

**TECHNETIUM-99M GENERATOR OF HIGH ACTIVITY FOR NUCLEAR
MEDICINE, CLINICAL APPLICATION WITH COLD KITS.**

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The aim of this research is the development of Technetium-99m generator of high activity that provides for a stable high yield of $\text{Na}^{99\text{m}}\text{TcO}_4$ sterile solution from the generator column and a good quality of the eluate for preparation of diagnostic-purpose radiopharmaceuticals with a wide range of cold kits in hospitals and effectiveness estimation of their clinical application.

It has been shown that generator has to contain the adsorbent packed in layers. One layer contains silica gel modified by manganese IV) dioxide and the other ones contain chromatographic aluminum oxides in different forms (acid, alkaline and neutral forms}.

Molibdenum-99 radionuclide has been adsorbed from nitric acid solution at pH 5,5 – 6,0. Molybdenum-99 activity adsorbed is 0.1 – 4 Ci.

Technetium-99 radiopharmaceutical has been eluted by the passage of the sodium chloride isotonic solution through the column containing multi-layer adsorbent. If the adsorbed molybdenum is high active (more than 4Ci) the column with the adsorbent is additionally packed by the upper layer containing aluminum oxide in the acid form in the elution direction.

Technetium-99m generator production technology of world level with 0.1 – 4.0 Ci activity has been developed with Tc-99m yield not less than 95%, Mn^{2+} and Al^{3+} ion concentrations – 0.1 – 5.0 $\mu\text{g/ml}$ and 0.3 – 1.0 $\mu\text{g/ml}$, correspondingly, and molybdenum-99 concentration – 10^{-4} – $10^{-5}\%$ of technetium-99m activity. Manganese concentration data comparison shows that proposed technology $\text{Na}^{99\text{m}}\text{TcO}_4$ prepartate production allows manganese content reduction in 1~2 order. It is important because the cold kits are very sensitive to stable chemical impurities. The other quality characteristics correspond to the requirements of Russian, British and US Pharmacopoeia.

Tc-99m generator production technology possesses a patent #2153357 of 03.08.2000 “Generator for technetium-99m sterile radiopharmaceutical production”.

High quality radiopharmaceuticals were obtained on the base of eluates when we used the available cold kits for Technetium-99m generator. Thus, our experience of the application

of a wide range of cold kits produced in Russia as well as by leading foreign companies (CIS bio international, Nycomed Amersham, Mallinckrodt Medical, etc.) demonstrates a high quality of the radiopharmaceuticals.

Clinical application of the Tc-99m generators made in SSC RF IPPE (State Scientific Center of Russian Federation – Institute of Physics and Power Engineering) has presented the eluate high quality at the Department of Radioisotope Diagnostics of MRRC RAMS (Medical Research Radiological Center of Russian Academy of Medical Science). Wide range of cold kits made both in Russia (Diamed, Medradiopreparat) and in the foreign companies (CIS BIO, Nycomed Amersham, Mallinckrodt Medical) is used for radiopharmaceuticals production for scintigraphy of brain (Ceretec), cardiovascular system (Techneteryl, MIBI, TCK-1, TCK-2, Cardiolite), lungs (Macrotech, Pulmocis), kidneys (TCK-6, MAG3, TCK-12, Pentatech, Technemec, Technemag), hepato-biliary system (Techneteryl, Coren, Bromezida, Mezida, TCK-1, TCK-15), skeleton (Pyrphotech, Technefor, TCK-7) and tumors (Technetruel, Carbomec) .

The operation of the investigating Technetium-99m generators produced by SSC RF IPPE in the Division of radioisotope diagnostics of MRRC RAMS demonstrated their convenience, reliability and safety during operation in hospitals. Different organs and systems of more than 2,000 patients were examined by radioisotope diagnostic methods with the use of Technetium-99m radiopharmaceuticals.

A number of patients treated with the help of every type of used cold kits is presented in the report. It has been stated, that the radiopharmaceuticals obtained on the base of eluates and cold kits enabled to perform the patients' efficient and qualitative examination.