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FORMULATION AND EVALUATION OF NICOTINE MUCOADHESIVE TABLET FOR SMOKING CESSATION

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ABSTRACT

One of the main antecedents of cancer, respiratory conditions, and cardiovascular conditions is smoking. Indeed however smoking is truly common or garden Throughout the world, smokers are constantly overpassed and don't allow helpful brace to stop. Operative treatment is demanded to support smokers in quitting in order to palliate this public health burden**.** Nicotine relief remedy with gradual abating of nicotine is one of the smoking conclusion styles. Mucoadhesive phrasings are among the new drug delivery systems that are available in the form of tablets and films, and can be used for NRT. Mucoadhesive nicotine tablets when placed in the upper slush will attach to the buccal mucosa and release nicotine content in a controlled manner. This will meet the immediate and long- term need of the individual to the nicotine, analogous that the person can drop his/ her reliance on smoking. One system of delivering nicotine into the bloodstream without smoking is relief treatment. Numerous smoking conclusion capsule forms have increased quitting rates, which has had a major positive impact on public health. The benefit of nicotine buccal mucoadhesive capsule forms for quitting smoking is their high absorption and lack of smelling demand. Significance of smoking conclusion programme on nicotine dependence, oral health, physiological And biochemical parameters among adult smoking stoners at named. His study examines an innovative strategy for quitting smoking, emphasizing the value of learning how to stop rather than actually stopping. The study's pretensions were fulfilled in a number of stages, including a review of material literature and the development of a suitable theoretical frame, upon which the program's content was established and perfected with the help of subject-matter experts.

KEYWORDS: Mucoadhesive tablet, nicotine, smoking cessation.

INTRODUCTION

Nicotine mucoadhesive phrasings is to replace nicotine from cigarettes to reduce provocation to bank and nicotine pullout symptoms, The primary active element in nicotine products that encourages a person to engage in nicotine dependence geste is nicotine.[1]

Nicotine's other constituents are what lead to the high rates of morbidity and mortality.[2] The pharmacological parcels of nicotine are what beget nicotine dependence, indeed though other constituents in cigarettes are responsible for nearly all of the dangerous goods of smoking.[3]

Therefore, as our understanding of the neurochemical underpinnings of nicotine dependence advances, so do pharmacological curatives for nicotine conclusion.[4] The primary modulator of the psychopharmacological goods linked to dependence and the primary alkaloid in nicotine bank is nicotine.[5]

Practical way to increase the bioavailability of specifics with low oral bioavailability is by buccal delivery.[6] Biting goo and sublingual tablets are popular styles, still when they're taken, a significant quantum of the cure may be eaten before being absorbed.[7]

For specifics with low bioavailability, the buccal route of administration provides simple access to systemic rotation, avoiding the first pass impact.[8] Still, this route's downsides, similar as the lozenge forms' reduced retention capacity and lower accessible face areas, affect in ineffective treatment.[9]

The tobacco factory's leaves are used to make tobacco by curing them.[1] The factory belongs to the Solanaceae family and the rubric Nicotiana. Nicotine, the primary phytochemical in tobacco, is responsible for the pharmacological goods of tobacco, including swoon and an increase in blood pressure, heart rate, and blood sugar.[2]

Nicotine contain the alkaloid drug nicotine.[3] The medicine affects the central and independent whim-whams systems in colorful ways.[4] Nicotine increases salivary inflow, stomach movements, and acid affair because it's an agonist of cholinergic receptors.[5] Also, it stimulates the heart, releases catecholamine's, and promotes supplemental vascular compression.[6]

Habitual nicotine smoking impacts every function in the body, making nicotine- related conditions a serious global health concern.[7] As a result, nicotine relief remedy was created as a smoking conclusion tool.[8] Multitudinous practical issues are linked to each of the nicotine relief remedy results that are commercially available on the request.[9] An established system of systemic drug delivery is medicine immersion through the mouth depression's mucosal epithelium, which is particularly helpful in cases where immersion following oral administration is inadequate or shy.[10] The number of cigarette smokers is adding and accordingly the rate of the conditions performing from smoking, similar as cardiovascular conditions, respiratory conditions, and different types of cancer, especially, head and neck, and lung cancers is growing.[11]

One of the most dangerous and pervasive types of dependence in the world is cigarette smoking.[12] According to some estimates, nicotine use is the leading cause of non-communicable conditions and is poised to spark a global epidemic unless immediate preventative measures are enforced.[13] According to thus Surgeon General, smoking cigarettes is addicting, and the behavioral and physiological mechanisms behind nicotine dependence are similar to those underpinning dependence to other substances, including heroin and cocaine.[14] The psychoactive element of nicotine that encourages continued use is nicotine.[15]

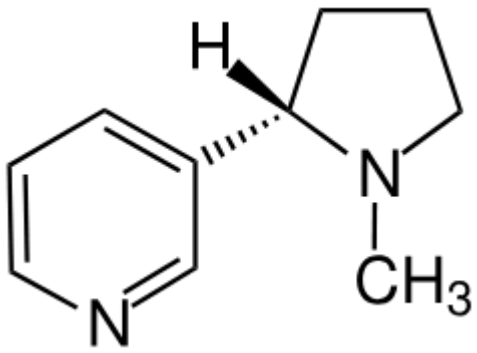

Figure 1: Chemical Structure of Nicotine.

Nicotine is a naturally produces the alkaloid nicotine, which is used extensively in recreational settings as an anxiolytic and stimulant. It is used as a medication to help people quit smoking by easing the symptoms of withdrawal.

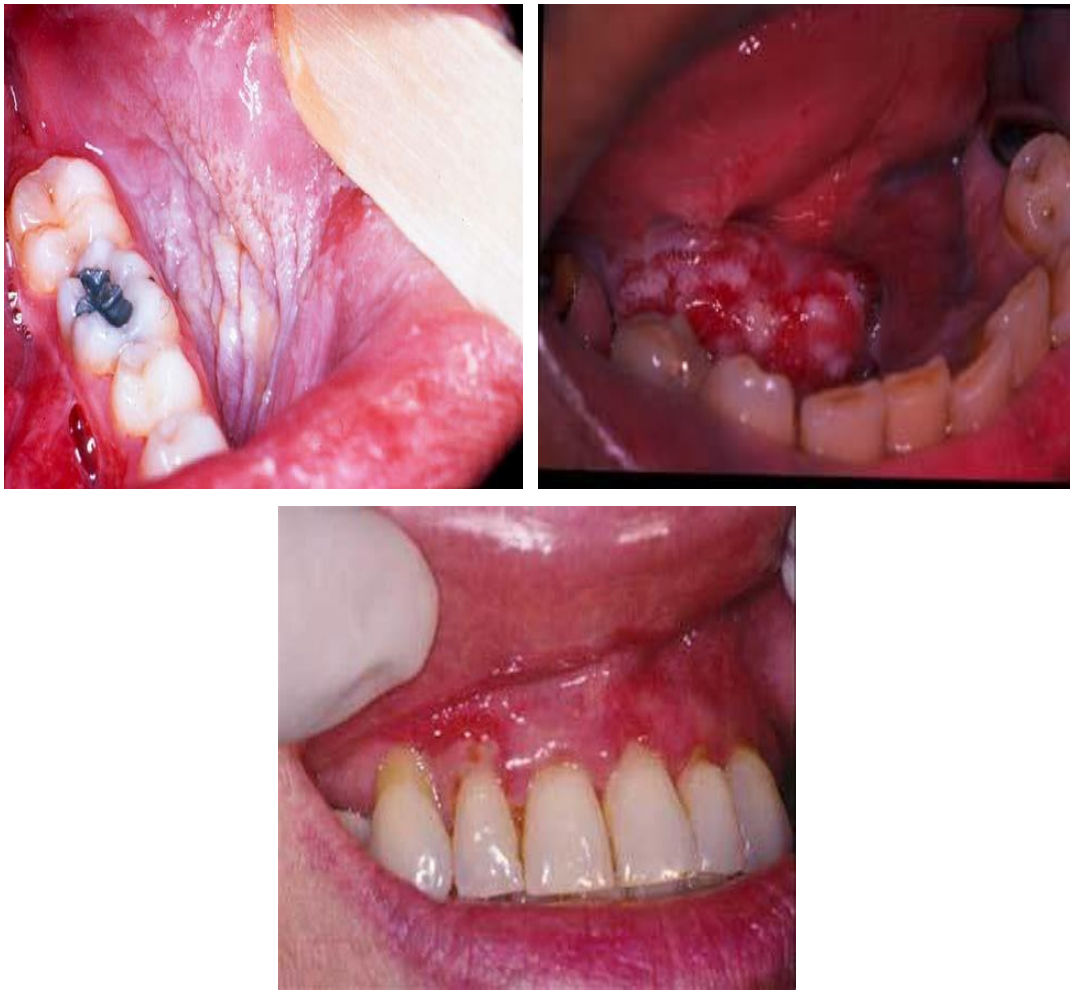

Figure 2: Oral Changes Associated with Tobacco Use.

Oral Cancer: The soft palate (the back part of the roof of the mouth), the sides and underside of the tongue, and the floor of the mouth (under the tongue) are the main locations for oral cancers. Oral cancer is covered in a different Patient Information leaflet. Early detection is the most important aspect for oral cancer survivors. The importance of having a thorough soft tissue examination performed by your dentist cannot be overstated. Because early cancer tissue changes can be subtle, your dentist must perform a comprehensive soft tissue examination in order to detect cancer early.

OBJECTIVE

1. To provide nicotine without the negative consequences of smoking, hence reducing cravings and withdrawal symptoms.
2. To progressively lessen dependence while providing a constant release of nicotine over time, assisting in maintaining stable blood nicotine levels.

3. To concentrate on minimizing negative side effects, minimizing the desire to smoke, and delivering nicotine where it works best—the oral mucosa.
4. To provide a more user-friendly format that could enhance program adherence to smoking cessation, which could result in better outcomes.
5. Nicotine is associated with cancers of the mouth, throat, and lungs.

MATERIAL AND METHODS

MATERIAL

Sr.no.	Chemicals	Quantity
1	Nicotine	5-6 mg
2	Hydroxypropyle methyl cellulose	5-10mg
3	Sodium starch glycolate	5mg
4	Lactose	40mg
5	Stearic acid	1mg
6	Citric acid or sodium citrate	2mg
7	Ethanol	1ml

PROCEDURE

Step1: Preparation of Nicotine result Take 2–4 mg Nicotine to prepare the result by dissolving nicotine in detergent similar as propylene glycol, vegetable glycerin or ethanol to produce result of asked attention (100 mg/ ml)

Step2: Preparation of Mucoadhesive polymer solution gm. HPMC greasepaint-100 ml/ water (stirrer)

Step3: objectification of Nicotine result and polymer result

Step4: objectification of recipient similar as polyvinyl pyrrolidine bounce Pollutants mannitol, microcrystalline cellulose, lactose Lubricant-magnesium stearate, stearic acid, Plasticizer- Glycerin, propylene

Step5: Granulation (Sieve 20)

Step6: Drying (Hot air roaster)

Step7: Compression

1. Primary contraction
2. Secondary contraction

SCOPE OF NICOTINE

1. Increased Bioavailability and Absorption

One asset of mucoadhesive systems is that they shake the first-pass metabolism, which happens when the liver processes nicotine after it has been devoured. This could conduct to ready pining reduction since further nicotine can enter the bloodstream.

Assimilated to vocal input or transdermal spots, systems similar as flicks, tablets, and spots guarantee that nicotine enters the bloodstream more fleetly. This can be a monumental asset, especially for smokers who have strong cravings.

2. Lower Reliance on Breathing

In addition to nicotine, smoking and vaping expose the body to hazardous chemicals like navigator, carbon copy monoxide, and carcinogens. Mucoadhesive systems have druggies to gain nicotine without the dangerous rudiments of tobacco bank, which could make smoking a safer option.

3. Adjustable Dosage: Because mucoadhesive nicotine results can be made in no identical nuisance, people can acclimate how important nicotine they consume grounded on how dependent they are.

Assimilated to ways like nicotine goo or spots, which might not invariably give constant nicotine situations throughout the day, tapering off nicotine with these systems may be a more regulated and tardy process.

4. Practicality and Usability: Unlike nicotine patches, which can be conspicuous, or gum, which can be awkward in social situations, mucoadhesive solutions, such as dissolvable tablets or films, are unobtrusive and easy to use, allowing smokers to continue their quitting routine without drawing attention to themselves.

APPARATUS

1. Blending outfit

Mixers or Blenders these are exercised to slightly integrate the nicotine with excipients (inactive constituents) like binders, paddings, and stabilizers.

2. Granulation Equipment

Wet Granulators If a wet granulation system is exercised, this outfit ensures that the constituents are mixed and compacted into grains.

Sot Granulators Alternately, dry granulation might be exercised for nicotine tablets to form the grains without adding liquid.

3. Tablet Press Machine: it applies the necessary pressure to form tablets of harmonious size and cargo.

4. Coating Equipment; (voluntary) If the tablet requires a defensive coating (e.g., for ruled release or taste masking), a tablet coating engine would be exercised.

5. Drying outfit: dry granulation might be used for nicotine tablets to form the granules without adding liquid.

6. Fluidizer Bed Dryers: These may be exercised to parch the grains before tablet contraction to insure the accurate humidity content.

7. Roaster or Charger Dryers: These are exercised for desiccating tablets or grains after granulation, depending on the process exercised.

8. Sieving Equipment: Sifters or Sieves exercised to ensure that the raw accouterments are of the accurate flyspeck size before process

EVALUATION TEST FOR NICOTINE TABLET

1. Appearance: Visual examination of the tablet's shape, color, and face quality. Check for blights similar to checks, abrasion, or irregularities.

2. Hardness: Measures the manpower needed to break up or crush the tablet. This is generally assessed utilizing a tablet hardness tester. The hardness ensures the tablet won't break up during running, yet will disintegrate duly when ingested.

3. Frangibility: Assesses the tablet's capability to repel mechanical pressure during running, transportation, and packaging. This test involves placing tablets in a swirling barrel for a prescribed time (generally 100 revolutions) to know how important the tablet breaks off. A

laboratory is exercised for this test. Tablets with inordinate frangibility may be inadequately formulated and apt to breaking up or worsening.

4. Coating Equipment: Measures the cargo of individual tablets from a package to insure thickness in the quantum of active component and recipients in each tablet. Tablets should fall within a respectable cargo range set by pharmacopeia norms (e.g., USP or BP).

5. Drying Equipment: Ensures that the tablet has harmonious consistency. A tablet consistency tester is exercised to measure it. Livery consistence ensures proper packaging and helps with decomposition interpretation.

6. Fluidized Bed Dryers: These may be used to dry the granules before tablet compression to ensure the correct moisture content.

7. Oven or Tray Dryers: These are used for drying tablets or granules after granulation, depending on the process used.

8. Sieving Equipment: Sifters or Sieves: Used to ensure that the raw materials are of the correct particle size before process.

RESULT

In the formulations, a 50 cps increase in HPMC slows down the rate of nicotine release. Nicotine is released gradually in formulations that contain carbapol. As the proportion of lactose in formulations increased, so did the rate of release. Formulations containing HPMC 50cps demonstrated the best adhesiveness, whereas formulations including carbapol did not. Formulations containing NaCMC had an unsuitable degree of adhesiveness and an incredibly fast release time. According to this study, the majority of oral symptoms were experienced by both traditional and electronic cigarette smokers. However, the fewest oral health issues were reported among hookah users. All smokers saw an increase in gingival index and DMFT, while traditional cigarette smokers saw the most increases.

CONCLUSION

The valuation of the tablets and mucoadhesive flicks. The most important specific of mucoadhesive flicks and tablets is their mucoadhesive quality, which is assessed by mucoadhesive inquiries or hearthstone time. The mucoadhesive capability of this lozenge shape has also been effectively estimated in vivo. Also, during the expression evolution

stage, standard-issue experiments involving ex Vito permeability and in vitro medicine release are conducted to figure the forcefulness of the alluded mucoadhesive flicks and tablets. Humans or beast models are exercised for the in vivo examinations. These bilayer mucoadhesive phrasings show off implicit advantages over usual nicotine medications like spots and epoxies.

REFERENCE

1. Wadgave, U., & Nagesh, L. Nicotine replacement therapy: an overview. International journal of health sciences, 2016; 10(3): 425.
2. Bahri-Najafi, R., Rezaei, Z., Peykanpour, M., Shabab, L., Solooki, R., &Akbari, P. Formulation of nicotine mucoadhesive tablet for smoking cessation and evaluation of its pharmaceuticals properties. Advanced Biomedical Research, 2013; 2(1): 88.
3. Scholar, B. U. E. Mini-review and comparative study: preparation and evaluation of nicotine-loaded buccal mucoadhesive tablets/films designed for smoking cessation.
4. Aslam, S. P., Leslie, S. W., & Morris, J. (2024). Nicotine addiction and smoking: Health effects and interventions. In StatPearls [Internet]. StatPearls Publishing.
5. Shiffman, S., Hughes, J. R., Pillitteri, J. L., & Burton, S. L. Persistent use of nicotine replacement therapy: an analysis of actual purchase patterns in a population based sample. Nicotine control, 2003; 12(3): 310-316.
6. Greaves, J. L., & Wilson, C. G. Treatment of diseases of the eye with mucoadhesive delivery systems. Advanced drug delivery reviews, 1993; 11(3): 349-383.
7. Nafee, N. A., Ismail, F. A., Boraie, N. A., & Mortada, L. M. Mucoadhesive buccal patches of miconazole nitrate: in vitro/in vivo performance and effect of ageing. International journal of pharmaceutics, 2003; 264(1-2): 1-14.
8. Lewis, S., Subramanian, G., Pandey, S., & Udupa, N. Design, Evaluation and Pharmacokinetic Study of Mucoadhesive Buccal Tablets of Nicotine for Smoking Cessation. Indian journal of pharmaceutical sciences, 2006; 68(6).
9. Salamat-Miller, N., Chittchang, M., & Johnston, T. P. The use of mucoadhesive polymers in buccal drug delivery. Advanced drug delivery reviews, 2005; 57(11): 1666-1691.
10. Park, C. R., &Munday, D. L. Development and evaluation of a biphasic buccal adhesive tablet for nicotine replacement therapy. International journal of pharmaceutics, 237(1-2): 215-226.

11. Silla, K., Beard, E., & Shahab, L. Nicotine replacement therapy use among smokers and ex-smokers: associated attitudes and beliefs: a qualitative study. BMC Public Health, 2014; 14: 1-8.
12. Amballa, H., Kaluva, N., Beri, S. G. P., Chinnala, K. M., & Konda, M. Formulation and characterization of eplerenone mucoadhesive buccal tablets. Research Journal of Pharmacy and Technology, 2021; 14(6): 3097-3103.
13. Kheawfu, K., Kaewpinta, A., Chanmahasathien, W., Rachtanapun, P., &Jantrawut, P. Extraction of nicotine from nicotine leaves and development of fast dissolving nicotine extract film. Membranes, 2021; 11(6): 403.
14. Khan, M. A., Ammen, S., Zia, A., Ijaz, U., Jahanzaib, H. M., Sehar, T., & Tabassum, N. Extraction, formulation and evaluation of fast dissolving oral films of nicotine for smoking cessation. Journal of Contemporary Pharmacy, 2018; 2(1): 1-6.
15. Pichayakorn, W., Maneewattanapinyo, P., Panrat, K., Monton, C., & Suksaeree, J. Formulation design of oral strip-films based on PVA/PVP polymer blends for nicotine delivery. Journal of Polymers and the Environment, 2022; 30(10): 4479-4491.
16. Wadgave, U., & Nagesh, L. Nicotine replacement therapy: an overview. International journal of health sciences, 2016; 10(3): 425.
17. Stead, L. F., Perera, R., Bullen, C., Mant, D., Hartmann-Boyce, J., Cahill, K., & Lancaster, T. Nicotine replacement therapy for smoking cessation. Cochrane database of systematic reviews, 2012; (11).
18. Benowitz, N. L. Neurobiology of nicotine addiction: implications for smoking cessation treatment. The American journal of medicine, 2008; 121(4): S3-S10.
19. Mahajan, S. D., Homish, G. G., &Quisenberry, A. Multifactorial etiology of adolescent nicotine addiction: a review of the neurobiology of nicotine addiction and its implications for smoking cessation pharmacotherapy. Frontiers in public health, 2021; 9: 664748.
20. Luty, J. Nicotine addiction and smoking cessation treatments. Advances in psychiatric treatment, 2002; 8(1): 42-48.
21. Bahri-Najafi, R., Rezaei, Z., Peykanpour, M., Shabab, L., Solooki, R., & Akbari, P. Formulation of nicotine mucoadhesive tablet for smoking cessation and evaluation of its pharmaceuticals properties. Advanced Biomedical Research, 2013; 2(1): 88.
22. Garg, S., & Kumar, G. Development and evaluation of a buccal bioadhesive system for smoking cessation therapy. Die Pharmazie-An International Journal of Pharmaceutical Sciences, 2007; 62(4): 266-272.

23. Konda, M., Chinnala, K. M., Samineni, L., Naznin, Y., Avirneni, J., & Kondamalla, K. C. Formulation and characterization of nicotine thin films for smoking cessation through buccal delivery. Research Journal of Pharmacy and Technology, 2016; 9(12): 2079-2086.\
24. Ikinci, G., Şenel, S. E. V. D. A., Wilson, C. G., & Şumnu, M. Development of a buccal bioadhesive nicotine tablet formulation for smoking cessation. International journal of pharmaceutics, 2004; 277(1-2): 173-178.
25. Rubinstein, M. L., Benowitz, N. L., Auerback, G. M., & Moscicki, A. B. A randomized trial of nicotine nasal spray in adolescent smokers. Pediatrics, 2008; 122(3): e595-e600.
26. Suksaeree, J., Chaichawawut, B., Srichan, M., Tanaboonsuthi, N., Monton, C., Maneewattanapinyo, P., & Pichayakorn, W. Applying design of experiments (DoE) on the properties of buccal film for nicotine delivery. E-Polymers, (2021; 21(1): 566-574.
27. Koirala, S., Nepal, P., Ghimire, G., Basnet, R., Rawat, I., Dahal, A.,& Parajuli-Baral, K. Formulation and evaluation of mucoadhesive buccal tablets of aceclofenac. Heliyon., 2021; 7(3).
28. Reibel J. Tobacco and Oral Diseases. Med PrincPract., 2003; 12 : 22-32.
29. Christen, A. G. (1994). A smoking cessation program for the dental office. The School.
30. Huang, R., Li, M., & Gregory, R. L. Effect of nicotine on growth and metabolism of Streptococcus mutans. European journal of oral sciences, 2012; 120(4): 319-325.
31. Rodin, J. Weight change following smoking cessation: the role of food intake and exercise. Addictive behaviors, 1987; 12(4): 303-317.
32. Winn, D. M. Tobacco use and oral disease. Journal of dental education, 2001; 65(4): 306-312.
33. Bernkop-Schnürch, A. Mucoadhesive systems in oral drug delivery. Drug discovery today: Technologies, 2005; 2(1): 83-87.
34. Chauhan, S. S., Lin, S., & Madan, P. L. Preparation and evaluation of nicotine hydrogen tartrate fast dissolving films for smoking cessation. Asian Journal of Pharmaceutical Sciences, 2012; 7(3).
35. Suksaeree, J., Chaichawawut, B., Srichan, M., Tanaboonsuthi, N., Monton, C., Maneewattanapinyo, P., & Pichayakorn, W. Applying design of experiments (DoE) on the properties of buccal film for nicotine delivery. e-Polymers., 2021; 21(1): 566-574.