

## PHARMACEUTICAL SCIENCES

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### DEVELOPMENT OF NEW RECTAL GEL FOR PROSTATITIS TREATMENT

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Introduction. Prostatitis is considered to be the most widespread disease of male reproductive system. This is inflammatory process of prostate gland which develops due to different negative factors such as pathogenic microorganisms, lack of sexual activity, sedentary lifestyle, super cooling, smoking etc. All of these factors may cause disturbances of blood circulation in gland and congestion of prostatic fluid that significantly deteriorates the quality of sexual life and reproductive function of men [1, p. 121].

The modern medication of prostatitis of different genesis includes "Prostatilen" – the complex of water soluble peptides obtained from prostates glands of cattle. "Prostatilen" normalizes microcirculation and spermatogenesis, has bacteriostatic effect [2, p. 21]. Nowadays, "Prostatilen" is available in two pharmaceutical dosage forms – injections and suppositories [3, p. 73]. Both of forms have some negative properties such as physical and chemical instability and discomfort when using. In contrast to suppositories, rectal gel in form of micro enema demonstrates more frequent absorption in rectum without leakage of medicine.

Taking into consideration the preferences of rectal pharmaceutical dosage forms for treatment of prostatitis, the purpose of investigation was to develop the "Prostatilen" contained rectal gel.

Materials and methods. During investigation the pharmaco-technological, microbiological, biological and statistical methods have been used. The microbiological researching has been carried out according to the requirements of State Pharmacopoeia of Ukraine (2-nd edition) [4, p. 103]. The pharmacological testing of Prostatilen rectal gel has been fulfilled on the model of chronic prostatitis in rats which was made by cryo trauma of ventral part of prostate gland. All the animals have been divided into three groups: first group

– intact rat males, second group – not treated with experimental prostatitis and third group – rats with prostatitis received experimental gel as a cure. The treatment of prostatitis has been carried out from the 15<sup>th</sup> day after pathology modeling by introduction of 0.5g of gel per animal. The experiment has been extended over two weeks. The experimental animals have been kept in standard conditions of vivarium of SI “V. Danilevsky Institute for Endocrine Pathology Problems of NAMS of Ukraine”, under natural sources of light, standard feeding and water regime ad libitum. The investigation has been carried out according to the National “General Principles for Animal Research Ethics” (Ukraine, 2001), which corresponds to the “European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes” (Strasbourg, 1985), and “Principles for Ethic Committee”, 2012.

The data obtained were statistically estimated by using Excel and Statistika 6,0 programs under Shapiro-Wilk test and t-Student test.

Results. The composition and technology of rectal gel based on “Prostatilen” has been elaborated. The Carbopol-940<sup>®</sup>-based hydrogel was used as a vehicle of pharmaceutical dosage form. The neutralization of Carbopol-940<sup>®</sup> suspension have been made up to pH=7 using ammonia solution for obtaining gel-base with appropriate viscosity.

After microbiological data obtaining the complex of preservatives in concentration of 0,2 % (Nipagin-Nipazol in 3:1 ratio) has been introduced into gel-base. The propylene glycol in concentration of 2 % has been used to be solvent of preservatives. The concentration of “Prostatilen” was 0,5 % .

The experimental samples of “Prostatilen” gel have been obtained with the following technology: calculated amount of Carbopol-940<sup>®</sup> has added to purified water, after polymer swelling the 15 % of ammonia solution has been introduced for gel neutralization up to pH=7. The “Prostatilen” has dissolved in appropriate part of water, preservatives – in propylene glycol. Solutions of “Prostatilen” and preservatives have been added to gel base, the mixture has homogenized until obtaining of transparent, yellowish gel.

The pharmacological researches have determined that rats of third group (treated by “Prostatilen” gel ) have had the increased number of motile sperms by 20 % and decreased by 43 % of pathologically changed spermatozoons comparing with not treated rats (second group) ( $p < 0,05$ ). Moreover, the using of “Prostatilen” gel has led to the decreasing of leucocytes up to  $11,8 \pm 0,6 \times 10^9/l$  in the contrast to second group of animals which demonstrated strong leukocytosis  $(20,0 \pm 0,4) \times 10^9/l$  due to prostatitis on the 20<sup>th</sup> day of experiment. This fact confirms the anti-inflammatory effect of “Prostatilen” gel.

Thus, the composition and technology of new rectal gel based on “Prostatilen” have been developed. Pharmacological researching has confirmed using of 0,5 % “Prostatilen” gel inhibited inflammation of prostate gland and recovered spermatogenesis.

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**ОСОБЛИВОСТІ ТЕХНОЛОГІЧНОГО ПРОЦЕСУ  
ВИГОТОВЛЕННЯ НОВОГО ЗАСОБУ ДЛЯ ПРОФІЛАКТИКИ  
УСКЛАДНЕНЬ ЗА УМОВ ВАГІТНОСТІ**

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Особливе занепокоєння викликає погіршення репродуктивного здоров'я жінок, яке проявляється в зростанні захворюваності серед вагітних, зниженні числа нормальних пологів і збільшенні відхилень розвитку плода. Відомо, що репродуктивна система жінки під час