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MINISTRY OF HEALTH OF UKRAINE
NATIONAL UNIVERSITY OF PHARMACY
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QUALIFICATION WORK

on the topic: **«DEVELOPMENT OF THE COMPOSITION OF SUPPOSITORIES WITH BISACODYL FOR USE IN VETERINARY MEDICINE»**

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Kharkiv – 2025

ANNOTATION

The qualification work is devoted to the research on development of rectal suppositories with bisacodyl for veterinary use.

The qualification work is set out on 53 pages of typewritten text, consists of an introduction, three chapters, general conclusions, list of references and 1 appendix. The bibliography contains 30 sources. The work is illustrated with 11 tables and 7 figures.

Key words: suppository, technology, bisacodyl, veterinary, cocoa butter.

АНОТАЦІЯ

Кваліфікаційна робота присвячена дослідженням з розроблення ректальних супозиторіїв на основі бісакодилу для ветеринарного застосування.

Кваліфікаційна робота викладена на 53 сторінках машинописного тексту, складається зі вступу, трьох розділів, загальних висновків, списку використаних літературних джерел та 1 додатку. Список літератури містить 30 джерел. Робота ілюстрована 11^{ма} таблицями та 7^{ма} рисунками.

Ключові слова: супозиторії, технологія, бісакодил, ветеринарія, масло какао.

CONTENTS

INTRODUCTION

Actuality of the topic. Bisacodyl is a powerful laxative that stimulates intestinal motility and is used to treat constipation in both humans and animals. Although its use in veterinary practice is less common, it can be useful in cases of severe constipation in dogs, cats, and some other species.

The use of bisacodyl in the form of suppositories is especially effective in cases where oral administration is not possible or when a rapid effect is required. Suppositories stimulate receptors in the rectum, causing defecation 15-60 minutes after administration. This is especially important in animals with chronic constipation associated with impaired intestinal motility, the postoperative period, or dehydration.

The main indications for the use of bisacodyl in animals are:

- Chronic constipation associated with a sedentary lifestyle or age-related changes.
- Preparation for diagnostic procedures, such as X-ray examination of the abdominal organs.
- Facilitates defecation in cases of anorectal pathologies (e.g. anal fistulas, rectal prolapse).

Despite the effectiveness of bisacodyl, possible contraindications and side effects should be considered. The drug is not recommended for intestinal obstruction, inflammatory bowel diseases or dehydration. In some cases, adverse reactions such as intestinal spasms and mucosal irritation are possible.

Before using bisacodyl in animals, a veterinarian should be consulted to determine the optimal dosage and avoid potential complications. The use of suppositories can be a useful tool in maintaining the health of the digestive system of animals, provided that the correct dosage and supervision by a specialist

Therefore, research on the creation of the new drug for animals with bisacodyl is a timely task of modern pharmacy.

The aim of our work is to develop suppositories with the API bisacodyl for the further usage in veterinary.

Tasks of the study

To achieve the aim, the following tasks were set:

- to analyze data from scientific literature regarding the peculiarities of the use of laxatives in animals;
- to analyze the prospects of bisacodyl as a laxative agent for domesticated animals like dogs and cats and the possibility of its incorporation into the form of suppositories;
- to develop the composition and compounding technology of suppositories with bisacodyl for animals;
- to study physicochemical and pharmacotechnological properties of the obtained suppositories and to evaluate their shelf-life.

Object of study. Pharmaceutical study of the development of composition and laboratory technology of veterinarian suppository with bisacodyl.

Subject of study. Development of composition and laboratory technology of veterinarian suppository with bisacodyl.

Methods of research. Bibliosemantic, well-known organoleptic (appearance), physico-chemical (average mass and deviation in mass), pharmacotechnological (melting point, resistance to destruction, time of complete deformation), organizational-economic and mathematical (statistical processing of results) methods were used to solve the problems set in the qualification work. The chosen study methods allow to objectively evaluate the qualitative indicators of the studied samples of suppositories on the basis of experimentally obtained and statistically processed results.

Practical significance of the obtained results. Research on the development of the composition and technology of suppositories based on the API bisacodyl for veterinary use will satisfy the existing need for laxatives for animals, primarily domestic dogs and cats, as such products are currently unavailable in Ukraine.

Implementation of results and publication. The results of the work were discussed within the framework of scientific seminar of the SSS of the pharmaceutical technology of drugs department during the XXXI International scientific and practical conference of young scientists and students “Topical issues of creating new drugs” (see App. A), 1 theses was published.

Structure and scope of qualification work.

The qualification work is set out on 53 pages of typewritten text, consists of an introduction, three chapters, general conclusions, list of references and 1 appendix. The bibliography contains 30 sources. The work is illustrated with 11 tables and 7 figures.

CHAPTER 1
PROSPECTS OF BISACODYL SUPPOSITORIES USAGE IN ANIMALS

1.1. Peculiarities of laxative usage in veterinary practice

Laxatives are a class of medications used to facilitate the passage of feces through the gastrointestinal (GI) tract. In veterinary practice, laxatives play a crucial role in managing constipation, obstipation, and other conditions that affect the normal function of the GI tract. The use of laxatives in animals, however, comes with its own set of peculiarities and considerations that differ from their use in humans [12].

There are 5 main types of laxatives: bulk-forming, osmotic, lubricant, stimulant and prokinetic [12, 14].

1. Bulk-Forming Laxatives

Bulk-forming laxatives, also known as fiber supplements, increase the volume and water content of the stool, making it easier to pass. Common examples include psyllium, methylcellulose, and bran. These laxatives are particularly useful in animals with chronic constipation or those that require a long-term solution to maintain regular bowel movements.

2. Osmotic Laxatives

Osmotic laxatives work by drawing water into the colon, which softens the stool and increases its volume. Examples include lactulose, magnesium sulfate, and polyethylene glycol (PEG). These laxatives are effective for acute constipation and can be used in a variety of species, including dogs, cats, and horses.

3. Lubricant Laxatives

Lubricant laxatives coat the feces, making them easier to pass through the GI tract. Mineral oil is a common example. While effective, mineral oil should be used with caution, especially in small animals, as it can cause aspiration pneumonia if ingested improperly.

4. Stimulant Laxatives

Stimulant laxatives increase the motility of the GI tract, promoting the movement of feces. Examples include bisacodyl and senna. These laxatives are typically used for short-term relief of constipation and should be used with caution in animals with underlying GI disorders.

5. Prokinetic Agents

Prokinetic agents enhance the motility of the GI tract by stimulating the muscles. Examples include metoclopramide and cisapride. These agents are useful in animals with decreased GI motility due to conditions such as ileus or megacolon.

Mechanisms of action of each type of laxative differ. It gives the veterinarian the opportunity to choose the one that solves the reason of constipation of the certain animals, including the differences in nutrition [12, 14, 20, 24].

Bulk-forming laxatives absorb water and expand, increasing the volume of the stool. This mechanical action stimulates the muscles of the colon to contract, facilitating the movement of feces. They are particularly effective in animals with a low-fiber diet or those that need to increase their stool bulk.

Osmotic laxatives work by creating an osmotic gradient that draws water into the colon. This increased water content softens the stool and increases its volume, making it easier to pass. Osmotic laxatives are particularly useful in animals with dehydration or those that require rapid relief from constipation.

Lubricant laxatives coat the surface of the feces, reducing friction and making it easier for the stool to pass through the colon. They are particularly useful in animals with hard, dry stools or those that have difficulty passing feces due to anatomical abnormalities.

Stimulant laxatives increase the motility of the GI tract by stimulating the muscles. They work by increasing the frequency and intensity of contractions, which helps to move the stool through the colon. These laxatives are particularly useful in animals with decreased GI motility or those that require rapid relief from constipation.

Prokinetic agents enhance the motility of the GI tract by stimulating the muscles. They work by increasing the frequency and intensity of contractions, which

helps to move the stool through the colon. These agents are particularly useful in animals with decreased GI motility due to conditions such as ileus or megacolon.

Also, indications of laxatives for the animals can covers different health conditions, among which there are main 5 directions: constipation, obstipation, megacolon, post-surgical care and preventive care.

1. Constipation

Constipation is one of the most common indications for the use of laxatives in veterinary practice. It can be caused by a variety of factors, including dietary issues, dehydration, lack of exercise, and underlying medical conditions (fig. 1.1). Laxatives can help to relieve constipation by softening the stool, increasing its volume, or stimulating the muscles of the colon [2, 9].

Fig. 1.1. Common causes of constipation in dogs

2. Obstipation

Obstipation is a severe form of constipation characterized by the inability to pass feces. It can be life-threatening and requires immediate intervention. Laxatives, particularly osmotic and stimulant laxatives, are often used in combination with other treatments to manage obstipation.

3. Megacolon

Megacolon is a condition characterized by a dilated and weak colon that is unable to effectively move feces. It is most commonly seen in cats but can also occur in other species.

Megacolon, in some cases, can occur after a large amount of stool leaves the colon distended and the nerves are permanently damaged in the large intestine. An example of how this may occur is trauma to the animal's pelvis. This would result in obstruction of the normal passage of the stool. However, any condition that results in the purposeful obstruction of feces will definitely cause megacolon. Other causes may be:

- Tumor
- Medication that causes constipation
- Painful elimination of stool
- Obstruction in the intestine such as a hair mass
- Spinal issues (some breeds may be predisposed)

Laxatives, particularly bulk-forming and osmotic laxatives, are used to manage the symptoms of megacolon and prevent the accumulation of feces [4, 19, 23].

4. Post-Surgical Care

Post-surgical care often involves the use of laxatives to prevent constipation and ensure that the animal can pass stool comfortably. This is particularly important in animals that have undergone abdominal surgery or those that are receiving pain medications that can cause constipation.

5. Preventive Care

Laxatives can also be used as part of a preventive care regimen in animals that are prone to constipation or have a history of GI issues. Regular use of bulk-forming laxatives, for example, can help to maintain regular bowel movements and prevent the development of constipation [8-10, 16].

Nevertheless, laxatives have contraindications and precautions such as obstruction, dehydration, electrolyte imbalance, aspiration risk, and possible drug interactions.

Laxatives should not be used in animals with a known or suspected obstruction of the GI tract. In such cases, the use of laxatives can worsen the condition and lead to complications. Diagnostic imaging and other diagnostic tests should be performed to rule out obstruction before administering laxatives.

Dehydration can exacerbate constipation and make the use of laxatives less effective. Animals that are dehydrated should be rehydrated before administering laxatives to ensure that the stool can be properly softened and passed.

Osmotic laxatives can cause electrolyte imbalances, particularly in animals that are already dehydrated or have underlying kidney disease. Electrolyte levels should be monitored in these animals, and appropriate adjustments should be made to the laxative regimen.

Lubricant laxatives, particularly mineral oil, can pose a risk of aspiration pneumonia if the animal vomits or regurgitates. These laxatives should be used with caution in animals that are at risk of aspiration, such as those with a history of vomiting or regurgitation.

Some laxatives can interact with other medications, particularly those that affect the GI tract. For example, stimulant laxatives can increase the absorption of certain drugs, while osmotic laxatives can decrease the absorption of others. It is important to consider potential drug interactions when selecting a laxative for an animal [12, 20, 21, 24].

The dosage and administration of laxatives can vary depending on the species, size, and condition of the animal. It is important to follow the manufacturer's guidelines and adjust the dosage as needed based on the animal's response. In some cases, a combination of laxatives may be necessary to achieve the desired effect.

Regular monitoring is essential to ensure that the laxative is effective and to detect any adverse effects. This may include monitoring the animal's bowel movements, hydration status, and electrolyte levels. Follow-up appointments may be necessary to adjust the laxative regimen and address any ongoing issues.

Dietary management is an important aspect of laxative therapy. Animals that are prone to constipation may benefit from a high-fiber diet or the addition of fiber

supplements. In some cases, dietary changes alone may be sufficient to manage constipation without the need for laxatives.

Environmental and behavioral factors can also play a role in the development of constipation. Ensuring that the animal has access to clean water, a comfortable environment, and regular exercise can help to prevent constipation and reduce the need for laxatives.

Client education is crucial for the successful management of constipation and the use of laxatives. Owners should be informed about the importance of regular bowel movements, the signs of constipation, and the proper use of laxatives. They should also be advised to monitor their pet's response to the laxative and report any adverse effects to their veterinarian.

In order to understand better the peculiarities of the usage laxatives in animals, the number of case studies were examined [2, 10].

Case 1: Chronic Constipation in a Cat

A 7-year-old domestic shorthair cat presented with a history of chronic constipation. The cat had a low-fiber diet and limited access to water. The veterinarian recommended a combination of a high-fiber diet and the use of psyllium as a bulk-forming laxative. The cat’s bowel movements improved, and the owner was educated on the importance of maintaining a high-fiber diet and ensuring adequate water intake.

Case 2: Obstipation in a Horse

A 10-year-old gelding presented with signs of colic and a history of obstipation. Diagnostic imaging revealed a large amount of impacted feces in the colon. The veterinarian administered a combination of magnesium sulfate and mineral oil to soften the stool and facilitate its passage. The horse was also rehydrated and monitored closely for signs of improvement.

Case 3: Post-Surgical Constipation in a Dog

A 5-year-old Labrador retriever presented with constipation following abdominal surgery. The dog was receiving pain medications that were known to cause constipation. The veterinarian prescribed lactulose as an osmotic laxative and

recommended regular walks to encourage bowel movements. The dog's constipation resolved, and the owner was advised to continue the laxative for a few days after the surgery.

Therefore, Laxatives are an essential tool in the management of constipation and other GI disorders in veterinary practice. The choice of laxative and the approach to treatment should be tailored to the individual animal, taking into account factors such as the underlying cause of the constipation, the animal's overall health, and the potential risks and benefits of the treatment. By understanding the peculiarities of laxative usage in veterinary practice, veterinarians can effectively manage GI issues and improve the quality of life for their patients.

1.2. The comparative analysis of the veterinary guides for the use of laxatives in domesticated animals

In order to choose the most appropriate laxative agent for the drug to be created, the comparative analysis of the veterinary guides for the use of laxatives in domesticated animals in Ukraine, the USA and the EU was conducted.

Ukraine

Regulatory Framework in Ukraine include 2 state levels and is also under the influence of the standards of the EU:

- Primary Regulatory Body: State Veterinary and Phytosanitary Service of Ukraine (Derzhveterinarnaya sluzhba Ukrainy).
- Influence of European Standards: Ukraine aims to align its veterinary practices with European standards, which can influence the types of laxatives approved and the protocols used.
- Local Regulations: Each region may have additional local regulations that veterinarians must follow.

According to the open-access information, the most frequently met laxatives, prescribed to animals in Ukraine, include the following agents:

- Bulk-forming laxatives: Psyllium, methylcellulose.
- Osmotic laxatives: Magnesium sulfate (Epsom salt), lactulose.

- Lubricant laxatives: Mineral oil, liquid paraffin.
- Stimulant laxatives: Senna, bisacodyl.
- Enemas: Less commonly used but available in some cases.

When prescribing these agents, veterinarians follow the rules of weight-based dosage, low-dosage in the beginning of the therapy, detailed dosing charts. Usually they prefer oral administration as the easiest, but enemas may be used in severe cases.

- Weight-Based Dosage: Dosage is typically based on the animal's weight and the specific condition being treated.
- Starting Low: Veterinarians often recommend starting with a lower dose and gradually increasing if necessary.
- Detailed Dosing Charts: Provided in veterinary textbooks and guidelines, which are regularly updated.

During the whole process of animal treatment veterinarians provide regular monitoring of the animal’s condition to ensure the laxative is effective and to avoid complications. It is also recommended to assess the animal’s response to treatment and to make any necessary adjustments, as well as to maintain the detailed records for each animal.

Special attention is given to the use of laxatives in pregnant or lactating animals, with caution advised to avoid adverse effects. Animals with underlying health conditions, such as kidney disease or heart problems, may require different protocols and dosages. The use of laxatives in exotic pets and small mammals may also require different protocols and dosages, often based on species-specific guidelines [14, 16].

The cost and availability of laxatives can vary, with some products being more accessible than others. Veterinarians often provide detailed instructions to pet owners on how to administer laxatives and what to watch for in terms of side effects.

The USA

In the USA, the primary regulatory bodies for veterinary medications, including laxatives, are the Food and Drug Administration (FDA) and the United

States Department of Agriculture (USDA). Additional oversight is provided by state veterinary boards, which can have their own specific regulations. All veterinary medications, including laxatives, must be FDA-approved and properly labeled.

The most common laxatives in domestic animals are :

- Bulk-forming laxatives: Psyllium, methylcellulose.
- Osmotic laxatives: Magnesium sulfate (Epsom salt), lactulose.
- Lubricant laxatives: Mineral oil, liquid paraffin.
- Stimulant laxatives: Senna, bisacodyl.
- Enemas: Fleet enemas, warm water enemas, and other types of enemas are commonly used.

Dosage is typically based on the animal's weight and the specific condition being treated. Veterinarians often recommend starting with a lower dose and gradually increasing if necessary. Detailed dosing charts are provided in veterinary textbooks and guidelines, which are regularly updated. Oral administration is the most common route, but enemas are also frequently used, especially in severe cases [2, 4, 6, 12, 20].

Regular monitoring of the animal's condition is essential to ensure the laxative is effective and to avoid complications. Follow-up visits are recommended to assess the animal's response to treatment and to make any necessary adjustments. Detailed records of treatment and response are maintained for each animal.

Special attention is given to the use of laxatives in pregnant or lactating animals, with caution advised to avoid adverse effects. Animals with underlying health conditions, such as kidney disease or heart problems, may require different protocols and dosages. The use of laxatives in exotic pets and small mammals may also require different protocols and dosages, often based on species-specific guidelines. There is a strong emphasis on evidence-based medicine, with many veterinarians consulting recent research and clinical trials to inform their treatment decisions.

The USA has a wide range of commercially available laxative products, which can vary in cost and availability. Veterinarians often provide detailed instructions to

pet owners on how to administer laxatives and what to watch for in terms of side effects. The use of telemedicine is becoming more common, allowing for remote consultations and follow-up.

The European Union (EU) Countries

The primary regulatory body for veterinary medications in the European Union (EU) is the European Medicines Agency (EMA) and the European Commission. Each EU country has its own national veterinary boards that enforce these regulations. The EU has harmonized standards for veterinary medications, ensuring a consistent approach across member states.

The most common laxatives in domestic animals are:

- Bulk-forming laxatives: Psyllium, methylcellulose.
- Osmotic laxatives: Magnesium sulfate (Epsom salt), lactulose.
- Lubricant laxatives: Mineral oil, liquid paraffin.
- Stimulant laxatives: Senna, bisacodyl.
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Dosage is typically based on the animal's weight and the specific condition being treated. Veterinarians often recommend starting with a lower dose and gradually increasing if necessary. Detailed dosing charts are provided in veterinary guidelines and textbooks, which are regularly updated. Oral administration is the most common route, but enemas are also frequently used, especially in severe cases.

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evidence-based medicine, with many veterinarians consulting recent research and clinical trials to inform their treatment decisions. The EU has strict regulations on the use of medications to ensure animal welfare and public health.

The EU has a wide range of commercially available laxative products, which can vary in cost and availability. Veterinarians often provide detailed instructions to pet owners on how to administer laxatives and what to watch for in terms of side effects. The use of telemedicine is becoming more common, allowing for remote consultations and follow-up. There are specific regulations for the import and export of veterinary medications between EU countries, which can affect availability and cost [23, 24].

Based on the information given above, comparative analysis of the veterinarians' approach to the use of laxatives in domesticated animals by the indicators of regulatory environment, common laxatives, their dosage and administration, monitoring and follow-ups, special consideration and practical consideration is shown on Table 1.1.

Table 1.1

Comparative analysis of the veterinarians' approach to the use of laxatives in domesticated animals

Ukraine	**The USA**	**The EU countries**
1	**2**	**3**
Regulatory environment		
Regulated by the State Veterinary and Phytosanitary Service, with guidelines influenced by European standards.	Regulated by the FDA and USDA, with additional oversight from state veterinary boards.	Regulated by the EMA and the European Commission, with national veterinary boards enforcing these regulations. The EU has the most stringent

Continuation of table 1.1

1	2	3
		regulations, ensuring high standards of animal welfare and public health.
Common Laxatives		
All three regions use similar types of laxatives, including bulk-forming, osmotic, lubricant, and stimulant laxatives.		
-	The USA and EU countries may have a wider range of commercially available products, including enemas.	
Dosage and Administration		
All regions recommend starting with a lower dose and gradually increasing if necessary. Detailed dosing charts are provided in veterinary guidelines and textbooks. The route of administration is primarily oral, with enemas used in severe cases.		
Monitoring and Follow-up		
All regions emphasize the importance of regular monitoring and follow-up visits to ensure the effectiveness of the treatment and to make any necessary adjustments. Detailed record-keeping is a standard practice in all regions.		
Special Considerations		
All regions pay special attention to the use of laxatives in pregnant or lactating animals and those with underlying health conditions. The use of laxatives in exotic pets and small mammals may require different protocols and dosages.		

End of table 1.1

1	2	3
-	The USA and EU countries place a strong emphasis on evidence-based medicine, with frequent updates in treatment protocols based on the latest research.	
Practical Considerations		
-	Cost and Availability: The USA and EU countries have a wider range of commercially available laxative products, which can vary in cost and availability.	
-	Telemedicine: The use of telemedicine is becoming more common in the USA and EU countries, allowing for remote consultations and follow-up.	
Client Education: Veterinarians in all regions provide detailed instructions to pet owners on how to administer laxatives and what to watch for in terms of side effects.		
		Cross-Border Regulations: The EU has specific regulations for the import and export of veterinary medications, which can affect availability and cost.

Therefore, the veterinary guidelines for the use of laxatives in domesticated animals in Ukraine, the USA, and EU countries share many similarities, particularly in the types of laxatives used, dosage and administration protocols, and the importance of monitoring and follow-up. However, there are some key differences in such areas as regulatory environment (the EU has the most stringent regulations, followed by the USA, with Ukraine aligning more closely with European standards), emphasis on evidence-based medicine (the USA and EU countries place a strong

emphasis on evidence-based medicine, leading to more frequent updates in treatment protocols), commercial availability (the USA and EU countries have a wider range of commercially available laxative products, including enemas) and telemedicine (the use of telemedicine is more prevalent in the USA and EU countries, enhancing the accessibility of veterinary care).

1.3. The use of bisacodyl in veterinary practice: practical applications, pros, and cons

Bisacodyl (fig. 1.2) is a stimulant laxative commonly used in human medicine, but it also has applications in veterinary practice, particularly for treating constipation and facilitating bowel evacuation in small and large animals.

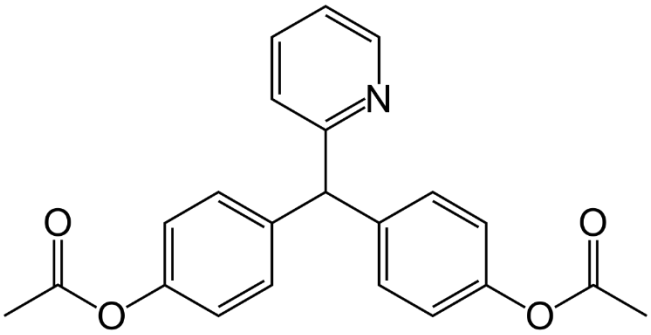

Fig. 1.2. Structural formula of bisacodyl

Bisacodyl is a diphenylmethane derivative that acts primarily on the colon by stimulating the myenteric plexus, increasing peristalsis, and promoting water and electrolyte secretion into the intestinal lumen. Unlike osmotic laxatives (e.g., lactulose, polyethylene glycol), bisacodyl does not rely on water retention but directly stimulates colonic motility, making it effective in cases of slow-transit constipation [1].

Practical use in veterinary medicine includes clinical recommendation both for small and large animals. The general guides are given below.

1. Small Animals (Dogs and Cats)

- Indications:

- Idiopathic constipation
- Postoperative ileus (in selected cases)
- Fecal impaction (as part of a multimodal approach)

- Dosage:
  - Dogs: 5–20 mg orally once daily (depending on size)
  - Cats: 2.5–5 mg orally once daily (use with caution due to sensitivity)
- Administration:
  - Best given on an empty stomach for faster action.
  - Available in enteric-coated tablets or suppositories (useful in hospitalized patients).

2. Large Animals (Horses, Ruminants)

- Horses: Used for impaction colic (5–30 mg/kg via nasogastric tube, though less common than mineral oil or osmotic agents).
- Ruminants: Rarely used due to the risk of disrupting forestomach motility; osmotic laxatives (magnesium sulfate) are preferred.

Advantages of Bisacodyl

1. Rapid Onset: Works within 6–12 hours (faster than lactulose, which takes 24–48 hours).
2. Predictable Effect: More reliable than bulk-forming laxatives (e.g., psyllium) in severe constipation.
3. Minimal Systemic Absorption: Low risk of systemic side effects when used at appropriate doses.
4. Cost-Effective: Cheaper than some prescription laxatives like lubiprostone or cisapride [12, 13].

As any other drugs, bisacodyl also has disadvantages and risks, that must be examined and evaluated by the veterinarian when prescribing it to the animal. There are main 4 risks that require special attention:

1. Potential for Overstimulation: Can cause abdominal cramping, diarrhea, or electrolyte imbalances (hypokalemia).

2. Not Suitable for Chronic Use: Prolonged use may lead to laxative dependency and colonic atony.

3. Limited Efficacy in Obstructions: Contraindicated in complete bowel obstruction.

4. Species Sensitivity: Cats are more prone to severe cramping; lower doses are recommended.

The comparison of bisacodyl and other popular laxatives in animals is given in Table 1.2 [1, 12, 13].

Table 1.2

Comparison with Other Laxatives

Laxative	Mechanism	Onset	Pros	Cons
Bisacodyl	Stimulant	6–12 h	Fast, reliable, cost-effective	Cramping, not for chronic use
Lactulose	Osmotic	24–48 h	Safe for long-term use	Slow, bloating, flatulence
Mineral Oil	Lubricant	12–24 h	Useful in horses/ruminants	Aspiration risk, malabsorption
Psyllium	Bulk-forming	24–72 h	Natural, good for mild cases	Requires adequate water intake
Cisapride	Prokinetic	12–24 h	Good for motility disorders	Expensive, limited availability

In order to evaluate the prospects of creating bisacodyl suppositories for veterinary use, the existing range of suppositories in veterinary practice was studied.

Bisacodyl Suppositories

Mechanism of Action: Bisacodyl is a stimulant laxative that increases the motility of the colon, promoting the movement of feces.

Indications: Acute and chronic constipation, post-surgical constipation.

Contraindications: Known or suspected GI obstruction, severe dehydration, and hypersensitivity to bisacodyl.

Glycerin Suppositories

Mechanism of Action: Glycerin is a hyperosmotic agent that draws water into the colon, softening the stool and facilitating its passage.

Indications: Acute constipation, obstipation, and post-surgical constipation.

Contraindications: Known or suspected GI obstruction, severe dehydration, and hypersensitivity to glycerin.

Bisacodyl and Glycerin Combination Suppositories

Mechanism of Action: Combines the stimulant action of bisacodyl with the osmotic action of glycerin to provide a dual mechanism for relieving constipation.

Indications: Severe constipation, obstipation, and post-surgical constipation.

Contraindications: Known or suspected GI obstruction, severe dehydration, and hypersensitivity to either bisacodyl or glycerin.

Docusate Sodium Suppositories

Mechanism of Action: Docusate sodium is a stool softener that reduces the surface tension of the stool, making it easier to pass.

Indications: Chronic constipation, post-surgical constipation.

Contraindications: Known or suspected GI obstruction, severe dehydration, and hypersensitivity to docusate sodium.

Bisacodyl and Docusate Sodium Combination Suppositories

Mechanism of Action: Combines the stimulant action of bisacodyl with the stool-softening action of docusate sodium.

Indications: Chronic constipation, post-surgical constipation.

Contraindications: Known or suspected GI obstruction, severe dehydration, and hypersensitivity to either bisacodyl or docusate sodium [1, 3, 12, 13].

Therefore, bisacodyl is a valuable tool in veterinary medicine for acute constipation management, offering rapid relief with minimal systemic effects. However, its use should be judicious, avoiding chronic administration and considering species-specific sensitivities. Compared to other laxatives, it is faster but carries a higher risk of cramping, making it best suited for short-term interventions under veterinary supervision.

1.4. The use of suppositories in veterinary practice: practical applications, pros and cons

Suppositories are a valuable but underutilized dosage form in veterinary medicine, offering an alternative route for drug administration when oral or injectable routes are impractical. They are particularly useful in small animals (dogs, cats), exotic pets, and occasionally in large animals.

Suppositories are solid, medicated preparations designed to melt, dissolve, or disperse at body temperature, releasing active ingredients for:

- Local action (e.g., laxatives, anti-inflammatory drugs in rectal/vaginal inflammation).
- Systemic absorption (e.g., analgesics, anticonvulsants when oral dosing is impossible).

Common bases are:

- Fatty/glyceride-based (e.g., cocoa butter): Melt at body temperature.
- Water-soluble (e.g., polyethylene glycol): Dissolve in rectal fluids [17, 18].

In veterinary medicine this dosage form is not as popular as in human one, but the range of drugs is quite huge.

1. Small Animals (Dogs and Cats)

- Indications:
    - Laxatives (Bisacodyl, glycerin): For constipation or post-surgical ileus.

- Anti-inflammatory (NSAIDs, corticosteroids): Local treatment of proctitis.
- Anticonvulsants (Diazepam): Emergency treatment of seizures when IV access is unavailable.

- Administration:
  - Insert 1–2 cm into the rectum (use lubrication).
  - Cats require smaller suppositories (pediatric human formulations often used).

2. Exotic Pets (Rabbits, Ferrets, Rodents)

- Common uses:
  - Pain management (opioids like buprenorphine) in rabbits post-surgery.
  - Glycerin suppositories for gastrointestinal stasis in rabbits.
- Challenges: Small size requires compounding or splitting human suppositories.

3. Large Animals (Horses, Cattle)

- Limited use due to practicality, but may be applied in:
  - Horses: Anti-inflammatory suppositories for rectal/vaginal conditions.
  - Cattle: Rare, but possible in research settings (e.g., hormonal treatments).

Advantages of suppositories includes the following:

1. Bypasses Oral Administration: Useful in vomiting, dysphagic, or NPO (nothing by mouth) patients.
2. Avoids First-Pass Metabolism: Some drugs (e.g., diazepam) have better bioavailability rectally than orally.
3. Local vs. Systemic Action: Targeted therapy for rectal/vaginal inflammation.

4. Ease of Use in Uncooperative Patients: Less stressful than injections in fractious cats or exotic pets.

However, in veterinary, there are such possible risks when using this dosage form as variable absorption, which is strongly influenced by the rectal health of the animal, discomfort of the animal, limited drug options (few veterinary-specific formulations; often require compounding) and species-specific challenges (poor absorption due to rectal anatomy in ruminants, rarely use in birds and reptiles due to cloacal anatomy) [7, 11, 15].

Comparison of advantages and disadvantages of suppositories and other routes of drug administration in animals is described in Table 1.3.

Table 1.3

Comparison with Other Drug Delivery Methods

Method	Pros	Cons
Suppositories	Bypasses GI issues, no first-pass metabolism	Variable absorption, patient resistance
Oral	Convenient, wide drug selection	Vomiting, palatability issues
Injectable	Rapid, reliable absorption	Invasive, requires skill
Transdermal	Non-invasive (e.g., fentanyl patches)	Slow onset, species variability

The current little but stable growth of popularity of suppositories in veterinary practice is often explained by emergency setting (e.g., diazepam for seizures), exotic pet medicine (limited alternatives), more common in Europe than the US, where compounding pharmacies facilitate access, and lack of approved veterinary products, owner compliance, and clinician familiarity [7, 15, 20].

Therefore, suppositories are a niche but valuable tool in veterinary medicine, particularly for small animals and exotic pets. Their use is limited by formulation availability and absorption variability but offers critical advantages in specific cases (e.g., seizures, constipation). As compounding and veterinary-specific products improve, suppositories may gain broader acceptance.

Conclusions to chapter 1

1. Peculiarities of laxative usage in animals was studied. It was discovered that the selection of a laxative and the treatment approach should be customized to each individual animal, considering factors such as the underlying cause of constipation, the animal's overall health, and the potential risks and benefits of the treatment. By understanding the unique aspects of laxative use in veterinary practice, veterinarians can effectively manage GI issues and enhance the quality of life for their patients.

2. The veterinary guidelines for the use of laxatives in domesticated animals in Ukraine, the USA, and EU countries share many similarities, particularly in the types of laxatives used, dosage and administration protocols, and the importance of monitoring and follow-up. However, there are some key differences in such areas as regulatory environment (the EU has the most stringent regulations, followed by the USA, with Ukraine aligning more closely with European standards), emphasis on evidence-based medicine (the USA and EU countries place a strong emphasis on evidence-based medicine, leading to more frequent updates in treatment protocols), commercial availability (the USA and EU countries have a wider range of commercially available laxative products, including enemas) and telemedicine (the use of telemedicine is more prevalent in the USA and EU countries, enhancing the accessibility of veterinary care).

3. Bisacodyl is a valuable tool in veterinary medicine for managing acute constipation, providing quick relief with minimal systemic effects. However, its use should be cautious, avoiding long-term administration and taking into account species-specific sensitivities. Compared to other laxatives, bisacodyl acts faster but

has a higher risk of causing cramping, making it most appropriate for short-term use under veterinary supervision.

4. Suppositories are a specialized but valuable tool in veterinary medicine, especially for small animals and exotic pets. While their use is limited by the availability of formulations and variability in absorption, they offer crucial advantages in specific situations, such as treating seizures and constipation. As compounding and veterinary-specific products improve, suppositories may become more widely accepted.

CHAPTER 2
OBJECTS AND METHODS OF RESEARCH

2.1. Objects of research

In the study of the pharmaceutical market of laxative suppositories in animals, the existing range of April 2025 was used as an object.

Bisacodyl (SPU 1.0, p. 334) – white or almost white crystalline powder. API.

Basics of calculating dosage of bisacodyl

The weight of the animal (mg/kg). The smaller the animal, the more accurate the calculation should be, since even a slight excess of the dose can cause side effects.

The concentration of the drug (mg/ml or mg/suppository). This determines how much active ingredient is contained in a certain volume or unit of the drug.

The recommended dose of the active ingredient (mg/kg). This is an indicator that determines how many milligrams of the drug are needed for each kilogram of the animal's body weight. It is based on studies of the effectiveness and safety of the drug.

Purified water (SPU 2.2, p. 129-131) – colorless, transparent liquid, odorless and tasteless, pH 5.0 - 7.0. Used as a solvent.

Cocoa butter (USP 32–NF27, p. 1207) (Butyrum Cacao) – light yellow solid with a characteristic pleasant chocolate odor, hydrophobic suppository base.

Beeswax (SIS 4667: 2006)(Cera libram) – a beekeeping product containing a unique combination of active substances, including macro- and microelements, vitamins, plant gums, polysaccharides, amino acids, phenols, etc. of plant origin.

Confectionery hard fat type A (SPU 1.0, p. 453) – white brittle waxy mass with a faint specific odor, hydrophobic suppository base.

All APIs, excipients and reagents used met the requirements of the relevant regulatory documentation and had the appropriate shelf life [5, 22, 26, 27].

2.2. Methods of research

Appearance

The evaluation of suppositories was carried out according to their organoleptic indicators: color, odor, surface, etc.

The appearance of the obtained suppositories was evaluated according to the general article on the dosage form “Medicines for rectal use” (SPU, ed. 2, Vol. 1, p. 1094).

Average weight of suppositories

The determination of the average mass of suppositories was carried out according to the SPU, ed. 2, section 2.9.5. Each unit was weighed separately, and then the average mass was calculated. The deviation should not exceed ± 5%.

Homogeneity

The determination of the homogeneity of suppositories was visually controlled according to the generally accepted article “Medicines for rectal use” SPU, ed. 2, Vol. 1, p. 1094. There should be no spots in the suppository mass, the presence of an air core or funnel is allowed. The study was conducted for each batch of manufactured suppositories.

Melting point

The melting point was determined by the method of the SPU, 2nd edition, 2.2.15. The melting point of rectal suppositories should not exceed 37.0 °C.

Complete deformation time

The complete deformation time was determined by the method of the SPU, 1st edition, p. 505. Complete deformation should not exceed 15 minutes.

Suppository fracture resistance

Conducted by the method of the SPU, 2nd edition, section 2.9.24.

Economic analysis

When conducting market analysis, well-known methods of mathematical and statistical analysis were used [28-30].

Statistical analysis of research results (State Federal Institute of Chemistry 2.1., section 5.3).

Statistical analysis of the study results was carried out in accordance with the requirements of the SPU 2.1, section 5.3.

Conclusions to chapter 2

1. The properties of the research objects are described, in particular, the active pharmaceutical ingredients (bisacodyl) and excipients (beeswax, purified water, cocoa butter, hard fat), which were used in the experimental part.

2. The methods and conditions for conducting economic, physicochemical, pharmacotechnological tests that were used in studying the properties of suppositories of the proposed composition are selected and described.

CHAPTER 3
DEVELOPMENT OF THE COMPOSITION AND TECHNOLOGY COMPOSITION OF SUPPOSITORIES WITH BISACODYL FOR USE IN VETERINARY MEDICINE

3.1. Analysis of the range of veterinary suppositories with laxative effect and recommendations of veterinarians in Ukraine

As the general base of veterinary drugs currently is missing in Ukraine, study of the available laxative suppositories for animals was conducted through the general search, oriented on domesticated dogs and cats. Most of them correspond to the group QC05AX Other veterinary drugs for the treatment of hemorrhoids and anal fissures for topical use. Such suppositories are used for cleaning the intestines of dogs and cats suffering from para-anal sinusitis and proctitis, but they do not show the true laxative effect (see table 3.1).

Table 3.1

Range of veterinary suppositories for domesticated dogs and cats

Name	Composition	Producer	Price, UAH
Зоохелс (fig. 3.1a)	APIs: benzocaine (anesthesin); xeroform; zinc oxide; sea buckthorn extract; menthol. Excipients: PEG-1500, PEG-400 The composition of the given drugs differs in the ration of APIs.	Ukraine	127.0
Дивопрайд (fig. 3.1b)		Ukraine	125.0

a b

Fig. 3.1. Veterinarian suppositories on Ukrainian pharmaceutical market

Even though there are lots of recommendations and descriptions for suppositories with laxative effect for animals, the available range is very little. As a rule, human suppositories with glycerin are used. It is necessary to save it in the refrigerator first and inject it deep into the rectum. For dogs of other breeds, it is permissible to cut the suppository open. It has a slight stimulation effect on the mucous membrane of the rectum and spontaneously stimulates peristalsis. It removes the loosening of feces, their evacuation, so it is logical to administer a medication and immediately take the animal a walk. Contraindications – injuries, acute illnesses and swelling of the rectum; high sensitivity to glycerol.

Therefore, the development of suppositories with bisacodyl for animals is a timely and relevant for the modern pharmacy and this master thesis is devoted exactly to the solution of the named problem.

3.2. Justification of the composition of laxative suppositories with bisacodyl

The first of our practical work was the calibration of a silicone reusable mold for casting suppositories (Fig. 3.2) using a solid fat type A base.

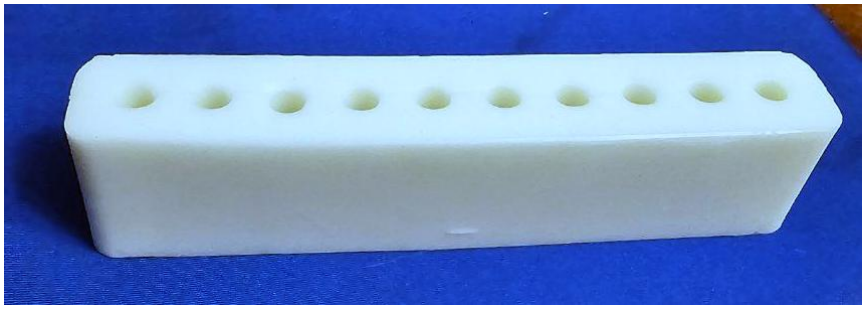

Fig. 3.2. Silicone reusable mold for casting suppositories

The suppository base was melted and casted into a mold, which was placed in the refrigerator for 15-20 minutes to solidify the suppositories. The resulting suppositories were weighed and the average weight of the suppositories was statistically determined. The study was conducted for 3 series of 10 suppositories, since the mold is designed to produce 10 suppositories. The results obtained are given in Table 3.2

Table 3.2

Mass of suppositories based on hard fat type A

N. of supp.	Mass, g	N. of supp.	Mass, g	N. of supp.	Mass, g
1	2.14	*11*	2.16	*21*	2.20
2	2.20	*12*	2.15	*22*	2.16
3	2.16	*13*	2.14	*23*	2.16
4	2.16	*14*	2.18	*24*	2.15
5	2.15	*15*	2.14	*25*	2.14
6	2.14	*16*	2.15	*26*	2.15
7	2.18	*17*	2.14	*27*	2.14
8	2.14	*18*	2.14	*28*	2.14
9	2.15	*19*	2.15	*29*	2.16
10	2.16	*20*	2.17	*30*	2.15

The obtainedsuppositories are white in color, with a smooth surface without chips or cracks, and there are no inclusions or air cavities on the longitudinal section (Fig. 3.3).

Fig. 3.3. Suppositories based on hard fat type A

Statistical processing of the obtained results was carried out by the Montseviciu-Ehringen method. The error of the arithmetic mean is calculated by the formula:

$m = \pm Sa \times k$,

where **m** is the error of the arithmetic mean of the average mass of suppositories;

S is the sum;

a is the absolute numerical value of deviations from the average mass without taking into account the plus and minus signs;

k is a value that depends on the number of variants, i.e. the number of experiments (n) for each sample, in our case it is equal to 0.29004.

$m_{average} = \sum m_{supp1\text{-}30} / 30 = 2.15$

2.15 – 2.14 = 0.01	2.15 – 2.16 = -0.01	2.15 – 2.20 = -0.05
2.15 – 2.20 = -0.05	2.15 – 2.15 = 0	2.15 – 2.16 = -0.01
2.15 – 2.16 = -0.01	2.15 – 2.14 = 0.01	2.15 – 2.16 = -0.01
2.15 – 2.16 = -0.01	2.15 – 2.18 = -0.02	2.15 – 2.15 = 0
2.15 – 2.15 = 0	2.15 – 2.14 = 0.01	2.15 – 2.14 = 0.01
2.15 – 2.14 = 0.01	2.15 – 2.15 = 0	2.15 – 2.15 = 0
2.15 – 2.18 = -0.03	2.15 – 2.14 = 0.01	2.15 – 2.14 = 0.01
2.15 – 2.14 = 0.01	2.15 – 2.14 = 0.01	2.15 – 2.14 = 0.01
2.15 – 2.15 = 0	2.15 – 2.15 = 0	2.15 – 2.16 = -0.01
2.15 – 2.16 = -0.01	2.15 – 2.17 = -0.02	2.15 – 2.15 = 0

$a = \sum |m_{average} - m_{supp}| = 0.34$

$m = 0.34 \times 0.29004 = 0.098$

$m = 2.15 \pm 0.098$ (g)

The next stage of the work was the calculations of the required amount of suppository bases and API.

The recommended single dose of bisacodyl is 5-20 mg for dogs and 2.5-5 mg for cats. The drug is used 1-2 times a day with an interval of 12-14 hours.

In order to meet the demands of both dogs and cats, the dose 5 mg per suppository was chosen.

It was found that a silicone mold for pouring reusable suppositories produces fat-based suppositories weighing 2.15 g with an error of ± 0.098 g. When administering 5 mg per suppository, the amount of API is 0.23 % of the content, therefore, the substitution coefficient is not taken into account.

Cocoa butter was chosen as the base, since this base is convenient to work with and has reparative properties and is easily tolerated by the organism of human or animal.

Since cocoa butter has a low melting point (32.0-34.0 °C), and the resulting suppositories should have a melting point in the range from 34.0 °C to 37.0 °, it is advisable to study the melting point of the finished suppositories on pure cocoa butter and with the addition of beeswax as a sealant [25].

Beeswax is a natural beekeeping product that contains a unique combination of active substances, including macro- and microelements, vitamins, herbal resins, polysaccharides, amino acids, phenols, plant tannins and glycosides. The composition of beeswax provides its mild anti-inflammatory, reparative and local anesthetic properties. In the composition of suppository bases, beeswax also acts as a sealant.

The next stage of the study was to determine the appropriate percentage of beeswax in suppositories with bisacodyl. Model suppository samples are given in Table 3.3.

Table 3.3

Composition of model suppository samples

Ingredient	Quantity, g per 1 suppository			
	Sample 1	Sample 2	Sample 3	Sample 4
Bisacodyl	0.005			
Beeswax	-	0.02 (≈1 %)	0.04 (≈2 %)	0.06 (≈3 %)
Cocoa butter	2.15	2.13	2.11	2.09

Bisacodyl is soluble in organic solvents such as DMSO and dimethyl formamide (DMF). The solubility of bisacodyl in these solvents is approximately 1 and 30 mg/ml, respectively. Bisacodyl is sparingly soluble in aqueous buffers. Thus, it was introduced into the samples by the suspensions type.

The compounding technology of sample 1 is as follows: in a mortar, a weighed amount of bisacodyl is ground first in a dry state, and then according to Deryagin’s rule with half the amount of peach oil.

In a porcelain cup in a water bath at a temperature of (33.0 ± 2.0) °C, the calculated amount of cocoa butter is melted.

Part of the suppository base is added to the mortar, thoroughly mixed until homogeneity, the resulting mixture is transferred to a porcelain cup to the rest of the base, mixed until homogeneity with a glass stick. If necessary, the suppository mass is heated and casted into the silicone mold.

The filled mold is shaken to remove air bubbles, left for 15-20 minutes at room temperature and transferred to the refrigerator for 45-60 minutes.

The compounding technology of samples 2-4 is as follows: in a mortar, a weighed amount of bisacodyl is ground first in a dry state, and then according to Deryagin's rule with half the amount of peach oil.

In a porcelain cup on a water bath at a temperature of (65.0 ± 2.0) °C, the calculated amount of beeswax is melted. The porcelain cup is removed from the water bath, then 1/3 of the weighed amount of cocoa butter is added and mixed until homogeneity. While mixing, another part of cocoa butter is added. Then the rest of the cocoa butter is added and mixed until homogeneity.

Part of the suppository base is added to the mortar, mixed thoroughly until homogeneity, transfered the resulting mixture to the rest of the base in a porcelain cup, mixed until homogeneity with a glass stick. If necessary, the suppository mass is heated and casted into a silicone mold.

The filled mold is shaken to remove air bubbles, left for 15-20 minutes at room temperature and transferred to the refrigerator for 45-60 minutes.

The resulting suppositories were tested for melting point by the SPU method. The results of the tests are given in Table 3.4.

Table 3.4

Evaluation of the melting point of the studied suppository samples

Sample	Melting point. °C			Average. °C
1	28.1	28.8	29.0	28.6
2	30.6	31.1	31.2	31.0
3	35.3	35.7	35.5	35.5
4	37.4	37.5	36.8	37.2

As can be seen from the results obtained (Table 3.4), samples 1 and 2 have too low a melting point, which can lead to melting of the suppository in human hands and cause inconvenience when using the drug in animals. Sample 4 has too high a melting point, which can lead to the long-term melting in the body of the animal. The best melting point indicator is demonstrated by sample 3.

Thus, the final composition of suppositories with papaverine hydrochloride is given in Table 3.5.

Table 3.5

Composition of suppositories with bisacodyl for animals

Ingredient	Quantity, g	
	Per 1 suppository	Per 10 suppositories
Bisacodyl	0.005	0.05
Peach oil	q.s.	q.s.
Beeswax	0.04	0.40
Cocoa butter	2.11	21.10

The resulting suppositories are yellow in color, with a pleasant smell of cocoa butter, with a smooth surface without chips and cracks, and there are no inclusions and air cavities on the longitudinal section (Fig. 3.4).

Fig. 3.4. Suppositories with bisacodyl

3.3. Justification of the technology of laxative suppositories with bisacodyl

The probable critical points of the technological process of compounding suppositories of the proposed composition was studied (Table 3.6).

Table 3.6

Critical points of the technological process of compounding suppositories with bisacodyl

Technological stage	Критичний параметр	Значення критичного параметру
Melting of the base	Melting point, °C	33.0 ± 1.0
Preparation of suppository mass	Suppository mass preparation temperature, °C	33.0 ± 1.0
Time and temperature of suppositories hardening	Temperature and time	15-20 min at room temperature and 45-60 min in the refrigerator

A flowchart of the technology of compounding suppositories with bisacodyl is shown in Fig. 3.5.

The next step of our research was to study the main physicochemical and pharmacotechnological properties of the proposed suppositories.

According to the SPU, suppositories were studied according to such parameters as deviation of the average mass, melting point, resistance to fracture, time of complete deformation. The obtained data are presented in Table 3.7.

As can be seen from the results (Table 3.7), suppositories obtained using the proposed technology are satisfactory in terms of their structural and mechanical properties; the melting point is 35.5 ° C and slightly higher than the melting point of cocoa butter. The suppositories meet the requirements of SPU in terms of the deviation of the average mass, melting point, resistance to destruction and time of complete deformation.

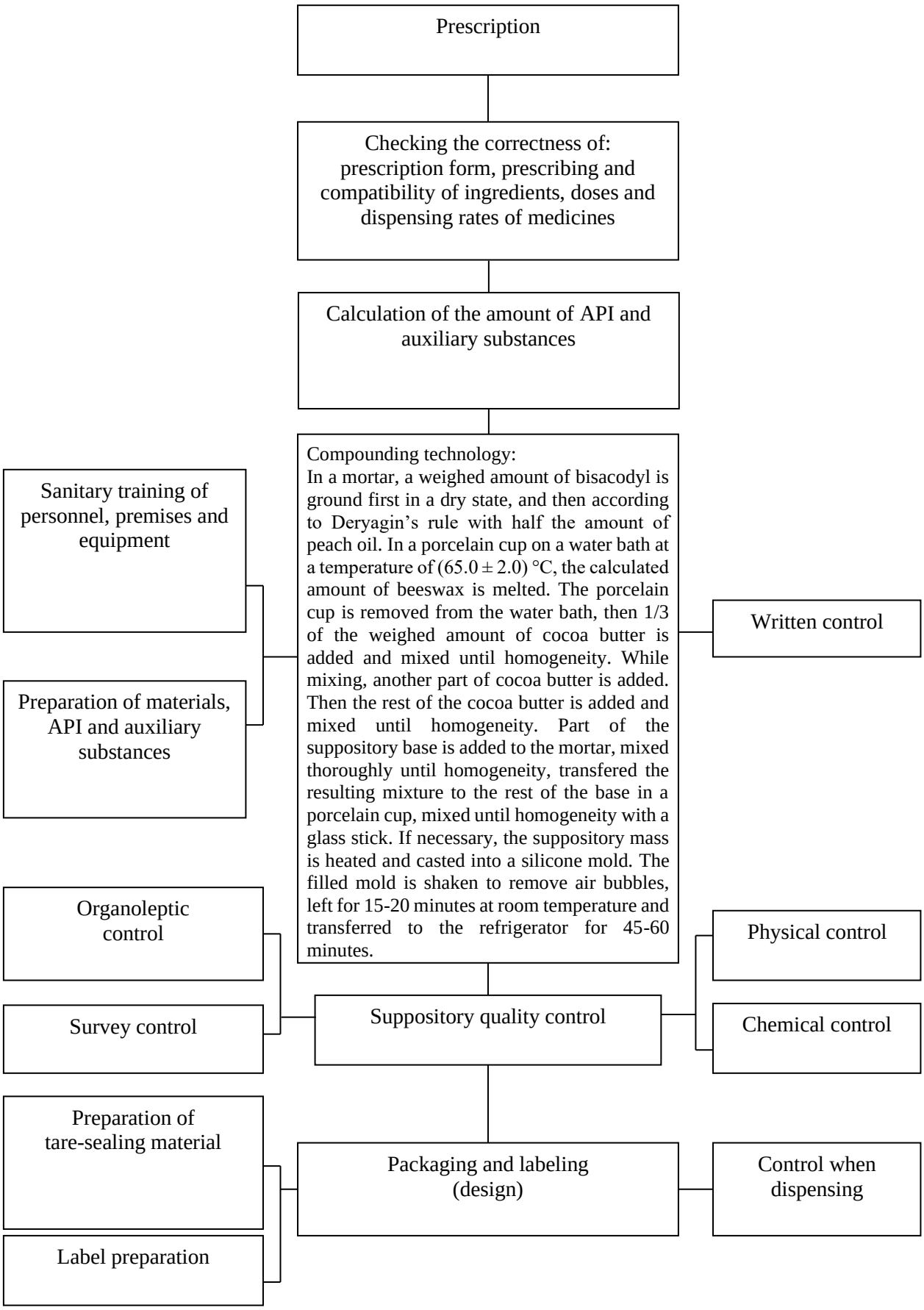

Fig. 3.5. Flowchart of the technology of compounding suppositories with bisacodyl

Table 3.7

Physicochemical and pharmacotechnological parameters of suppositories with bisacodyl, (n = 5)

Parameter	SPU requirements	Results
Average mass, g	Up to 4,0 g	2.15 ± 0,08
Deviation of the average mass, %	Not more than 5	± 3
Melting point, °C	Not more than 37.0	35.5 ± 0.5
Resistance to destruction, kg	-	2.6 ± 0.2
Time of complete deformation, min.	Not more than 15	7.3 ± 0.4

In order to establish a possible shelf life, the stability of the proposed suppositories was investigated for 6 months when stored in a refrigerator (Table 3.8). Quality control was carried out according to the requirements of the SPU (appearance, mass uniformity, melting point, resistance to destruction, time of complete deformation).

Table 3.8

Results of a study of the stability of suppositories with bisacodyl for 6 months

Parameter	Results		
	At the beginning	After 3 months	After 6 months
1	2	3	4
Appearance	Suppositories are yellowish in color with a pleasant cocoa smell.		
Average mass, g	2.15 ± 0.06	2.15 ± 0.07	2.15 ± 0.07
Uniformity of mass, %	± 2.3	± 2.5	± 2.5

End of table 3.8

1	2	3	4
Melting point, °C	35.5 ± 0.5	35.5 ± 1.0	35.0 ± 0.5
Resistance to destruction, kg	2.6 ± 0.2	2.6 ± 0.2	2.4 ± 0.2
Time of complete deformation, min.	7.3 ± 0.4	7.2 ± 0.5	7.2 ± 0.3

It was found that the obtained suppositories with bisacodyl meet the requirements of SPU and remain stable for 6 months. The recommended storage conditions are as follows: store in the refrigerator.

The results obtained showed that the proposed composition and technology of suppositories with bisacodyl with laxative activity for animals ensure the proper quality of the product.

Conclusions to chapter 3

1. The range of laxatives for animals was studied. Despite the numerous recommendations and descriptions for laxative suppositories for animals, the available options are quite limited. Typically, human glycerin suppositories are used. Contraindications include injuries, acute illnesses, and swelling of the rectum, as well as high sensitivity to glycerol. Therefore, the development of bisacodyl suppositories for animals is a timely and relevant topic in modern pharmacy.

2. Based on the study of the melting point of finished suppositories, the introduction of beeswax in the amount of 2 % into the composition of the suppository mass was justified, since this provides a melting point in the range of 34.0 - 37.0 °C.

3. When developing the technology for compounding suppositories with bisacodyl, probable critical points of the production process were established: melting of the suppository base, preparing of the suppository mass, time and

temperature of solidification of suppositories. The flowchart of compounding technology in pharmaceutical conditions is described.

4. Studies of suppository samples stored for 6 months showed that they fully meet the requirements of the SPU in terms of appearance, average mass, mass uniformity, melting point, resistance to destruction, and time of complete deformation.

CONCLUSIONS

1. The conducted literature analysis showed that the use of laxatives in animals requires customization based on the underlying cause of constipation, the animal's overall health, and the risks and benefits of the treatment. Understanding these unique aspects helps veterinarians effectively manage GI issues and improve their patients' quality of life. Veterinary guidelines for laxative use in Ukraine, the USA, and EU countries share similarities in types of laxatives, dosage, and monitoring. However, key differences include regulatory environment (the EU has the strictest regulations, followed by the USA, with Ukraine aligning more closely with Europe), emphasis on evidence-based medicine (stronger in the USA and EU), commercial availability (wider range in the USA and EU), and telemedicine (more prevalent in the USA and EU). Bisacodyl is effective for managing acute constipation in animals, providing quick relief with minimal systemic effects. However, its use should be cautious, avoiding long-term administration and considering species-specific sensitivities. Bisacodyl acts faster than other laxatives but has a higher risk of causing cramping, making it suitable for short-term use under veterinary supervision. Suppositories are valuable in veterinary medicine, especially for small animals and exotic pets. Despite limitations in availability and absorption variability, they offer crucial advantages in treating conditions like seizures and constipation. As compounding and veterinary-specific products improve, suppositories may become more widely accepted.

2. The properties of active pharmaceutical ingredients (bisacodyl) and excipients (beeswax, hard fat, cocoa butter) used in the experimental part of the research are described, as well as the methods and conditions for conducting economic, physicochemical, and pharmacotechnological tests that were used in studying the properties of suppositories.

3. Despite numerous recommendations, the range of laxative suppositories for animals is limited. Human glycerin suppositories are often used, but they have

contraindications such as injuries, acute illnesses, rectal swelling, and glycerol sensitivity.

4. The addition of 2 % beeswax to the suppository composition was justified, as it ensures a melting point of 34.0 - 37.0 °C. Critical points in the production process of bisacodyl suppositories include melting the base, preparing the suppository mass, and the time and temperature for solidification. The flowchart of compounding technology is described.

5. Suppository samples stored for 6 months met all SPU requirements, including appearance, average mass, uniformity, melting point, resistance to destruction, and time of complete deformation.

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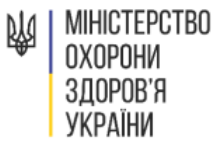
APPENDIXES

APPENDIX A



МІНІСТЕРСТВО ОХОРОНИ ЗДОРОВ'Я УКРАЇНИ
НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ
РАДА МОЛОДИХ ВЧЕНИХ
СТУДЕНТСЬКЕ НАУКОВЕ ТОВАРИСТВО

ПРОГРАМА

XXXI Міжнародної науково-практичної конференції
молодих вчених та студентів
«АКТУАЛЬНІ ПИТАННЯ СТВОРЕННЯ НОВИХ ЛІКАРСЬКИХ ЗАСОБІВ»

23-25 квітня 2025 р.

Харків – 2025

Continuation of app. A

Засідання гуртків СНТ на кафедрах

Кафедра аптечної технології ліків

1. **Сучасні матеріали для перев'язувальних засобів**
   Доповідач: Капріор Іван
   Науковий керівник: Буряк М.В., к. фарм. н., доц.
2. **Обґрунтування складу комплексу біологічно активних речовин у розробці добавки дієтичної для схуднення**
   Доповідач: Бріт Вікторія
   Науковий керівник: Ковальова Т.М., к. фарм. н., доц.
3. **Похідні вітаміну А у догляді за шкірою**
   Доповідачі: Боднарук Варвара, Торлова Олена
   Науковий керівник: Боднар Л.А., PhD, асистент
4. **Використання гомеопатичних препаратів в лікуванні дисменореї**
   Доповідач: Рижук Анастасія
   Науковий керівник: Олійник С. В., к. фарм. н., доц.
5. **Analysis of the assortment and composition of extemporaneous suspensions**
   Доповідач: Шукрі-Хаміуі Аюб
   Науковий керівник: Ковальов В.В. к. фарм. н., доц.
6. **Перспективи використання екстракту джимнеми лісової (Gymnema Sylvestre) при створенні лікарських препаратів для лікування цукрового діабету 2 типу.**
   Доповідач: Сусляк Ірина
   Науковий керівник: Зуйкіна С. С. д фарм. н., проф.
7. **Розробка складу дерматологічної емульсії для лікування розацеа**
   Доповідач: Онущак Анна
   Науковий керівник: Боднар Л.А., PhD, асистент
8. **Розвиток гомеопатії в Німеччині**
   Доповідачі: Яременко Марія, Сергієнко Тетяна
   Науковий керівник: Олійник С. В., к. фарм. н., доц.
9. **Аналіз рідких гомеопатичних форм як складової наномедицини**
   Доповідач: Яворська Валерія
   Науковий керівник: Олійник С. В., к. фарм. н., доц.

Continuation of app. A

20 **Development of the composition of suppositories with bisacodyl for use in veterinary medicine**
Доповідач: Камаль Саїд
Науковий керівник: Семченко К.В. д фарм. н., проф.

21 **Розроблення складу та технології екстемпорального гелю на основі ацетилтетрапептиду-5**
Доповідач: Мороз Ксенія
Науковий керівник: Ковальова Т.М., к. фарм. н., доц.

22 **Розроблення серцево-судинного збору для виготовлення в аптеці**
Доповідач: Заіченко Аліна
Науковий керівник: Марченко М.В. к. фарм. н., доц.

23 **Розроблення складу і технології екстемпоральної мазі ранозагоювальної дії**
Доповідач: Чиркова Марія
Науковий керівник: Вишневська Л.І., д. фарм. н., проф.

24 **Дослідження з обґрунтування складу дерматологічного засобу захисної та зволожувальної дії**
Доповідач: Чорноусенко Катерина
Науковий керівник: Половко Н.П. д фарм. н., проф.

Ф А 2.2.1-32-366

National University of Pharmacy

Faculty for foreign citizens' education
Department drugs technology
Level of higher education master
Specialty 226 Pharmacy, industrial pharmacy
Educational and professional program Pharmacy

APPROVED
The Head of drugs technology department

Liliia VYSHNEVSKA
" 30 " August 2024

ASSIGNMENT
FOR QUALIFICATION WORK
OF AN APPLICANT FOR HIGHER EDUCATION

Said KAMAL

1. Topic of qualification work: «Development of the composition of suppositories with bisacodyl for use in veterinary medicine», supervisor of qualification work: Kateryna SEMCHENKO, Doctor of Pharmacy, prof. approved by order of the NUPh from "27" September 2024, № 237

2. Deadline for submission of qualification work by the applicant for higher education: May 2025

3. Outgoing data for qualification work: suppository, technology, bisacodyl, veterinary, cocoa butter.

4. Contents of the settlement and explanatory note (list of questions that need to be developed):
- to analyze data from scientific literature regarding the peculiarities of the use of laxatives in animals;
- to analyze the prospects of bisacodyl as a laxative agent for domesticated animals like dogs and cats and the possibility of its incorporation into the form of suppositories;
- to develop the composition and compounding technology of suppositories with bisacodyl for animals;
- to study physicochemical and pharmacotechnological properties of the obtained suppositories and to evaluate their shelf-life.

5. List of graphic material (with exact indication of the required drawings):
tables – 11, figures – 7.

6. Consultants of chapters of qualification work

Chapters	Name, SURNAME, position of consultant	Signature, date	
		assignment was issued	assignment was received
1	Kateryna SEMCHENKO, professor of higher education institution of drugs technology department	06.09.2024	06.09.2024
2	Kateryna SEMCHENKO, professor of higher education institution of drugs technology department	19.10.2024	19.10.2024
3	Kateryna SEMCHENKO, professor of higher education institution of drugs technology department	03.02.2025	03.02.2025

7. Date of issue of the assignment: «30» August 2024

CALENDAR PLAN

№ з/п	Name of stages of qualification work	Deadline for the stages of qualification work	Notes
1	Topic selection	September 2024	**done**
2	Literature data analysis	September-November 2024	**done**
3	Conducting experimental research	October 2024-January 2025	**done**
4	Work design	February-April 2025	**done**
5	Submission of finished work to the commission	May 2025	**done**

An applicant of higher education _____ Said KAMAL

Supervisor of qualification work _____ Kateryna SEMCHENKO

ВИТЯГ З НАКАЗУ № 237

По Національному фармацевтичному університету

від 27 вересня 2024 року

Затвердити теми кваліфікаційних робіт здобувачам вищої освіти 5-го курсу Фм20(4,10д) 2024-2025 навчального року, освітньо-професійної програми – Фармація, другого (магістерського) рівня вищої освіти, спеціальності 226 – Фармація, промислова фармація, галузь знань 22 Охорона здоров'я, денна форма здобуття освіти (термін навчання 4 роки 10 місяців), які навчаються за контрактом (мова навчання англійська та українська) згідно з додатком № 1.

Прізвище, ім'я здобувача вищої освіти	Тема кваліфікаційної роботи		Посада, прізвище та ініціали керівника	Рецензент кваліфікаційної роботи
• **по кафедрі аптечної технології ліків**				
Камаль Саїд	Розроблення складу супозиторіїв з бісакодилом для застосування у ветеринарії	Development of the composition of suppositories with bisacodyl for use in veterinary medicine	проф. Семченко К.В.	проф. Гриценко В.І.

Ректор

Вірно. Секретар

ФА2.8-03-317

ВИСНОВОК

експертної комісії про проведену експертизу
щодо академічного плагіату у кваліфікаційній роботі

здобувача вищої освіти

«30» квітня 2025 р. № 331090646

Проаналізувавши кваліфікаційну роботу здобувача вищої освіти Камаль Саїд, групи Фм20(4,10д)а – 04, спеціальності 226 Фармація, промислова фармація, освітньої програми «Фармація» навчання на тему: «Розроблення складу супозиторіїв з бісакодилом для застосування у ветеринарії / Development of the composition of suppositories with bisacodyl for use in veterinary medicine», експертна комісія дійшла висновку, що робота, представлена до Екзаменаційної комісії для захисту, виконана самостійно і не містить елементів академічного плагіату (компіляції).

Голова комісії,
проректор ЗВО з НПР,
професор **Інна ВЛАДИМИРОВА**

Ф А 2.2.1-32-353

REVIEW

of scientific supervisor for the qualification work of the master's level of higher education of the specialty 226 Pharmacy, industrial pharmacy

Said KAMAL

on the topic: «Development of the composition of suppositories with bisacodyl for use in veterinary medicine».

Relevance of the topic. Bisacodyl, a powerful laxative that stimulates intestinal motility, is used to treat constipation in both humans and animals, though its use in veterinary practice is less common. It is particularly effective in the form of suppositories for severe constipation in dogs, cats, and other species, especially when oral administration is not possible or a rapid effect is needed.

Practical value of conclusions, recommendations and their validity. Research on developing the composition and technology of bisacodyl suppositories for veterinary use will meet the existing need for laxatives for animals, particularly domestic dogs and cats, as such products are currently unavailable in Ukraine.

Assessment of work. The successful solution of tasks enabled the author of the qualification work to achieve the goal and obtain practical and theoretical results. The work was done at a sufficient scientific level, which indicates the author’s ability to work with literary sources, analyze, systematize and generalize the experimental data obtained.

General conclusion and recommendations on admission to defend. The qualification work of Said KAMAL meets all the requirements for qualification works and can be presented for the defense at the Examination Commission of the National University of Pharmacy.

Scientific supervisor _____ Kateryna SEMCHENKO

«15» May 2025

Ф А 2.2.1-32-356

REVIEW

for qualification work of the master's level of higher education, specialty 226 Pharmacy, industrial pharmacy

Said KAMAL

on the topic: «Development of the composition of suppositories with bisacodyl for use in veterinary medicine».

Relevance of the topic. Developing bisacodyl suppositories for animals is crucial because it addresses a significant gap in veterinary medicine. These suppositories offer a rapid and effective solution for severe constipation, especially in cases where oral administration is not feasible or when immediate relief is necessary. They are particularly beneficial for animals with chronic constipation, postoperative conditions, or dehydration, as they stimulate rectal receptors to promote defecation within 15-60 minutes. This not only enhances the treatment options available to veterinarians but also improves the comfort and quality of life for their animal patients.

Theoretical level of work. The peculiarities of laxative usage in veterinary practice was researched. The comparative analysis of the veterinary guides for the use of laxatives, namely bisacodyl, in domesticated animals was conducted. The prospects of suppositories as a possible veterinary dosage form were analyzed.

The author's suggestions on the topic of research. The study justified the addition of 2% beeswax to the suppository composition, as it ensures a melting point within the range of 34.0 - 37.0°C. During the development of the compounding technology for bisacodyl suppositories, critical production points were identified, including the melting of the suppository base, preparation of the suppository mass, and the time and temperature for solidification. A detailed flowchart of the compounding technology under pharmaceutical conditions is provided. Additionally, samples of the suppositories stored for 6 months were found to fully comply with the SPU

requirements in terms of appearance, average mass, mass uniformity, melting point, resistance to destruction, and time of complete deformation..

Practical value of conclusions, recommendations and their validity. In the course of his work, the higher education applicant mastered methods of analyzing and summarizing data from scientific literature, physicochemical, pharmacotechnological and statistical methods of research of practical interest.

Disadvantages of work. There are incorrect expressions and grammatical errors in the work.

General conclusion and assessment of the work. The qualification work of Said KAMAL based on the results of research and volume of the experiment performed can be presented for the defense at the Examination Commission of the National University of Pharmacy.

Reviewer _____ prof. Vita HRYTSENKO

«16» May 2025

Ф А2.2.1-91-287

МІНІСТЕРСТВО ОХОРОНИ ЗДОРОВ'Я УКРАЇНИ
НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ

ВИТЯГ З ПРОТОКОЛУ № _17_
«_19_» _травня_ 2025_ року
м. Харків

засідання кафедри
аптечної технології ліків
(назва кафедри)

Голова: завідувачка кафедри, проф. Вишневська Л. І.
Секретар: докт. філ., ас. Боднар Л. А.

ПРИСУТНІ:

проф. Половко Н.П., проф. Семченко К.В., проф. Зуйкіна С.С., доц. Ковальова Т.М., доц. Буряк М.В., доц. Ковальов В.В., доц. Олійник С.В., доц. Марченко М.В., ас. Іванюк О.І.

ПОРЯДОК ДЕННИЙ:
1. Про представлення до захисту кваліфікаційних робіт здобувачів вищої освіти.

СЛУХАЛИ: проф. Вишневську Л. І. – про представлення до захисту до Екзаменаційної комісії кваліфікаційних робіт здобувачів вищої освіти.

ВИСТУПИЛИ: Здобувач вищої освіти групи Phm20(4,10d)eng – 04 спеціальності 226 «Фармація, промислова фармація» Said KAMAL – з доповіддю на тему «Development of the composition of suppositories with bisacodyl for use in veterinary medicine» (науковий керівник, проф. Катерина СЕМЧЕНКО).

УХВАЛИЛИ: Рекомендувати до захисту кваліфікаційну роботу.

Голова
Завідувачка кафедри, проф. _____ **Лілія ВИШНЕВСЬКА**

Секретар
Асистент _____ **Любов БОДНАР**

Ф А2.2.1-32-042

НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ

ПОДАННЯ
ГОЛОВІ ЕКЗАМЕНАЦІЙНОЇ КОМІСІЇ
ЩОДО ЗАХИСТУ КВАЛІФІКАЦІЙНОЇ РОБОТИ

Направляється здобувач вищої освіти Said KAMAL до захисту кваліфікаційної роботи за галуззю знань 22 Охорона здоров'я
Спеціальністю 226 Фармація, промислова фармація
Освітньо-професійною програмою Фармація
на тему: «Development of the composition of suppositories with bisacodyl for use in veterinary medicine».

Кваліфікаційна робота і рецензія додаються.

Декан факультету _____ /Микола ГОЛІК /

Висновок керівника кваліфікаційної роботи

Здобувач вищої освіти Said KAMAL в процесі роботи розробив супозиторії на основі АФІ бісакодил для застосування у ветеринарній практиці. Була досліджена якість та ймовірний термін зберігання розроблених супозиторіїв. Здобувач вищої освіти Said KAMAL допускається до захисту кваліфікаційної роботи в Екзаменаційній комісії Національного фармацевтичного університету.

Керівник кваліфікаційної роботи

_____ Катерина СЕМЧЕНКО

«15» травня 2025 року

Висновок кафедри про кваліфікаційну роботу

Кваліфікаційну роботу розглянуто. Здобувач вищої освіти Said KAMAL допускається до захисту даної кваліфікаційної роботи в Екзаменаційній комісії.

Завідувачка кафедри аптечної
технології ліків

_____ Лілія Вишневська

«19» травня 2025 року

Qualification work was defended

of Examination commission on

« ___ » of June 2025

with the grade _____

Head of the State Examination commission,

D.Pharm.Sc, Professor

_____ / Volodymyr YAKOVENKO