USP Dissolution Apparatus II (paddle type). The paddle rotation speed was maintained at 50 rpm. During the study, 5 mL samples were withdrawn at intervals of 5 minutes and replaced with an equal volume of fresh dissolution medium to maintain sink conditions. The amount of drug released was determined using a UV spectrophotometer at a wavelength of 262 nm against a suitable blank, and the percentage drug release was calculated[15].

RESULT AND DISCUSSION:

Chewable tablets were formulated using microcrystalline cellulose and mannitol as diluents, sodium starch glycolate as a superdisintegrant, xylitol as a sweetening agent, fruit as a flavouring agent, and magnesium stearate and talc used as a lubricant. The tablets were prepared by the direct compression method. The prepared chewable tablets were evaluated for various physicochemical parameters, and the results were found to comply with the required pharmaceutical specifications.

Flow properties

Flow characteristics: The bulk density, Hausner's ratio, Carr's index, and angle of repose of different batches were assessed. The outcomes are displayed in Table 3. These results show that the manufactured powder mix had good flow characteristics and fell within the Indian Pharmacopoeia's compendial limits.

Table 3: Results of flow properties of powder blend

Formulation code	Bulk density (mg/ml)	Tapped density (mg/ml)	Compressibility index(%)	Hausner's ratio	Angle of repose
NT1	0.461	0.617	25.24	1.33	32.43
NT2	0.514	0.703	26.62	1.35	33.10
NT3	0.554	0.710	21.81	1.26	28.66
NT4	0.648	0.742	12.68	1.14	21.19
NT5	0.602	0.791	23.91	1.32	31.77
NT6	0.544	0.760	30.81	1.44	36.52

Post compression parameters

Physical characteristics, weight fluctuations, thickness, friability, hardness, disintegration time, and assay percentage were all evaluated for Nicotine polacrilex tablets. Table 4 displays the post-compression parameter results.

Table 4: Results of Evaluation of Post compression parameters:

Formulation code	Physical appearance	Average weight(mg)	Thickness (mm)	Friability (%)	Hardness (kg/cm^2)	Disintegration time (sec)
NT1	White colour	139	3.24	0.83	3.2	58
NT2	White colour	141	3.28	0.91	3.3	55
NT3	White colour	140	3.02	0.75	3.4	48
NT4	White colour	138	2.96	0.42	3.6	28
NT5	White colour	142	3.27	0.76	3.5	40
NT6	White colour	139	3.03	0.87	3.3	43

FTIR Studies

FTIR analysis confirms drug-excipient compatibility and demonstrates that Nicotine Polacrilex remains chemically stable within the Chewable Tablet formulation.

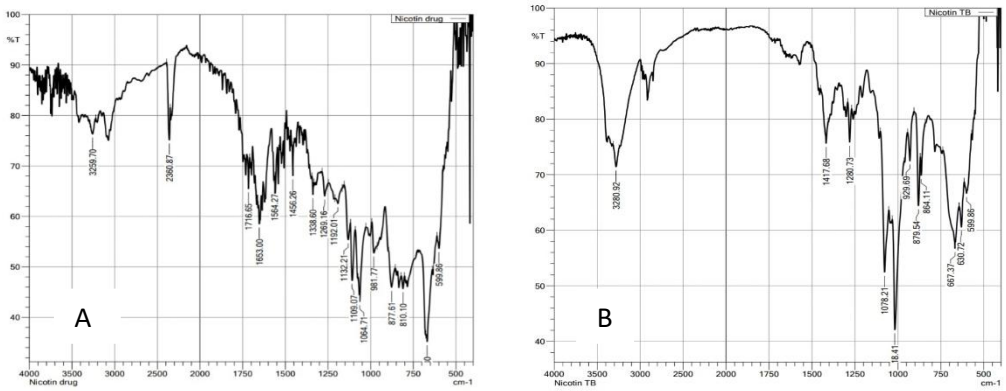

Figure 1: FTIR spectrum ofNicotine Polacrilex (A)&FTIR of formulation NT4 (B)

Preparation of Calibration Curve of Nicotine Polacrilex

The calibration curve Nicotine Polacrilex was constructed using concentrations ranging from 2 to 10 µg/mL in distilled water. The absorbance was measured at a λmax of 262 nm using a UV spectrophotometer. The standard calibration curve showed a regression equation of y = 0.0638x + 0.0265 with an R^2 value of 0.9942, indicating good linearity over the selected concentration range.

Table 5: Calibration curve of nicotine polacrilex

SR NO	Concentration	Absorbance
1	2	0.168
2	4	0.298
3	6	0.423
4	8	0.536
5	10	0.647

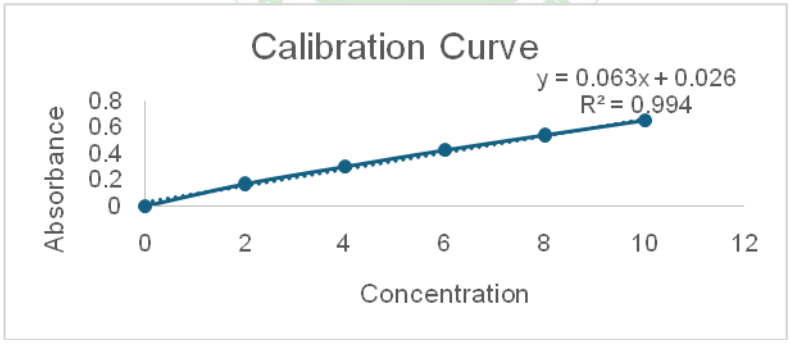

Figure 2: Preparation of Calibration Curve ofNicotine Polacrilex in Water

In-vitro Drug Release:

The in-vitro drug release of NT4 showed a sustained release, reaching 97 % at 30 minutes.

Table 6: In-vitro release profile study of different formulation(NT4)

Time (min)	% Drug Release
5	49
10	63
15	74
20	85
25	93
30	97

CONCLUSION

The present study successfully formulated and evaluated nicotine polacrilex chewable tablets using the direct compression method. The use of suitable excipients helped achieve good flow properties, acceptable mechanical strength, and improved palatability of the tablets. All formulations met the required pharmaceutical standards for weight variation, hardness, friability, and disintegration time. Among the different batches, formulation NT4 showed the most optimized results with better physical properties and faster drug release. The in-vitro dissolution study confirmed that the tablets can effectively release nicotine in a controlled manner, making them suitable for rapid relief from withdrawal symptoms. Therefore, nicotine chewable tablets can be considered a promising and patient-friendly dosage form for nicotine replacement therapy, improving compliance and supporting smoking cessation.

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