Contribution ID: **40** Type: **not specified**

# Formulation and Radiolabelling of Ethambutol with Technetium-99m for Detection of Extrapulmonary Tuberculosis

*Tuesday, 29 October 2019 23:44 (15 minutes)*

ABSTRACT
Background. According to World Health Organisation (WHO) tuberculosis (TB) is one of the top 10 causes of death worldwide. It was also reported in the world in 2017 that 10 million people fell ill with TB and 1.6 million died from the disease. TB is an infection caused by the bacterium Mycobacterium tuberculosis. TB usually attacks lungs, but it can also spread to other organs, this TB is commonly called extrapulmonary TB. This type of TB is relatively difficult to be detected by conventional methods, therefore a proper and specific method is needed. Center for Radioisotope and Radiopharmaceutical Technology (CRRT) –National Nuclear Energy Agency of Indonesia (BATAN) has been developed single-vial ethambutol radiopharmaceutical kits which can be used to detect this type of TB. The single-vial ethambutol kit is an improved form of the previous developed two-vial ethambutol kits.
Methodology. Lyophilized ethambutol kits aseptically prepared in the clean room. and consisted of ethambutol, SnCl2.2H2O, mannitol and sodium pyrophosphate. Lyophilization of ethambutol kits was performed using freeze dryer with freezing step, primary drying and secondary drying for 42 hours,3 hours and 3.5 hours respectively. Evaluation of single-vial ethambutol kit included clarity, pH, radiochemical purity, sterility and endotoxin. Radiochemical purity, sterility and endotoxin tests were performed using thin layer chromatography, direct inoculation and Tachypleus Amebocyte Lysate (TAL) respectively. Radiolabelling of ethambutol with technetium-99m was prepared by incubating the kit erials dissolved in 1.5 mL of Tc-99m at room temperature for 10 minutes.
Results dan Discussion. Freeze-dried and sterile ethambutol kit has been prepared. Each ethambutol kit vial comprised a lyophilized mixture of 3.5 mg ethambutol, 1 mg SnCl2.2H2O, 5 mg mannitol and 17.5 mg sodium pyrophosphate. Radiolabelling of single-vial ethambutol was carried out using 1.48 GBq of Tc-99m to result in a clear 99m Tc-ethambutol complex with radiochemical purity of above 85% and pH 9. Endotoxin test which performed using TAL gave concentration Lysate < 0.25 EU/mL. The sterile lyophilized single-vial ethambutol kits, radiolabeled with Tc-99m, have been clinically test for diagnosis of extrapulmonary TB in adult as well as children patients at Hasan Sadikin Hospital, Bandung, Indonesia. The result showed that 99mTc-ethambutol can be used as a safe, effective and non-invasive alternative modality for diagnosis of extrapulmonary TB.
Conclusion. Freeze-dried ethambutol kit, a sterile product, has been developed and suitable for diagnosis of extrapulmonary tuberculosis.
Keywords : tuberculosis, extrapulmonary, ethambutol, technetium-99m,99mTc-ethambutol.

**Primary author:** Ms LESTARI, Wening (Center for Radioisotope and Radiopharmaceutical Technology,National Nuclear Energy Agency)

**Co-authors:** Mrs ROSELLIANA, Anna (Center for Radioisotop and Radiopharmaceutical Technology,National Nuclear Energy Agency); Mrs LESTARI, Enny (Center for Radioisotop and Radiopharmaceutical Technology,National Nuclear Energy Agency); Mrs MUJINAH, Mujinah (Center for Radioisotop and Radiopharmaceutical Technology,National Nuclear Energy Agency); Mrs WITARTI, Witarti (Center for Radioisotop and Radiopharmaceutical Technology,National Nuclear Energy Agency); Mr ARIYANTO, Agus (Center for Radioisotop and Radiopharmaceutical Technology,National Nuclear Energy Agency); Mr WIDJAKSANA, Widyastuti (Center for Radioisotop and Radiopharmaceutical Technology,National Nuclear Energy Agency)

**Presenter:** Ms LESTARI, Wening (Center for Radioisotope and Radiopharmaceutical Technology,National Nuclear Energy Agency)