

SHORT THESIS FOR THE DEGREE OF DOCTOR OF PHILOSOPHY (PhD)

Development of personal nasal protective device and device for
formulated nanoparticles

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Introduction

Nasal drug administration has been a key focus of scientific research for decades due to its numerous advantages in targeted drug delivery. Various drug delivery systems and devices are being developed to enhance treatment effectiveness and improve patient comfort. The benefits of intranasal drug delivery are well-established, as the nasal mucosa provides an excellent surface for the rapid and efficient absorption of active compounds. The extensive nasal surface area and high absorption capacity enable certain substances to reach the central nervous system directly, bypassing the blood-brain barrier. Pharmaceutical formulations intended for nasal application are typically solutions or liquid-based dispersions such as emulsions and suspensions. In recent years, the development of nanostructured drug carriers has advanced significantly. Solid-phase heterogeneous dispersion systems represent a novel approach in pharmaceutical technology, facilitating the efficient delivery of a wide variety of active ingredients. Our research aimed to develop a solid drug delivery system that integrates these well-known advantages. By utilizing nanoparticles, we not only leveraged their small size but also optimized the adhesive and penetration-enhancing properties of excipients to improve efficiency. Beyond drug-based nasal treatments, increasing emphasis is being placed on respiratory protection against both infectious and non-infectious environmental hazards. With growing concerns over pollution-related illnesses, there is a heightened interest in personalized protective solutions against various pathogens. The development of innovative protective devices relies not only on medical advancements but also on engineering and technological innovations. One promising approach is the use of customized nasal filters, which can effectively block airborne pollutants and pathogens. These small nasal devices are designed to filter out dust, allergens, and microorganisms from inhaled air. Additionally, personalized nasal filters may contribute to immune system support by adapting protection to an individual's genetic and immunological profile. During development, not only efficiency but also user preferences are prioritized, as comfort and ease of use are crucial for widespread adoption. Industrial research increasingly seeks to integrate technological advancements into practical, user-friendly solutions for everyday life. Consequently, customized nasal filters present an innovative and promising method for safeguarding against air pollution and harmful microbes. Through continuous technological research and development, these devices could have a lasting impact on both human health and environmental protection. Ongoing studies and novel solutions give hope that in the future, we will be able to protect our health in even more advanced and effective ways, despite ever-evolving environmental challenges.

The administration of drugs through the nasal route has long been a focus of scientific interest due to the favorable properties of the nasal mucosa, which promote the absorption of active ingredients. The nasal lining not only provides a large surface area for drug uptake but also allows direct delivery to the brain, bypassing the blood-brain barrier. Additionally, hepatic metabolism can be reduced, enhancing drug efficacy. Various studies have demonstrated that a wide range of active compounds, including macromolecules such as proteins and peptides, can be absorbed through the nasal mucosa, particularly when permeability enhancers are used. The growing importance and availability of intranasal drug delivery systems are particularly beneficial for conditions requiring rapid and effective treatment. Most nasal pharmaceutical formulations are solutions or liquid-dispersed systems such as emulsions and suspensions. Although these dosage forms are relatively easy to prepare and exhibit good stability, patients often report an unpleasant experience due to fluid runoff into the pharynx, resulting in an undesirable taste. Another pharmacological challenge is the rapid elimination of active substances from the nasal cavity, which can be mitigated by using excipients that enhance adhesion and prolong drug retention. This research aimed to develop and investigate novel solid lipid nanoparticles to enhance the penetration of active substances. In addition to formulating the active pharmaceutical ingredient, an innovative nasal drug delivery device was designed and tested. Chlorpromazine (CPZ), a dopamine receptor antagonist primarily used to treat psychotic disorders such as schizophrenia and bipolar disorder, was selected as the model drug due to its well-characterized analytical profile. By reducing its therapeutic dose, it is possible to mitigate common and severe side effects, including dyskinesia, drowsiness, dry mouth, orthostatic hypotension, and weight gain. Severe adverse reactions such as tardive dyskinesia, neuroleptic malignant syndrome, seizure threshold reduction, and leukopenia remain a concern, and its safety during pregnancy is uncertain. Nanoparticles represent a promising approach in modern drug delivery, enabling targeted administration of active substances to tissues and cells while minimizing systemic side effects and toxicity. As a result, they offer new possibilities in the diagnosis and treatment of various diseases, particularly in oncology. Biodegradable nanoparticles can be synthesized using materials such as polylactic acid (PLA), polylactic-co-glycolic acid (PLGA), and polymethyl methacrylate (PMMA). The combination of polymer-based drug carriers with permeability-enhancing surfactants allows for improved bioavailability, although cytotoxicity studies are essential to assess potential adverse effects. Research has shown that the integration of permeation enhancers and polymeric carriers can significantly improve drug absorption efficiency. Self-

assembling emulsion systems can be formed using titrimetric dilution with appropriate surfactant combinations, optimizing drug delivery. To ensure safety, the developed systems underwent biocompatibility testing on RPMI 2650 immortalized nasal epithelial cell lines using the MTT viability assay, confirming their suitability for intranasal administration. One of the fastest-growing areas of pharmaceutical technology is the development of nanoscale carrier systems. The formulation technique was chosen based on reliability and efficiency, with spray drying technology emerging as one of the most promising methods. The solid-phase nanoparticles were produced using the Büchi Nano Spray Dryer B-90 HP, which is particularly well-suited for laboratory-scale nanoparticle formulations. The production process involves four key steps: sample preparation, atomization and droplet drying, particle collection on an electrode, and recovery of the final powder. The physicochemical properties of the nanoparticles were analyzed using the Malvern Nano Zetasizer ZSP, while morphological characterization was performed via scanning electron microscopy (SEM). To ensure precise and efficient administration of the nanoparticulate formulations, a custom nasal dosing device was developed using FDM 3D printing technology. The design was tailored to anatomical features and further refined based on user feedback. The results of this research provide valuable insights into future advancements in nasal drug delivery systems, offering new opportunities for enhanced treatment efficacy and patient compliance.

Objectives

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We aimed to create a nasal filter with market potential, capable of providing effective protection against inhaled harmful substances and pathogens.

Our goal was to create a device that could be used both for air filtration and the intranasal administration of pharmaceutical compounds.

To enhance intranasal drug delivery, our aim was to develop different nanometer-sized drug carrier systems composed of penetration-enhancing excipients. These systems optimized the efficiency of drug absorption through the nasal mucosa.

A key goal was to conduct detailed analyses of the physical and chemical properties of the drug delivery systems. Additionally, our aim was to emphasize safe application by subjecting the nanocarrier systems and their components to rigorous biocompatibility tests.

Our aim was to establish a solid scientific foundation that could contribute to the long-term advancement of intranasal drug formulation and the development of personalized protective devices in the pharmaceutical industry and healthcare innovation

Methods

Design and prototype development of a custom nasal filters

Respiratory allergies and diseases are commonly caused by airborne allergens present in our environment. While improving overall air quality is an arduous and often impractical task, current efforts to mitigate air pollution frequently exacerbate the problem rather than solve it. Given these limitations, enhancing personal protective equipment (PPE) represents a more feasible and immediate solution. An ideal PPE should be simple, cost-effective, efficient, durable, and aesthetically unobtrusive. At present, surgical masks are the most commonly used form of airway protection. Despite significant advancements since their inception centuries ago, masks alone do not provide adequate protection against all airborne hazards. On the other hand, gas masks, while highly effective, are impractical for daily use due to their bulky design. The situation detailed above inspired the project, in which we apply a new approach to creating a unique nasal filter. The nasal filtration system consists of two subtypes: the nasal internal filter (NIF) and the nose external filter (NEF). These small portable individual devices are discreet, allowing users to wear them without any hassle wearing them. In operation, the device uses exclusively physical mechanisms, does not require external support, for example, a power source. It offers a wide range of customizable options to meet individual needs and ergonomic protection specifically for the nasal passages, which serve as the primary interface for air exchange between the body and the external environment. The improved nose filter can be considered a miniature, highly effective gas mask, designed to fit perfectly into the nasal cavity, providing targeted protection against airborne contaminants while maintaining user comfort and convenience, which was the most important goal of the project.

Nasal Filter Prototypes

The development of the Nasal Internal Filter (NIF) involved several prototypes, each with unique features and improvements. Below is a summary of each version:

MK.1

The first prototype, MK.1, was designed with two main components: the Shell and the Mobile Phase. The Shell acts as the structural framework, providing a comfortable fit for the user, while the Mobile Phase includes the tunnel that houses the filter core. Three variations of the

tunnel were created to meet different filtration needs, with the standard, extended, and extended finned tunnels offering various filtration capacities. The MK.1 features a unique bidirectional airflow system, ensuring air purification during inhalation and easy exhalation. The core filter is replaceable, allowing for efficient and cost-effective use. However, the system's small diameter can limit airflow, potentially making breathing difficult.

MK.2

The MK.2 prototype aimed to maximize the surface area for air exchange. The design included a coil spring with optimized damper and rebound settings, and a collapsible railing frame to protect the nasal cavity in case of impact. The expanded diameter of the tunnel improved airflow efficiency, but the thinner construction made it more fragile, and the presence of protruding moving parts could be uncomfortable for users. The MK.2 also improved upon the design of the tunnel to enhance functionality during both inhalation and exhalation.

MK.3

The MK.3 served as a compromise between the MK.1 and MK.2, combining the larger diameter of the MK.2's filtering tunnel with a more user-friendly design. It enclosed all moving parts within the shell, offering a comfortable and aesthetically pleasing solution. The MK.3 maintained the functionality of the previous models but faced challenges with fragility and complexity, making it somewhat more difficult to manufacture.

MK.4

The MK.4 design prioritized simplicity and ease of production. It utilized a pin mechanism to secure the filter core, allowing for easy replacement. This model is particularly suited for children due to its simplified manufacturing and smaller size. However, it has limited compatibility with different filter types, restricting its versatility.

MK.5

The MK.5, introduced in 2018, combined the best features of previous models while achieving optimal simplicity and efficiency. The MK.5 consists of only four parts—two shells, a coil spring, and a filter core—making it easier to manufacture. The design offers a larger filter surface similar to MK.2 and introduces a versatile ball-shaped filter core. This model has proven to be the most suitable for 3D printing, with the prototype successfully

produced using PLA filament. Several iterations of the MK.5 have been tested, with the final design offering both structural simplicity and durability.

Each iteration of the NIF prototype brought incremental improvements to the device's functionality, user comfort, and manufacturability. The MK.5 is currently considered the most effective and efficient design, especially for 3D printing applications.

NEF

The development of the Nose Emergency Filter (NEF) involved several prototypes, each designed to improve upon the previous version. Below is a summary of the different models:

NEF MK.1

The NEF MK.1 was the first prototype of the system, designed as a two-part device with a main housing and a removable filter core. The main housing was made of flexible polymer, shaped to accommodate a designated core channel and opening path. The filter core was cylindrical and easy to insert, providing effective nose protection in emergency situations. The core was designed for easy replacement, and the NEF could be used in environments where subtlety was secondary, such as in smoke-filled areas or during a tear gas attack. The NEF MK.1 was developed with the goal of providing enhanced protection while maintaining comfort and breathability, especially when worn under a standard surgical or cloth mask.

NEF MK.2

The NEF MK.2 improved upon the MK.1 by offering a lighter design and optimizing airflow. The tubular duct of the previous model was replaced with a more complex system that included additional vents to improve air exchange. This version also featured an upgraded design, which enhanced comfort and usability. The MK.2 was later updated to the E2 variant, which further improved the efficiency of air exchange by integrating additional vents on the surface. The MK.2 E2 was seen as a significant improvement, providing better airflow while maintaining the practicality and modularity of the original design.

NEF MK.1 E2

The NEF MK.1 E2, the final prototype, combined the design principles of the earlier models with enhancements to improve air exchange efficiency. The MK.1 E2 retained the key features of the original MK.1 but offered better overall performance due to its improved

airflow and filtration capabilities. The modular design, with interchangeable filters, made the device adaptable for different users and environments, making it an ideal choice for emergency situations.

The NEF system utilized SYNFAFASAN G3 filters, known for their durability and efficiency. These filters are highly effective, meeting the G3 standard for filtration and able to withstand extreme conditions, including high humidity and temperatures up to 100°C. The SYNFAFASAN G3 filter provides excellent breathability and energy efficiency, making it an ideal choice for the NEF. It also offers a high dust-proof capacity, reducing the need for frequent filter replacements and lowering operating costs. Throughout its development, the NEF system remained focused on providing efficient and reliable nose protection in emergency situations, with an emphasis on ease of use, breathability, and modularity. The final NEF MK.1 E2 prototype represents a highly functional and versatile respirator, suitable for a range of emergency applications.

The combination of personal nasal filters and pharmaceutical nasal dispensers offers a novel solution for respiratory health, providing both preventive and therapeutic benefits. Nasal filters block allergens and pollutants, while pharmaceutical sprays deliver medication directly to the affected areas. This synergy improves treatment effectiveness, extends drug lifespan by reducing degradation, and enhances patient adherence. Our research shows that pairing these systems offers a comprehensive approach to respiratory care, improving compliance and outcomes.

Solid Nanoparticles for Nasal Formulations

Nasal drug delivery is beneficial for rapid drug absorption and bypassing the blood-brain barrier. It reduces the first-pass metabolism in the liver, and many large molecules can be delivered nasally with the help of permeability enhancers. Traditional nasal preparations, such as solutions or suspensions, are stable but may cause discomfort and limited drug absorption. Solid lipid nanoparticles (SLNs) were developed to improve drug penetration, and a new nasal dispenser was designed to complement this formulation.

Chlorpromazine (CPZ), used for psychotic disorders, was chosen for its well-known side effects and the need to reduce doses. Nanoparticles reduce systemic effects and toxicity, improving drug delivery. Biodegradable nanoparticles made from PLA, PLGA, and PMMA enhance targeted therapy, especially with the addition of amphiphilic compounds. These

compounds increase the bioavailability of poorly soluble drugs, though they may cause irritation, requiring cytotoxicity testing.

Nanoparticle formulation process

In our experiments, solid nanoformulations were produced using spray-drying technology, with particle sizes ranging from 30 to 300 nm. Specialized nasal dispensers were developed using 3D printing for precise drug delivery. Nasal administration provides quick absorption and reduces side effects, though challenges remain. Ongoing research into nanoparticles and drug delivery systems is crucial to improving nasal therapies and ensuring better therapeutic outcomes.

Examination methods of particles

For the examination of formulated nano-sized drug carriers, several standard instrumental pharmacofarm analyses were performed. Solid-phase nanoparticles were generated using the Büchi Nano Spray Dryer B-90 HP apparatus. The size, shape, and surface area of the formulated nanoparticles were analyzed using a Hitachi Tabletop SEM. The particle size of the formulated nanoparticles was determined using a dynamic light-scattering device. The dissolution profile of CPZ was assessed according to the European Pharmacopoea, using an ERWEKA DT 950 dissolution tester. The disintegration of nanoparticles was studied in a neutral pH physiological saline solution (0.9% sodium chloride) according to the Pharmacopoea. Stability test had been performed according to the standard industrial normal state and forced stability methods. Each cases LC-MS was employed for all experiments to determine the concentration of the active ingredient. To ensure biocompatibility various cell viability and preoliferation test had been carried out. To evaluate the toxic characteristics of the excipients selected in the study, an 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide) assay was performed on RPMI and Caco-2 cells.

Results

Selection of Core Materials and Excipients for Nasal Particles

We followed pharmaceutical guidelines to select excipients, ensuring their purity and quality. Based on prior research and international literature, we assessed potential incompatibilities and confirmed stability through standard and accelerated tests. The formulations remained stable, including UV protection for the active ingredient after four weeks of storage. In vitro cell culture studies ensured non-toxicity, and European Pharmacopoeia methods were employed. Self-assembling heterogeneous systems were developed using CPZ and excipients, and a pseudoternary phase diagram was constructed. Five compositions were selected, which remained stable after four weeks. The active ingredient concentration was increased to 250 mg for animal study requirements.

Setting Formulation Parameters

We identified key manufacturing parameters in spray-drying to achieve desired characteristics. Initial tests showed a significant CPZ loss, prompting adjustments, including reducing inlet temperature to 60 °C and raising chamber pressure. The flow rate was increased, and light exclusion was implemented. These parameters allowed safe and effective nanospray technology usage for the second series of experiments.

Determination of Particle Size and Distribution

The particle size distribution of formulations ranged from 10 to 900 nm. Compositions 1–5 showed small size differences, while Compositions 6–9 displayed particles between 250 nm and 750 nm. Spray drying Composition 9 resulted in larger particles (~750 nm), whereas Composition 8 had smaller particles (~250 nm).

Evaluation of Size and Morphology of Solid Nanostructures

Scanning Electron Microscope (SEM) evaluations confirmed spherical particles with a heterogeneous distribution in the 10–900 nm range for all compositions. Both experimental series displayed consistent morphology, verifying the design.

Evaluation of Cytotoxicity on RPMI 2650 Nasal Epithelial Cells

MTT assays showed no significant reduction in cell viability for any excipients or their mixtures. Slight cytotoxicity occurred at higher concentrations, but values did not approach the IC50 threshold.

CPZ Dissolution Measurements

Dissolution tests revealed rapid release of CPZ, with 60% released within 15 seconds and 100% within 45 seconds. The dissolution profiles remained similar across compositions, with 70–75% of the active ingredient encapsulated during formulation. No significant differences in dissolution kinetics were found.

Animal Studies of CPZ Utilization

The CPZ content in formulations exceeded the expected 50%, with Composition 9 showing the highest at 62.9%. Animal studies indicated that Compositions 8 and 9 were most promising. Composition 9 displayed rapid CPZ absorption, while Composition 8 reached a plateau phase with higher blood levels than Compositions 6 and 7. The inclusion of HPBCD likely enhanced solubility, bioavailability, and permeability, improving absorption and prolonging blood levels. These results suggest HPBCD's role in stabilizing drug release and facilitating faster, more efficient absorption across membranes, warranting further investigation.

Discussion

The first part of my dissertation explores the potential of personalized nasal filters to transform healthcare by offering targeted respiratory protection and drug delivery. These filters, designed as small, easy-to-use devices placed in the nasal passages, effectively block airborne pathogens and allergens, benefiting individuals with respiratory diseases such as asthma and allergies. Combined with a suitable drug delivery system, they take advantage of the high absorption capacity of the nasal mucosa to deliver medication efficiently, reducing side effects. My research emphasizes the importance of collaboration between engineers and healthcare professionals to develop and clinically evaluate these tools. Future advancements in ultrafine filter technology, sustainable materials, and IoT integration for performance tracking offer promising directions for the field. These innovations are crucial for broadening the adoption of personalized nasal filters in healthcare. The second phase of my research focused on the development of solid-phase nano drug delivery systems using amphiphilic excipients. I examined key factors in nanospray drying, such as temperature and light exclusion, which significantly improved the stability of active pharmaceutical ingredients (APIs). Five self-organizing, heterogeneous dispersed systems were produced, showcasing the potential of nanospray drying technology for stable, efficient drug carriers. All formulations underwent biocompatibility testing on RPMI 2650 nasal cells, confirming the safety of the excipients used. Stability and dissolution tests showed rapid API release, and microCT analysis ruled out excessive nanoparticle aggregation. A 3D-printed nasal dosing device was designed for precise drug administration, ensuring practical applicability. These findings contribute to the development of nasal or oral nanosystems and related biocompatibility tests for targeted drug delivery. In the third phase, I investigated nasal formulations containing chlorpromazine and amphiphilic permeation enhancers to improve drug absorption. Amphiphilic compounds were shown to stabilize particle size, contributing to consistent therapeutic outcomes. Among the tested compositions, Composition 8 exhibited the least impact on cell viability, indicating its safety, while Composition 5 showed lower tolerability due to cytotoxic potential. Dissolution studies revealed no significant differences among the compositions, but Composition 8 ensured the fastest disintegration. Animal studies confirmed that Composition 8 was the most biocompatible, while Composition 5, despite its promising results, required caution due to potential nasal mucosa irritation. These findings underscore the importance of optimizing excipient concentration and exploring new amphiphilic compounds for the development of innovative nasal medicines.

New findings

In the course of our research, we have successfully developed a special drug delivery system that combines the advantages of nasal screening and drug intake with an innovative nasal protective device

- Development of a multifunctional, marketable nasal screening and drug delivery device: We have created an innovative device that is suitable for filtering out harmful substances and pathogens in the air as well as for administering medicines through the nasal mucosa. This makes the tool not only protective against respiratory diseases, but also provides new opportunities for targeted intranasal therapies.
- Development of nanoscale drug delivery systems: We have created nano-carrier systems containing penetration-enhancing excipients that optimize the absorption of active ingredients through the nasal mucosa, increasing therapeutic efficacy.
- Perform detailed physical and chemical analyses: Detailed physical and chemical characterization of drug delivery systems ensures that they remain stable and effective under the desired application conditions.
- Performing biocompatibility tests: In order to ensure safe application, the developed nanosystems and their components have been subjected to comprehensive biocompatibility tests, confirming their adequate tolerability.
- Laying the scientific foundation for future developments: The results of this research can contribute to the long-term development of intranasal formulation and the development of personalised protective equipment in the pharmaceutical and healthcare innovations.

These results will facilitate the further development of targeted drug delivery systems and provide a new perspective for therapeutic options through the nasal mucosa.

Summary

In summary, my experimental work demonstrates the transformative potential of personalized nasal filters and advanced drug delivery systems in modern medicine. By adapting filters to individual needs, patients with respiratory conditions can experience enhanced protection and improved quality of life. The rapid absorption of drugs through the nasal mucosa presents an effective alternative to systemic administration, minimizing side effects and enhancing therapeutic outcomes. The application of nanospray drying technology for solid-phase nano drug carriers has shown promise in creating stable and biocompatible formulations for nasal use. The role of amphiphilic compounds in improving drug absorption and stability is critical for the development of efficient nasal drug delivery systems. This research offers valuable insights into the future of nasal drug delivery and respiratory protection, laying the groundwork for innovations in the field.



Registry number: DEENK/35/2025.PL
Subject: PhD Publication List

Candidate: Thinh To Quoc
Doctoral School: Doctoral School of Pharmacy

List of publications related to the dissertation

1. To Quoc, T., Bíró, K., Pető, Á., Kósa, D., Haimhoffer, Á., Lekli, I., Pallér, Á., Bak, I., Gyöngyösi, A., Fehér, P., Bácskay, I., Ujhelyi, Z.: The Role of Amphiphilic Compounds in Nasal Nanoparticles.
AAPS PharmSciTech. 25 (8), 1-14, 2024.
DOI: <http://dx.doi.org/10.1208/s12249-024-03000-8>
IF: 3.4 (2023)
2. To Quoc, T., Bíró, K., Pető, Á., Kósa, D., Sinka, D. Z., Lekli, I., Kiss-Szikszai, A., Budai, I., Béres, M., Vecsernyés, M., Fehér, P., Bácskay, I., Ujhelyi, Z.: Development and Evaluation of an FDM Printed Nasal Device for CPZ Solid Nanoparticles.
Molecules. 28 (11), 1-15, 2023.
DOI: <http://dx.doi.org/10.3390/molecules28114406>
IF: 4.2
3. To Quoc, T., Bácskay, I., Fehér, P., Pallér, Á., Papp, B., Bíró, K., Ujhelyi, Z.: Personalized Nasal Protective Devices: Importance and Perspectives.
Life (Basel). 13 (11), 1-14, 2023.
DOI: <http://dx.doi.org/10.3390/life13112116>
IF: 3.2

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The Candidate's publication data submitted to the iDEa Tudóstér have been validated by DEENK on the basis of the Journal Citation Report (Impact Factor) database.



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