

Sirim conducts various levels of testing to ensure Sinovac safety

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Sirim Bhd is conducting various levels of testing to validate the process while ensuring a safe and efficacious final product of vaccine in injectable vials for Sinovac, which were received in bulk quantities from China via Pharmaniaga Bhd.

Sirim general manager for the Industrial Biotechnology Research Centre (IBRC) Dr Ahmad Hazri Ab Rashid said the tests needed are part of the process validation for collecting and evaluating data which is provided during the process design stage throughout production, to establish scientific evidence such as toxicity, stability and potency of the bulk and final product to assure safety and quality.

He said IBRC, which is performing Safety Test-Abnormal Toxicity Tests and Immunoassay (Relative Potency) and test in animals, has received the vaccine in two to three batches every week since last March in a particular container that

keeps the temperature at two to eight degrees Celsius.

“The vaccines are then pooled and kept at room temperature for more than two hours before being injected in mice or guinea pigs to check any abnormal behaviour, body weight and mortality for 24 hours to seven days post-injection for abnormal toxicity test.

“Meanwhile, for the 14 days post-injection immunoassay, we will withdraw the blood. The Enzyme-Linked Immunosorbent Assay kit will be used to detect the antibody titer of mice serum against a reference vaccine,” he told Bernama in an exclusive online interview.

After that, he said the relative potency ratio between the antibody titer of the test with the reference vaccine of the same dose will be calculated.

He said the time frame given to Sirim to deliver for the abnormal toxicity test is eight days, and for the immunoassay it's 14 days.

Explaining the process, he said Pharmaniaga performs the filling from bulk volume into injectable vials before labelling and packing.

The samples of vials will be rigorously tested for submission to National

Pharmaceutical Regulatory Agency (NPRA) prior to release which includes potency, toxicity, microbiology, chemical and physical characterisation test.

Ahmad Hazri said vaccine vials will be sent to the government for distribution to the vaccination centres once approved by the NPRA with strict standard operating procedures (SOP) in terms of product tracking and storage temperature to ensure that there are no errors or mistakes in the vaccination process.

He mentioned that process validation involved three stages namely process design, process validation or process qualification and continued process validation.

Malaysia had received 3,687,880 doses of Sinovac as of June 21.

Touching on the Malaysian-made Covid-19 vaccine which is now at the cloning stage, Ahmad Hazri said Sirim hopes to be part of the vaccine development programme.

“We hope to support the government by providing the environment testing facilities for us to test the new vaccine. For new vaccine, there will be more tests needed, not just chemical and physical, but also biological and pre-clinical tests,”

he added.

It was reported that Malaysia is developing two Covid-19 vaccines - the mRNA vaccine and inactivated vaccine - in an effort to boost the country's vaccine development capacity and preparedness in facing future pandemics.

Ahmad Hazri also stressed that Sirim has developed the facilities and capabilities to perform a number of tests and continually working with the government, scientific testing laboratories and the pharmaceutical industry to provide fully comprehensive service support and ensure Malaysia is able to undertake a vaccine development programme.

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