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THE RATIONALE FOR THE SELECTION OF QUALITY INDICATORS IN THE STANDARDIZATION OF RADIOPHARMACEUTICAL PREPARATION "SODIUM PERTECHNETATE [^{99m}Tc], EXTRACTIONAL, SOLUTION FOR INJECTION"

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Technetium-99m has optimal characteristics for use in nuclear medicine and is a priority in the selection of radiopharmaceuticals for the diagnosis of oncological diseases. An important stage in the complex of scientific and research works on the creation of the radiopharmaceutical preparation «Sodium pertechnetate [^{99m}Tc], extractional, solution for injection» is standardization, which includes the establishment of requirements for the quality of the drug. When developing the specification for the drug, a set of quality indicators was determined, taking into account the type of dosage form. Acceptance criteria and testing methods were established. Sections of the specification were compiled, which will be used to control the quality of the drug and included in section P of the registration dossier of the common technical document (CTD) format during drug registration.

Incidence and mortality from oncology continue to grow steadily both in our country and abroad. Cancer is the cause of more than 15% of all deaths and is second only to cardiovascular diseases in this indicator. According to the World Health Organization estimates, the number of cancer cases in the world will almost double by 2050. This problem is also very acute in Ukraine [1]. In this regard, early diagnosis and selection of optimal treatment tactics for cancer patients remain relevant. To solve these problems, the search, development and implementation of various diagnostic methods capable of detecting the presence and progression of the tumor process are ongoing. Along with clinical methods, radionuclide diagnostic methods play an important role in cancer patients [2]. For this purpose, radiopharmaceuticals (RPPs) containing one or more radioactive isotopes are used.

When selecting the radionuclide, its physical characteristics (half-life, radiation energy), chemical reactions necessary for the radionuclide incorporation into the monoclonal antibody molecule, and the radiation exposure to the patient are taken into account.

Technetium-99m is most often used to label monoclonal antibodies. The advantages of the universal use of this radioisotope are a relatively short half-life of 6.01 hours, the emission of pure γ-radiation with 140 keV energy, which is sufficient for medical examining the metabolic process while minimizing the radiation dose received by the patient compared to the parent molybdenum-99, the half-life of which is about 66 h.

It should be noted that technetium is used for various visualization methods. The gamma radiation of technetium-99m extends its application beyond the SPECT range, enabling multimodal imaging that improves diagnostic accuracy. This adaptability is key to expanding the diagnostic range and meeting diverse clinical requirements [3]. The wide availability of technetium-99m further strengthens its position as a preferred radionuclide.

In oncology, technetium-99m is used for diagnosis, initial diagnosis, and rediagnosis of almost all organs of patients [4, 5].

Today, the main range of RPPs for the diagnosis of cancer is formed at the expense of foreign production. There is no domestic production of this extremely important radioisotope. Therefore, the primary task for the development of nuclear medicine in Ukraine is to organize the production and quality control of the radiopharmaceutical preparation «Sodium pertechnetate [^{99m}Tc], extractional, solution for injection», which is the most common radiopharmaceutical in PET studies for the detection of malignant neoplasms.

Quality control in the production of radiopharmaceuticals plays an important role in ensuring the supply of high-quality drugs for the diagnosis and treatment of cancer patients. Permission to use radiopharmaceuticals directly depends on the results of analytical control. Complete physicochemical, biological and pharmaco-technological quality control of the drug is confirmed by quality control methods (QC).

NSC KIPT has been working for a long time to organize the production of radiopharmaceuticals based on technetium-99m in the form of a solution for injection.

The purpose of our work is to determine the set and criteria of quality indicators, selection or development of methods for their control for inclusion in the specification when developing the radiopharmaceutical preparation "Sodium pertechnetate [^{99m}Tc], extractional, solution for injection".

MATERIALS AND METHODS

The object of the research is "Sodium pertechnetate [^{99m}Tc], extractional, solution for injection".

The developed laboratory batches of the drug were analyzed using analytical methods. Analytical studies were carried out by the method of descending chromatography on paper (SPhU, *2.2.26*) (determination

of radiochemical purity, identification technetium-99m); by the method of gas chromatography (SPhU, *2.2.28*) on a chromatograph of SHIMADZU Nexis GC-2030 (Germany) (determination of residual amounts of organic solvents); by the method of gamma spectrometry (SPhU, *2.2.66*) on a gamma spectrometer of Canberra (USA) (determination of radionuclide purity, identification technetium-99m); by the method of potentiometric titration on a titrator of Metrohm (Switzerland) (SPhU, *2.2.20*) (determination of sodium chloride); by potentiometry (SPhU, *2.2.3*) on a Metrohm 827 pH meter (Switzerland) (pH determination) using electronic scales Radwag (Poland) and class A measuring glassware. To collect γ-spectra of the studied samples, a wide-range detector based on high-purity germanium of the BEGe 3830 type (Canberra, USA) with an area of 38 cm^2 and a thickness of 3 cm was used with the following energy resolution values: 0.468 keV for energy 5…9 keV; 0.572 keV for energy 122 keV and 1.51 for energy 1332 keV. The software for calculating the detector registration efficiency when irradiated with radioactive sources of complex form ISOCS (In Situ Object Counting System), which is included in the spectrometer kit, was used to process the experimental spectrometric data. The portable radionuclide identification detector identiFINDER®2 was used as auxiliary equipment.

The activity of sodium pertechnetate [^{99m}Tc] solutions were determined using the ISOMED 2010 dose calibrator from MED Nuklear-Medizintechnik Dresden GmbH (Germany) by determining the radioactivity of the radionuclide per packaging unit (vial). Content of inactive impurities aluminium, molybdenum, copper, silicon, boron, arsenic, bismuth, chromium, cadmium, nickel, lead, tin, antimony, zinc, manganese, iron were determined on a spectrometer “Thermo Fisher Scientific iCAP 7400 Duo” (USA) method of inductively coupled plasma-atomic emission spectrometry (SPhU, *2.2.57*). The method of inductively coupled plasma-atomic emission spectrometry (SPhU, *2.2.57*), spectrometer "Thermo Fisher Scientific iCAP 7400 Duo" (USA) was also used for the identification of the sodium ion.Microbiological tests were carried out according to SPhU, *2.6.1*, *2.6.14*.

The drug was standardized for all quality indicators that are necessary for RPP for parenteral use, namely solutions for injections, in accordance with the requirements of the State Pharmacopoeia of Ukraine [6].

When performing quality control of the drug, the radiochemical engineer must comply with radiation safety rules and prepare samples for testing using individual cumulative and direct-indicating dosimeters in a special fume hood with lead protection in accordance with the Radiation Safety Standards NRBU-97 and the Basic Sanitary Rules for Ensuring Radiation Safety of Ukraine OSPU-2005 [7, 8].

Individual dosimetric control of personnel was carried out using thermoluminescent dosimeters of the RADOS individual thermoluminescent dosimetry complex. Contamination control of personnel’s hands and feet was carried out using LB-147 radiometer. Radiation control (monitoring) in the rooms was carried out using MKS-AT1117M radiometer-dosimeter with a BDKG-01 detection unit.

RESEARCH RESULTS AND DISCUSSION

An important stage in the complex of scientific and research works on the RRP creation is standardization, which includes establishing the quality of the drug in accordance with the established standards [9, 10], without which the registration and production of a new medical preparation is impossible.

A number of regulatory documents of the Ministry of Health of Ukraine on the standardization of finished medical products have been developed and put into effect in Ukraine, harmonized with the regulatory documents of the European Union (EU), the International Conference on Harmonization of Technical Requirements for Registration of Medical Products for Human Use (ICH), the Pharmaceutical Inspection Convention (PIC), and the Pharmaceutical Inspection Cooperation System (PIC/S).

These documents are updated in accordance with the strategy of Ukraine integration into the EU. A number of documents regulating the registration of the finished medical product and requirements for their quality are among these regulatory documents. Recommendations for the development of specifications for medical products included in sections "P" and "Pharmaceutical development" of the registration dossier in the CTD format are given in Guideline 42-3.2:2004. Medical products. Specifications: test procedures and acceptance criteria [9–12].

When compiling sections of the registration dossier for the radiopharmaceutical preparation «Sodium pertechnetate [^{99m}Tc], extractional, solution for injection», it is necessary to establish a set of quality indicators, justify their acceptance criteria and select test methods for inclusion in the specification for the drug. The methods for conducting general and specific tests that are included in the specification for control must be described in the State Pharmacopoeia of Ukraine (SPhU) or the Eurorean Pharmacopoeia (EP), and for those that are not described, new methods must be developed and validated.

It should be noted that the requirements for the drug «Sodium pertechnetate [^{99m}Tc], extractional» are established in SPhU and EP [13, 14].

Taking into account the indicators and criteria for acceptability established and given in SPhU for the drug, a set of criteria was established that the studied radiopharmaceutical preparation «Sodium pertechnetate [^{99m}Tc], extraction, solution for injection» must meet for inclusion in the specification required for drug control and its registration. Medical and biological indicators for the dosage form – solution for injection (pH, osmolarity) were also taken into account for effective and safe diagnosis.

The choice of quality indicators and the appropriate control method was determined depending on the time of analysis, the use of ultra-small sample volumes for analysis, and the possibility of selling the drug. It was also taken into account that the production of RRP is in small series.

It is proposed to carry out the quality control of the drug according to the following indicators: “Description”, “Identification”, “pH”, “Radiochemical purity”, “Radionuclide purity”, “Radioactivity”, “Mechanical inclusions”, “Aluminium“, “Residual amounts of organic solvents”, “Inactive impurities”, “Bacterial endotoxins”, “Sterility”, “Quantitative determination”, “Marking”. Such a set of quality indicators was established to fulfill all the requirements of the SPhU for the RRP [6].

The "Description" indicator is introduced into the specification. Its analysis was carried out visually. The indicators "Transparency" and "Degree of color", which are specific for injectable drugs, were not included, since it is impossible to strictly determine the transparency and degree of color in aqueous solutions of RRP according to the conditions given in the SPhU, since the volume of the entire series is less than the amount of the required determination.

Certainly, proof of radionuclide identification and determination of its activity is necessary. The presence or absence of radionuclide impurities must also be established. Changes in the content of radionuclide impurities may be the cause of additional radiation exposure in organs where accumulation of the target radionuclide is not observed.

For the indicators “Identification”, “Radiochemical purity”, “Radionuclide purity”, the research methods used are given in SPhU “Sodium pertechnetate [^{99m}Tc], extractional” [13]. The same control criteria and permissible limits are included in the specification for the drug. Since the test product is a radioactive compound with sodium, the "Identification" section included a test for sodium by method of inductively coupled plasma-atomic emission spectrometry when determining inactive impurities.

The main thing that determines the path of RFP in the body, and therefore its effectiveness and safety, is the content of the radionuclide in the required chemical form, that is, radiochemical purity. The test of "Radiochemical purity" is proposed to be carried out by the method of descending chromatography on paper. The criteria for the acceptability of the indicator are established as in the monograph on the drug [13].

Drugs, in the production or purification of which organic solvents are used, must be controlled for the content of residual amounts of these solvents. According to the recommendations of the Guideline 42-3.2:2004, such control should be included in the category “Impurities”, which is part of the general tests.

In the technological process of «Sodium pertechnetate [^{99m}Tc], extractional» production the methylethylketone is used as an organic solvent. According to SPhU, 5.4 methylethylketone belongs to class 3 – low-toxic solvents. The maximum concentrations of such impurities in the medical product in an amount corresponding to 5000 ppm (0.5 %) are acceptable without justification [6]. The specification for the drug includes the same control criteria for residual amounts of methylethylketone. The determination was carried out by the method of gas chromatography (GC). The selection of chromatographic conditions was carried out in such a way as to ensure sufficient sensitivity for the determination of methylethylketone.

The method of obtaining the drug "Sodium pertechnetate [^{99m}Tc], extraction" is based on the nuclear reaction: ^{98}Mo(n,γ)^{99}Mo(β-)^{99m}Tc.

The β-decay of ^{99}Mo to the daughter nuclide ^{99m}Tc occurs in an extraction generator. An alkaline carbonate solution is used as the aqueous phase, and methylethylketone is the extractant. Therefore, there is a possibility of metal impurities from the extraction generator.

The permissible content of inactive chemical impurities in RRP solutions is strictly regulated, since impurities can competitively bind with chemical substances included in the RRP, which will lead to a change in its radiochemical purity and, accordingly, pharmacokinetics. Therefore, control of inactive impurities, in particular aluminum, heavy metals, etc., is specific and necessary for quality control of drugs for parenteral drugs in the form of solutions.

Control of metals (inactive impurities) the SPhU methodology was applied, 2.2.57. It is proposed to leave the aluminum impurity standardization at the level established in the SPhU monograph [13]. The acceptance criteria for molybdenum, copper, silicon, boron, arsenic, bismuth, chromium, cadmium, nickel, lead, tin, antimony, zinc, manganese, and iron are given in Table.

The indicators "pH", "Mechanical inclusions" are included in the set of specific criteria for parenteral drugs. Mechanical inclusions directly affect safety. It is recommended to determine this indicator in accordance with the conditions given in the SPhU.

The pH of the medium is an important characteristic when creating parenteral dosage forms. It is necessary to determine the optimal pH value at which the stability of the radionuclide and pharmacotherapeutic activity are maintained. Based on experimental studies, the pH standardization of 4.0-8.0 has been proposed. The pH of the solution is within the limits that are close to the blood.

According to the requirements of SPhU, drugs for parenteral introduction must be isotonic, that is, their osmotic pressure must correspond to the osmotic pressure of body fluids (blood, plasma, lymph) and be about 300 mosmol/l [15]. Sodium chloride performs the functional purpose of an eluent in the preparation.

When administering sodium pertechnetate-^{99m}Tc solution for injection, it must be taken into account that the drug contains sodium chloride, the concentration of which should be monitored in patients on a low-sodium diet.

It is proposed to carry out the quantitative determination of sodium chloride by potentiometric titration. The sodium chloride content in the radiopharmaceutical preparation «Sodium pertechnetate [^{99m}Tc], extractional, solution for injection» is standardized with in ±5.0% upon release and during the shelf life. The limits of sodium chloride content established in the specification meet the requirements of Guideline 42-3.2: 2004.

The "Radioactivity" indicator was determined using a dose calibrator by determining the radioactivity of the

radionuclide per unit of packaging (vial). The standardization is established from 74 to 1480 MBq/ml on the date and time indicated on the package. The criterion for the acceptability of the technetium-99m content in the preparation is standardized from 90 to 110% of the declared radioactivity of technetium-99m on the date and time indicated on the package.

RRP for parenteral use must be manufactured with care to eliminate microbiological contamination and ensure sterility. It is proposed to carry out the quality indicator "Sterility" by membrane filtration according to the method (SPhU, *2.6.1*) [6]. To conduct the test, it is necessary to use liquid thioglycol and soy-casein media. Incubate the cultures for 14 days. The RRP passes the test for sterility, if no growth of microorganisms is detected during the recording**.**

According to the requirements of the SPhU, RRP for parenteral use must withstand tests for bacterial endotoxins. High values will affect patient safety. The determination of "Bacterial endotoxins" must be carried out using the Endosafe® Nexgen-LAL-test Portable Test System (Charles River Laboratories) automatic bacterial endotoxin determination device in accordance with the article (SPhU, *2.6.14*). The results of microbiological studies will be presented in a separate publication**.**

Based on the requirements of regulatory documents and the experimental results obtained, a specification has been drawn up for general and specific control criteria for the radiopharmaceutical preparation «Sodium pertechnetate [^{99m}Tc], extractional, solution for injection» (see Table).

SPECIFICATION OF ACCEPTABILITY OF QUALITY INDICATORS OF THE RADIOPHARMACEUTICAL PREPARATION "SODIUM PERTECHNETATE [^{99m}Tc], EXTRACTIONAL, SOLUTION FOR INJECTION"

Indicator name	Acceptable limits	Control methods
Description	Clear, colorless solution	Visually
Identification - technetium-99m	A. Record of the spectrum of decayed gamma radiation. The most active gamma photon of technetium-99m has an energy of 0.141 MeV. B. On the radiochromatogram of the test solution, obtained during the test for radiochemical purity, the retention coefficient of the main peak is about 0.6.	SPhU *2.2.66* (method of gamma spectrometry) SPhU *2.2.26* (method of descending chromatography on paper)
- sodium chloride	Characteristic lines with wavelengths 330.23 and 330.29 (doublet)	SPhU *2.2.57*
pH	From 4.0 to 8.0	SPhU *2.2.3*
Radionuclide purity	*Impurity A (Molybdenum-99)* – not more than 0.1% of total radioactivity. The most active gamma photons have energies of 0.181 MeV, 0.740 MeV and 0.778 MeV; the half-life of molybdenum-99 is 66.0 hours. *Other gamma-emitting impurities* – not more than 0.01% of total radioactivity.	SPhU *2.2.66* (method of gamma spectrometry)
Aluminium	Up to 0,0005 % (5ppm)	SPhU *2.2.57*
Inactive impurities Molybdenum, Mo Copper, Cu Silicon, Si Boron, B Arsenic, Bismuth, Chromium, Cadmium, Nickel, Lead, Tin, Antimony, Zinc, Manganese, Iron	 Up to 0.00002 % Up to 0.00001 % Up to 0.0005 % Up to 0.00025 % Must not be revealed	 SPhU *2.2.57*
Mechanical inclusions - visible particles - invisible particles	Practically free from particles Average number of particles: ≥10 μm must be no more than 6,000 per vial; ≥25 μm must be no more than 600 per vial	SPhU *2.9.20* SPhU *2.9.19, method 1*
Sterility	Must be sterile. The preparation may be released for use before completion of the test.	SPhU *2.6.1*
Radioactivity technetium-99m	From 74 to 1480 MBq/ml on the date and time indicated on the package (90 per cent to 110 per cent of the declared technetium-99m radioactivity at the date and time stated on the label)	SPhU *2.2.66* (method of gamma spectrometry)

Radiochemical purity [^{99m}Tc] pertechnetate ion	Not less than 95% of the total radioactivity due to technetium-99m	SPhU *2.2.26* (method of descending chromatography on pape)
Residual amounts of organic solvents	Methylethylketone – no more than 0.5% (5000 ppm)	SPhU *2.2.28* (method of gas chromato-graphy)
Bacterial endotoxins	No more than 175/V IU/mL V – total dose in ml at the time of production	SPhU *2.6.14*
Quantitative definition - sodium chloride	From 8.55 to 9.45 mg in 1 ml of the drug	SPhU *2.2.20* (method of potentiometric titration)

In accordance with the requirements of the Instruction ST-N MOZU 42-4.0:2020 [16], an authorized person may issue a permit for the release (sale) of a batch of the radiopharmaceutical preparation «Sodium pertechnetate [^{99m}Tc], extractional, solution for injection» before the completion of all chemical and microbiological tests based on the evaluation of production protocols, since it has a short shelf life. First of all, this applies to the indicator "Sterility", since the tests are carried out for 14 days. Therefore, it is important to ensure all the requirements of the pharmaceutical quality system as much as possible to guarantee the safety and effectiveness of the radiopharmaceutical.

For drugs, it is necessary to ensure correct labeling and information about the drug. This test was carried out visually. Using a laser marker, the following information is applied to the bottle: name of the manufacturing company, name of the radiopharmaceutical, dosage form, batch number, shelf life, sterile, sign "radiation hazard".

The label of the transport packaging set with the radiation hazard sign indicates the name of the manufacturing company, its address, the name of the drug, composition, activity, date and time of production, intravenous, sterile, batch number, expiration date, storage conditions, type and number of the container, transport index and category, registration certificate number, class of substance, barcode, manipulation signs "Top" and "Caution, fragile".

The radiopharmaceutical preparation «Sodium pertechnetate [^{99m}Tc], extractional, solution for injection» should be stored in its original packaging at a temperature not exceeding 25°C in accordance with national and international rules for the storage of radioactive substances, placed in a special radioprotective lead container. The preparation cannot be frozen.

CONCLUSIONS

Based on the conducted complex of scientific and research works, a set of quality indicators for the control of radiopharmaceutical preparation «Sodium pertechnetate [^{99m}Tc], extractional, solution for injection» was determined. Acceptance criteria and testing methods were determined. Sections of the specification were compiled, which will be used for quality control of the drug and included in section «P» of the registration dossier of the CTD format when registering the drug in the State Expert Center of the Ministry of Health of Ukraine and obtaining a registration certificate.

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ОБГРУНТУВАННЯ ВИБОРУ ПОКАЗНИКІВ ЯКОСТІ ПРИ СТАНДАРТИЗАЦІЇ РАДІОФАРМАЦЕВТИЧНОГО ПРЕПАРАТУ «НАТРІЮ ПЕРТЕХНЕТАТ [^{99m}Tc], ЕКСТРАКЦІЙНИЙ, РОЗЧИН ДЛЯ ІН'ЄКЦІЙ»

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Радіоізотоп технецію ^{99m}Tc має оптимальні характеристики для використання в ядерній медицині та є пріоритетом у виборі серед радіофармацевтичних лікарських препаратів для діагностики онкологічних захворювань. Важливим етапом у комплексі науково-дослідних робіт по створенню радіофармацевтичного препарату «Натрію пертехнетат [^{99m}Tc], екстракційний, розчин для ін'єкцій» є стандартизація, яка включає встановлення вимог до якості лікарського засобу. При розробці специфікації на препарат визначено набір показників якості з урахуванням виду лікарської форми. Встановлено критерії прийнятності та методики проведення випробувань. Складено розділи специфікації, які будуть використані для контролю якості препарату і включені в розділ Р реєстраційного досьє формату ЗТД при реєстрації препарату.