

Faculty of Pharmacy UGM Has BA/BE Test Laboratory

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Universitas Gadjah Mada (UGM) keeps making an improvement, particularly in the development and establishment of educational facilitations. This time, Laboratorium of Advanced Pharmaceutical Sciences (APS) of Faculty of Pharmacy UGM acquires an accreditation of BA (Bioavailability)/BE (Bioequivalency) Test Laboratory from the National Accreditation Committee ISO 17025 certification and obtains a recommendation from Medicine and Food Supervision Institute (BPOM) as a GCP and GLP standard test laboratory.

The BA/BE test was performed to analyze whether a copy medicine has the same availability with the innovator one or not. BA/BE test is expected to show the ratio of therapy quality and effectivity between a copy medicine and its innovator. Bioequivalency test also aims to ensure the efficacy, security, and quality of medicine products.

According to BPOM, there are at least two aspects which have to be fulfilled by a BA/BE Test Laboratory. The first aspect is that laboratory has to fulfill Good Laboratory Practice (GLP) which is shown by ISO 17025 certificate from the National Accreditation Committee for the tested medicine. The second aspect is it has to fulfill Good Clinical Practice (GCP) which is shown by a GCP certificate for the researcher who is in charge and a clinic laboratory with ISO 15189 certificate as well as adequate medical facilities for the blood taking process. The APS Laboratory of Faculty of Pharmacy UGM has fulfilled those two aspects thus it can perform the BA/BE Test.



Vice Dean for Research, Community Service, Cooperation, and Alumnae of Faculty of Pharmacy UGM, Dr. R. R. Endang Lukitaningsih, M.Si., Apt., said all of the equipments owned by APS Laboratory cannot be utilized for students practice and have to be calibrated every year. Endang also said the comparison standards also have to be available and unexpired. The standards are not only implemented for the laboratory equipment, but also the people in charge of performing BA/BE Test who have obtained an ISO 17025 training.

Endang further explained APS Laboratory has been opening a testing service which has been accredited by ISO 17025 for simultaneously multivitamin analysis (Vitamin B1, B2, B6, B12, C) in solid and liquid preparations. Until 2014, APS Laboratory had 10 research areas including analysis of several types of medicine in spiked plasma. Then, in 2016, those areas were expanded into 15 areas.

“The test showed there are 7 types of medicine testing in spiked plasma,” said Endang.

She also said there are 7 types of BE testing which can be performed in APS Laboratory including Ciprofloxacin, Levofloxacin, Na-diclofenac, Simvastatin, Rifampicin, and Furosemide. Several types of BE Testing from pharmaceutical industries have been tested and some of them are still ongoing.

Endang hopes the research areas which can be tested at APS Laboratory can increase in the future, particularly the generic medicine which becomes the priority in Social Security for Health (BPJS).

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