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Scientific and Methodological Rationale for Developing a Standard Operating Procedure for In-Pharmacy Quality Control Using 0.02% Sterile Furacilin Solution as an Example

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ABSTRACT

BACKGROUND: The *ex tempore* preparation of medicinal products in pharmacy organizations, along with the implementation of in-pharmacy quality control, ensures compliance with the regulatory requirements of the Ministry of Health of the Russian Federation, particularly those related to drug quality assurance. This article describes the development process of a standard operating procedure for in-pharmacy quality control of 0.02% sterile furacilin solution in accordance with current legislative and regulatory acts governing the preparation and quality control of medicinal products.

AIM: to develop a standard operating procedure for the in-pharmacy quality control of a medicinal product—using 0.02% sterile furacilin solution as an example—prepared in pharmacy organizations authorized to manufacture aseptic medicinal products, including those under the jurisdiction of the Ministry of Health and the Ministry of Defense.

MATERIALS AND METHODS: The study applied a systems-based and problem-oriented methodological approach using content analysis, structural–functional analysis, logical analysis, and comparative and descriptive methods.

RESULTS: In accordance with current quality requirements for medicinal products, testing procedures based on physicochemical and chemical methods were proposed. A list of instruments, laboratory glassware, auxiliary materials, and reagents required for chemical quality control was also compiled. The proposed standard operating procedure may serve as a methodological guide for pharmacy organizations authorized to produce aseptic medicinal products within both civilian and military healthcare systems. It can be used for in-pharmacy quality control of 0.02% sterile furacilin solution and as a model for developing similar standard operating procedures.

CONCLUSION: The authors emphasize the necessity of implementing in-pharmacy quality control procedures in accordance with the updated requirements of the State Pharmacopoeia of the Russian Federation, 15th edition. Proper execution of control procedures is expected to enhance the production activities of civilian and military pharmacies, thereby contributing to improved effectiveness of medical care delivery.

Keywords: pharmacy organization; extemporaneous compounding; in-pharmacy quality control; quality management system; standard operating procedure; chemical quality control; extemporaneous medicinal products.

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Научно-методическое обоснование подходов к разработке стандартной операционной процедуры «внутриаптечный контроль качества» (на примере стерильного раствора фурацилина 0,02%)

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АННОТАЦИЯ

Актуальность. Изготовление в аптечных организациях лекарственных препаратов *ex tempore* и проведение внутриаптечного контроля качества является гарантией выполнения регуляторных требований Министерства здравоохранения Российской Федерации, в части, касающейся контроля качества лекарственных препаратов. В статье показана процедура формирования стандартной операционной процедуры для проведения внутриаптечного контроля качества стерильного раствора фурацилина 0,02% в соответствии с действующими законодательными и нормативными правовыми актами в области изготовления и контроля качества лекарственных средств.

Цель — разработка стандартной операционной процедуры по внутриаптечному контролю качества лекарственного препарата (на примере стерильного раствора фурацилина 0,02%), изготавливаемого в аптечных организациях с правом изготовления асептических лекарственных препаратов, в том числе подведомственных как Министерству здравоохранения, так и Министерству обороны.

Материалы и методы. В ходе исследований использовались системный и проблемный методологические подходы, реализация которых осуществлялась с помощью контент-анализа, структурно-функционального, логического анализа, методов сравнения и описания.

Результаты. В соответствии с современными требованиями к качеству лекарственных средств предложены методики проведения испытаний физико-химическими и химическими методами, а также произведен подбор номенклатуры приборов, лабораторной посуды, вспомогательного материала, реактивов, необходимых для проведения химического контроля. Предложенная стандартная операционная процедура может быть использована аптечными организациями с правом изготовления асептических лекарственных препаратов в гражданском и военном здравоохранении как методический инструмент по осуществлению внутриаптечного контроля качества стерильного раствора фурацилина 0,02%, а также как шаблон для разработки аналогичных стандартных операционных процедур.

Заключение. Авторы статьи делают заключение о необходимости проведения внутриаптечного контроля качества с учетом новых требований Государственной фармакопеи Российской Федерации XV издания. Надлежащее выполнение контрольных процедур позволит улучшить производственную деятельность гражданских и военных аптек и, следовательно, будет способствовать повышению эффективности оказания медицинской помощи.

Ключевые слова: аптечная организация; аптечное изготовление; внутриаптечный контроль качества; система менеджмента качества; стандартная операционная процедура; химический контроль; экстемпоральные лекарственные препараты.

Как цитировать

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ЭКО•ВЕКТОР

BACKGROUND

Enhancing the production activities of pharmacies is among the priority areas of activity aimed at improving the effectiveness of public drug supply under the current socio-economic conditions of the Russian Federation. In particular, the increased use of extemporaneous preparations in clinical practice is considered crucial for implementing the concept of Predictive, Preventive, and Personalized Medicine [1, 2].[1] Compounded medicinal products (MPs) must comply with the requirements of the general pharmacopeial monographs (GPM), pharmacopeial monographs (PMs), and other regulatory legal acts. Standard operating procedures (SOPs) should be developed to prevent errors during the performance of diverse processes and operations within the quality management system of a pharmacy. Adopted SOPs must also be regularly updated and supplemented with relevant instructions, guidelines, manuals, etc. [3–5]. Only such an approach can ensure the reliable production of high-quality, effective, and safe MPs, thereby contributing to achieving the key goals of the National Healthcare Project.[2]

The study aimed to justify the approaches undertaken to develop SOPs for controlling the quality of the MPs that are compounded in pharmacies (exemplified by a 0.02% sterile nitrofurazone solution).

MATERIALS AND METHODS

The study materials included: legislative and regulatory acts of the Russian Federation, regulatory acts of the federal authorities (including the Russian State Pharmacopeia [SPh XV][3]), scientific works on the manufacturing process and quality control of MPs, and other related scientific, methodological, and reference publications. The study applied a system-based and problem-oriented methodological approach using content-based, structural–functional, and logical analyses, along with comparative and descriptive methods.

RESULTS AND DISCUSSION

The quality attributes of extemporaneous preparations must be monitored across all pharmacies authorized to dispense medications, regardless of their ownership or departmental affiliation. The list of controlled parameters and the frequency of in-pharmacy quality control (IQC) must comply with the established regulations[4], as well as the requirements for the preparation, dispensing, and labeling of MPs stipulated by GPMs and PMs [6, 7].

Post-preparation quality control of the MPs must be prompt, utilizing minimal amounts of reagents and other consumables. For the qualitative–quantitative analysis of extemporaneous preparations, physicochemical and other research methods available in pharmacies are employed; these methods enable the rapid and reliable assessment of specified parameters, including in the field environment.

A drug supply analysis in civilian and military healthcare institutions indicated that infusion and sterile solutions were the most in-demand extemporaneous preparations for emergency and urgent healthcare (Table 1) [8–10].

A survey of surgeons across various fields of expertise (thoracic surgery, military field, urology, combustiology, etc.) revealed that 0.02% furacilin (nitrofuran) for topical and external use is one of the most crucial extemporaneous sterile MPs. It is used in the treatment of injuries and burns, for the washing of organs and tissues (bladder, stomach, etc.), and as a mouth or throat rinse.

Currently, the Russian State Registry of Medicines[5] lists multiple pharmaceutical forms of MPs with the international non-proprietary name Nitrofuran, which include sterile solutions, concentrates, and tablets for preparing solutions for local and external use. However, furacilin solution prepared by dissolving tablets cannot be used to treat damaged skin (e.g., post-burns) or washing wounds owing to its non-sterile nature. The furacilin solution concentrate contains non-indifferent excipients (polyethylene glycol –400 and povidone K30), which may cause adverse effects in certain cases.

An analysis of the prescription (order) data demonstrates that the most practical and cost-effective furacilin dosage form for surgical and combustiology departments is a sterile 0.02% solution (350 mL vials) composed of NaCl 3.15 mL, furacilin 0.07 mL, and purified water 350 mL.

This product has no equivalent among the ready-made dosage forms currently manufactured by pharmaceutical companies in the Russian Federation.

The sequence of actions for developing an SOP for the IQC of extemporaneous MPs is presented as a flowchart in Fig. 1.

[1] Order of the Ministry of Health of the Russian Federation No. 186 dated April 24, 2018, *On Approval of the Concept of Predictive, Preventive, and Personalized Medicine.*

[2] Passport of the Healthcare National Project was approved following the meeting of the Presidium of the Presidential Council for Strategic Development and National Projects on December 24, 2018.

[3] Order of the Ministry of Health of the Russian Federation No. 377 dated July 20, 2023, *On Approval of General Pharmacopeial Monographs and Pharmacopeial Monographs.*

[4] Order of the Ministry of Health of the Russian Federation No. 249n dated May 22, 2023, On *Approval of the Rules for Manufacturing and Dispensing of Medicinal Products for Human Use By Pharmacy Organizations Licensed for Pharmaceutical Activities.*

[5] https://grls.rosminzdrav.ru

Table 1. Nomenclature of key extemporaneous infusion solutions and sterile preparations
Таблица 1. Номенклатура важнейших экстемпоральных растворов для инфузий и стерильных растворов

Name
Concentrate for 10% potassium chloride solution for infusion
Concentrate for 10% sodium chloride solution for infusion
Ringer's solution for infusion
0.45% sodium chloride solution for infusion
0.9% sodium chloride solution for infusion
4% sodium bicarbonate solution for infusion
0.5% procaine hydrochloride solution for infusion
0.25% procaine hydrochloride solution for infusion
5% glucose solution for infusion
10% glucose solution for infusion
Water for injection
0.02% nitrofurazone solution

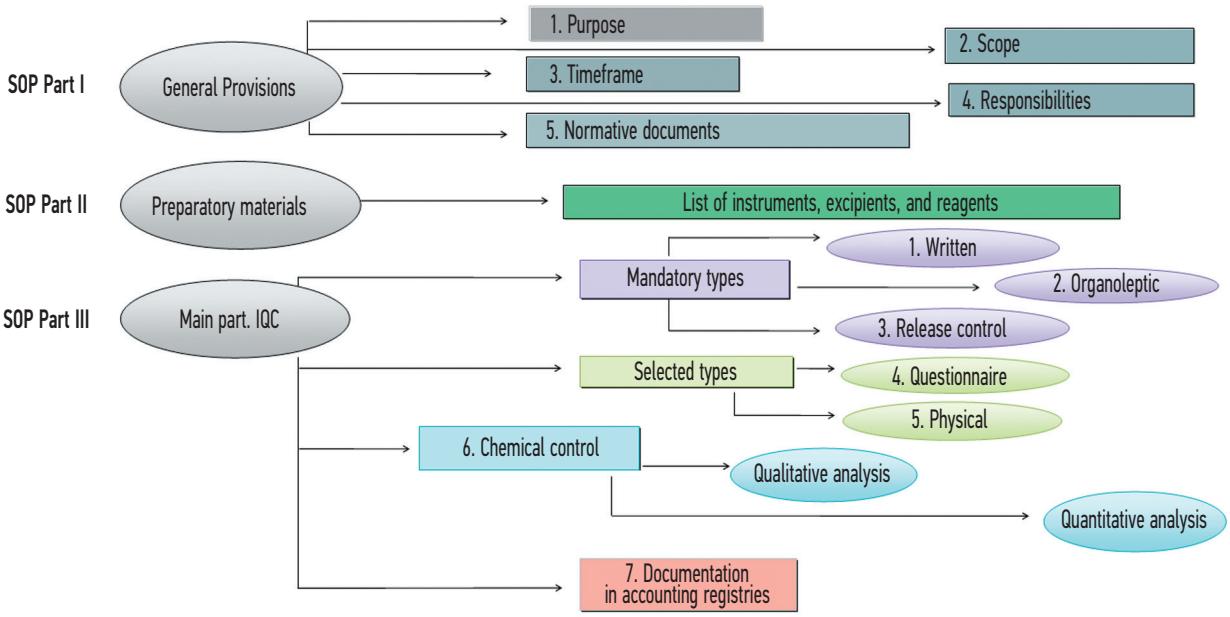


Fig. 1. Flowchart of standard operating procedure development sequence.
Рис. 1. Схема последовательности действий при разработке СОП.

The first part of the SOP contains general provisions, including purpose, scope, responsibilities, and effective date.

1. SOP development aims to standardize operations for the IQC of MPs prepared in pharmacy settings.

2. The scope applies to furnishings and equipment within premises designated for compounding and quality control of the MPs.

3. Time of use: during the preparation and quality control of MPs.

4. Responsibilities for compliance with legislative and regulatory requirements lie with the pharmacy technician and pharmacists engaged in compounding, while quality control responsibility rests with the pharmacy analyst.

5. Regulatory documentation used for SOP development. Currently, the primary documents governing IQC implementation include the Russian State Pharmacopeia XV edition, Orders of the Ministry of Health of the Russian Federation, and other guidelines (methodological instructions, recommendations, etc.) regarding MP quality control.

The title page of the SOP description should be tabulated (Table 2).

Table 2. Example of the cover page format for a standard operating procedure
Таблица 2. Пример оформления титульного листа СОП

Standard Operating Procedure (SOP) No. ___ In-Pharmacy quality control of compounded medicinal products	
Executing unit:	Pharmacy
Developed by:	Head of Pharmacy Department
Approved by:	Chief Medical Officer / Medical Facility Director
Effective date:	(Date)
Replaces:	First Issue / Reissue dated ___

Part II of the developed SOP outlines preparatory activities, including personnel, premises, equipment, auxiliary material preparation, etc.

The list of laboratory and pharmacy glassware, auxiliary materials, and equipment required for compounding 0.02% furacilin solution, 350 mL, No. 10 includes the following:

1) Electronic balance (or pharmacy hand scales: BP1 and BP20);
2) Medical surgical suction device OM1, Armed 23 D (or other pharmaceutical filtration and dispensing apparatus);
3) Semi-automatic vial capping machine (e.g., PZR-M) or aluminum cap crimping device (POK-N);
4) Measuring glassware: 2000, 1000, and 500 mL, 1 pc. each;
5) Bottles for infusion solutions and blood substitutes (450 mL), 10 pcs.;
6) Type 4Ts rubber medical stoppers, 10 pcs.;
7) Aluminum medical caps, 10 pcs.

The list of laboratory glassware required for full chemical control of one prepared MP sample:

1) Alcohol lamp, 1 pc.;
2) Graphite rod, 1 pc.;
3) Transparent neutral glass test tube, 1 pc.;
4) Flat-bottom neutral glass flask, 1 pc.;
5) Graduated measuring pipettes: 10 mL, 1 pc.; 2 mL, 2 pcs.

The list of instruments, titrated solutions, reagents, and indicators required for chemical control of one prepared MP sample:

1) Purified water, 10 mL;
2) 10% NaCl solution, 0.1 mL;
3) Diluted HNO_3 (16%), 0.5 mL;
4) Diluted H_2SO_4 (16%), 2 mL;
5) $AgNO_3$ (2%), 2 mL;
6) 0.01 M $Na_2S_2O_3$ (method 1), 2 mL;
7) 0.5 M I_2 solution (method 1), 2 mL;
8) Starch (method 1), 1 mL;
9) K_2CrO_4 solution (method 1), 0.1 mL;
10) Photo-electro colorimeter (PhEC, method 2);
11) 3 mm optical path cuvettes (method 2);
12) 0.1 M NaOH (method 2), 0.1 mL;
13) 0.02% standard furacilin solution (0.0001 g), 0.5 mL;
14) Particulate matter testing apparatus.

Part III of the SOP describes all IQC procedures for compounding sterile 0.02% furacilin solution, 350 mL, No. 10. The algorithm used for maintaining IQC compliance per established requirements[6] is shown in the figure above. The process is as follows:

1. Written control. Before preparing the 0.02% furacilin solution, the pharmacist performs all the necessary calculations and fills the reverse side of the written control certificate (WCC). After preparation, the front side is completed.

The reverse side of the WCC looks as indicated in Fig. 2.

The front side of the WCC is shown below (e.g., from the City Hospital No. 1, St. Petersburg, Russia) (Fig. 3).

After completing the WCC, the prepared MP product is sent to a pharmacy analyst for the required testing.

2. Mandatory organoleptic control involves the verification of odor, color, and absence of visible particulate matter: a transparent yellowish-greenish liquid, odorless, and particle-free. Particles are inspected visually using devices such as UK-2 or SvetoChek®-FM against a white background.

3. Release control is mandatory and ensures compliance of the MP physicochemical properties with its packaging: a hermetically sealed vial with appropriate labeling.

4. Questionnaire control is performed at random following compounding by a pharmacist (no more than five MPs per shift).

[6] Order of the Ministry of Health of the Russian Federation No. 249n dated May 22, 2023, *On Approval of the Rules for Manufacturing and Dispensing of Medicinal Products for Human Use by Pharmacy Organizations Licensed for Pharmaceutical Activities.*

$$m_{\text{furacilin}} = \frac{0.02\,\% \cdot 3500\,ml}{100\%} = 0.7$$

$$m_{NaCl} = \frac{0.9\,\% \cdot 3500\,ml}{100\%} = 31.5$$

$$V\,H_2O = 3500\,ml$$

Fig. 2. Reverse side of the written control passport.
Рис. 2. Оборотная сторона паспорта письменного контроля.

25, Nevsky Ave., St. Petersburg
Production pharmacy of St. Petersburg State Budgetary Healthcare Institution City Hospital No. 1
WCC
Date: June 13, 2024 Department Order No.
Surgical suite (injury, No. 187)
Taken: Aqua purificata 3,500 mL
Furacelinum 0.7
Natrium cloridium 31.5
V= 3,500 mL
Packaging:
350 mL No. 10
Prepared: Verigo Analysis No.: 155
Checked: Smirnova signature of a pharmacy analyst E. A. Smirnova
Packaged: Ryzhkova

Fig. 3. Front side of the written control passport.
Рис. 3. Лицевая сторона паспорта письменного контроля.

5. Physical control is conducted at random to assess total volume and sealing integrity. V_{total}=350 mL, permissible deviations ±1% (range: 346.5–353.5 mL).

6. Pre-sterilization chemical control of the 0.02% furacilin solution is mandatory. The pharmacy analyst performs qualitative and quantitative tests.

In accordance with the requirements of the GPM 1.8.0001 Pharmacy-prepared MPs, chemical control is performed using procedures specified in the GPM, PM, and quality control documents. Chemical control of pharmacy-prepared MPs may be conducted using express analysis methods, which are typically non-destructive, characterized by high speed of execution, simple procedures, and minimal requirements for test samples and reagents.

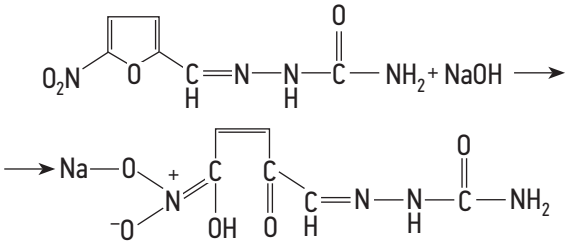
Qualitative analysis of NaCl involves the following chemical reactions[7]:

1) Sodium ion detection: A graphite rod moistened with the test solution is introduced into a burner flame, producing a yellow colored flame.

2) Chloride ion detection: Add 0.5 mL of diluted HNO_3 (16%) and 0.5 mL of 2% $AgNO_3$ to 1 mL of the test solution. A white opalescence is observed.

$$AgNO_3 + NaCl \rightarrow AgCl \downarrow + NaNO_3.$$

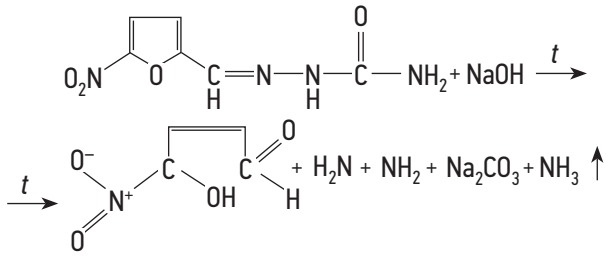
Furacilin is qualitatively analyzed by adding several drops of 10% NaOH to 1 mL of the MP. An orange-red color develops.



Furacilin can be assayed using several methods, namely:

1. Iodometric back titration. Procedure: Add 2 mL of 0.05 M iodine (I_2) solution and several drops of 10% NaOH solution to 10 mL of the test solution until a straw-yellow color develops. Dark-incubate for 1 min, and then add an excess of diluted 16% H_2SO_4. Titrate with 0.01 M $Na_2S_2O_3$ until decolorization (if necessary, use 2–3 drops of freshly prepared 10% starch solution as an indicator) [11, 12].

[7] GPM.1.2.2.0001.15 General Identification Reactions.



$I_2 + 2NaOH \rightarrow NaIO + NaI + H_2O$;

$H_2N–NH_2 + 2NaIO \rightarrow NaI + N_2\uparrow + 2H_2O$;

$NaIO + NaI + H_2SO_4 \rightarrow I_2 + Na_2SO_4 + H_2O$;

$2Na_2S_2O_3 + I_2 \rightarrow 2NaI + Na_2S_4O_6$.

From the total volume of the MP, furacilin is quantified using the following formula:

$$X = \frac{(VI|2 - VNa_2S_2O_3) \cdot T \cdot G}{a},$$

where VI_2 = 2 mL; T = 0.004954 g/mL; G, volume of the dosage form (mL); a, an aliquot of the MP taken for titration (mL).

$$X, g = \frac{(2\ mL - 1.6\ mL) \cdot 0.004954\ g/mL \cdot 3500\ mL}{10\ mL} = 0.69.$$

Based on the requirements of the GPM.1.8.0001 Pharmacy-prepared MPs, permissible deviations in the weights of individual ingredients in liquid forms prepared by mass–volume method for 0.7 are ±7%, with an interval of 0.651–0.749.

2. In pharmacies of large-sized healthcare institutions, the assay of furacilin using a physicochemical method (photocolorimetry) is feasible[8] [12]. Procedure: Add 7.5 mL of purified water and 2 mL of 0.1 M NaOH to 0.5 mL of the test solution, and then mix. After 20 min, measure the optical density (D_1) of the colored solution using a photoelectric colorimeter (PhEC) at ~450 nm (blue light filter) using a 3-mm pathlength cuvette. Use purified water as the control. In parallel, perform the same reaction with 0.5 mL of 0.02% standard furacilin solution (0.0001 g) and measure its optical density (D_2).

Calculate furacilin content (%) using the following formula:

$$X, \% = \frac{D_1 \cdot 0.0001 \cdot 100\ mL}{D_2 \cdot 0.05}.$$

NaCL is quantified by the Mohr argentometric method. Procedure: Add two drops of K_2CrO_4 indicator to 1 mL of the test solution and titrate with 0.1 M $AgNO_3$ until a brick-red precipitate forms.

$$AgNO_3 + NaCl \rightarrow AgCl\downarrow + NaNO_3.$$

Within the total volume of the MP, NaCl is quantified using the following formula:

$$X = \frac{VAgNO_3 \cdot T \cdot G}{a},$$

where T = 0.005844 g/mL; G, volume of the dosage form (mL); a, weight of the MP taken for titration (mL).

$$X, g = \frac{1.54\ mL \cdot 0.005844\ g/mL \cdot 3500\ mL}{1\ mL} = 31.49.$$

Based on the requirements of the GPM.1.8.0001 Pharmacy-prepared MPs, permissible deviations in the weights of individual preparations in liquid dosage forms prepared by the mass–volume method for 18.0 are ±3%, with an interval of 30.55–32.44.

As complete chemical control is applied for this MP, the analysis number certified by the pharmacy analyst is indicated on the front side of the WCC. Upon satisfactory results, subsequent steps include filtration, dispensing, and capping of the MP.

3. Documentation in accounting registers. In compliance with the established requirements for MP quality control in pharmacies, the IQC results for the 0.02% sterile furacilin solution are recorded in the following logbooks:

Logbook for recording organoleptic, physical, and chemical control results of the MPs prepared as prescriptions, orders, in-pharmacy stocks, concentrated solutions, triturations, ethyl alcohol, and MP packaging;

Logbook for recording control results of the individual stages during the preparation of solutions for injections and infusions;

Logbook for recording the sterilization parameters of initial drug compounds, prepared MPs, auxiliary materials, glassware, etc.

After completing the IQC procedures, the packaged MP is sterilized with saturated steam at 120°C–122°C under 120 kPa for 12 min.

The above methods of qualitative and quantitative analysis are available to the pharmacies and comply with the current regulatory requirements; they allow for a sufficiently rapid and easy assessment of the physicochemical quality parameters of the prepared MP. The described methods were tested for several years in the daily IQC of a 0.02% sterile furacilin solution at the production facility of the St. Petersburg State Budgetary Healthcare Institution City Pokrovskaya Hospital (St. Petersburg).

CONCLUSION

The presented SOP for the IQC of a 0.02% sterile furacilin solution can serve as a basis for developing similar SOPs for the compounding and quality control of

[8] PM 2.1.0528 Nitrofurantoin

extemporaneous MPs. A detailed description is provided for the various SOP sections, including preparatory activities, equipment setup, processing of auxiliary materials, containers, and reagents. The chemical analysis methods used in pharmacies should be reliable, simple, and cost-effective.

Thus, developing SOPs applicable to pharmaceutical compounding and quality control within the pharmacy quality management system is an essential operational requirement. Proper IQCs can enhance production activities in civilian and military pharmacies and help achieve the key objective of domestic healthcare, which is improving the efficiency of medical care delivery.

ADDITIONAL INFO

Contribution of each author. E.Yu. Alekseychuk, concept and design of the study, conducting the study, analyzing the obtained data, writing the text; Yu.V. Miroshnichenko, editing the text, approving the final version; E.A. Klimkina, collecting and processing materials, analyzing the obtained data, editing the text; R.A. Enikeeva, collecting and processing materials, analyzing the obtained data, editing the text; S.N. Egorova, editing the text, approving the final version.

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ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ

Вклад каждого автора. Е.Ю. Алексейчук — концепция и дизайн исследования, проведение исследования, анализ полученных данных, написание текста; Ю.В. Мирошниченко — редактирование текста, утверждение окончательного варианта; Е.А. Климкина — сбор и обработка материалов, анализ полученных данных, редактирование текста; Р.А. Еникеева — сбор и обработка материалов, анализ полученных данных, редактирование текста; С.Н. Егорова — редактирование текста, утверждение окончательного варианта.

Конфликт интересов. Авторы заявляют об отсутствии конфликта интересов.

Финансирование. Поисково-аналитическая работа проведена на личные средства авторского коллектива.

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