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Synthesis, quality control and stability studies of 2-[¹⁸F] fluoro-2-deoxy-D-glucose (18F-FDG) at different conditions of temperature by physicochemical and microbiological assays

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The introduction of 2-[¹⁸F] fluor-2-deoxy-D-glucose (¹⁸F-FDG) has provided a valuable tool for the study of glucose metabolism in both normal and diseased tissue in conjunction with positron emission tomography (PET). ¹⁸F-FDG is the most important radiopharmaceutical to be used in nuclear medicine for studying the brain, heart and tumor. In this manuscript, we explain the synthesis, quality control and stability studies of ¹⁸F-FDG (evaluate the physicochemical and microbiological stability of ¹⁸F-FDG, stored at room temperature (18-23°C), and 35-40°C, at different time intervals). We investigated how the influence of environmental factors in different lengths of time, alters the quality of this radiopharmaceutical. The pH, radionuclidic identity and purity, radiochemical identity and purity, chemical purity, bacterial endotoxins and sterility of ¹⁸F-FDG were evaluated according to the European Pharmacopoeia 7ed. analytical methods and acceptance criteria. The results suggest that under experimental conditions ¹⁸F-FDG has physicochemical and microbiological stability up to 10 hours after the end of synthesis.

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