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Development of a new method for the microbiological analysis of radiopharmaceuticals case of Iodine 131

OBJECTIVE:
The main aim of this study is to develop a new microbiological control method for the solution of iodine 131 in a closed system for radiopharmacy services not equipped with a class A Hot Cell dedicated to microbiological analysis according to GMP requirements.

METHODS:
The method is based on the preparation of perforated petri dishes containing three culture media. The perforation of the Petri dishes was realized under a class A laminar flow hood using a heated metal cylindrical rod. A sterile magnetic stir bar was then placed in each Petri dish before closing the hole and sealing Petri dishes with autoclaving adhesive.
First, the method was tested inside a class C room then inside an unclassified area by perforating the adhesive with a sterile syringe and injecting a volume of sterile water before the perforation was closed by a second sterile adhesive. Seeding was performed by moving each Petri dish on a magnet. Then the Petri dishes were incubated inside the Hot Cell at room temperature for Yeast and Mold at 32.5 ℃ and for Total Aerobic Microbial and Total Coliform.
A positive control (bacterial suspension) and a negative control (sterile water) were performed for each culture medium.
Finally, the method was tested inside a class C Hot Cell for three production batches of sterile iodine-131.

RESULTS:
After 5 days incubation at 32,5℃ and 7 days at room temperature, The Petri dishes was sterile for both tests performed in class C room and for the unclassified room. The same result was obtained with the solution of iodine131 in the three production batches.

CONCLUSION:
This new method has shown good efficiency to keep the sterility of culture medium during the microbiological analysis independently of the environmental class. It could be adopted by radiopharmacy services for the control of the solution of iodine131 and other radiopharmaceuticals. This method would make it possible to carry out the microbiological analysis of radiopharmaceuticals quickly without waiting for the decay. Moreover, it allows to minimize the risk of exposure of the laboratory technicians by iodine inhalation.

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