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CRITICAL POINTS FOR IMPROVEMENT OF PERFORMANCE IN A SUMMARY OF MODULE SYNTHERA 18FDG.

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Abstract

The development of new material synthesis modules with a single use kit type is designed to facilitate the maintenance of equipment and compliance with Good Practice Radiopharmaceuticals (GRPP).

Objectives

Check the robustness and reliability of production at 130 synthesis of 18FDG Synthera made with the module (IBA), to analyze the influence of various parameters on the performance of radiopharmaceutical production and purity of the product and find the critical points.

Methodology:

Analysis of the production yields (activity corrected for decay), radiochemical purity (% fluorine-18 free) and quantity of waste solvents. Checking synthesis parameters.

Results

The performance of the first 80 synthesis was 64.8%. The critical points were located (1) the system checks carried out on the IFP (Integrated Fluidic Processor) before the synthesis: variation in flow, pressure and vacuum tubes and (2) the need for a emptying wash of white. Depending on the deviation of these parameters for the level prescribed by the manufacturer, the following results:

	Desviaciones < 1%			Desviaciones > 1%		
	Flujo	Presión	Vacío	Flujo	Presión	Vacío
Rendimiento	79,8%	79,9%	59,65%	74,9%	75%	20-55%
% $^{18}F^-$	0,42%	0,43%	0,45%	0,43%	0,42%	2,54
Acetonitrilo (ppm)	2	2	16	2	2	80
Etanol (ppm)	2475	2475	2500	2475	2600	4700

Deviations <1% did not affect the performance or quality radiopharmaceutical but variations between 1-4% lower both yield and purity radiopharmaceutical, especially when the deviation affects the level of vacuum.

Comparing the performance of the module with respect to the modules previously used in our center (FDG Tracerlab FX) the yield is almost 20% higher and the% of Fluorine-18 and acetonitrile are lower, while the% of ethanol is somewhat higher.

There were 3 synthesis failed: 2 (1.53%) due to defective IFP and 1 (0.78%) to human error.

Conclusions

The identification of critical points and the corrective measures undertaken have helped increase the production yield by 15% (up 80.4%, n = 50) and improve the

quality radiopharmaceutical The traceability obtained is much higher than expectations .