

NFSU to now export vial examination kits

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Ahmedabad: What happens if a micro-sized fragment of glass or fabric gets inserted in a vial of medicine? If injected into the bloodstream, it can cause severe complications for the patient including death. Thus, global standards for the injectables are very high, and discovery of a small anomaly can lead to rejection of entire batches.

Thus, National Forensic Sciences University (NFSU) developed a kit for training of the personnel handling the vials and calibrate the machines to find the smallest of the inconsistencies. The kit, which is used by over 10 multinational drug manufactures based in India, recently got their first overseas orders from Indonesia and Singapore.

Jayrajsinh Sarvaiya, a faculty with NFSU, said that the university is associated with



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the quality control for long with various firms. "USFDA and other authorities have stringent standards about particulate matter contamination which can be in micron to sub-micron range. Recently even top companies' batches were rejected. Thus, we decided to make our own kit to identify every possible contamination and how to identify them," he

said.

The kit contains different vials, which are presented to the personnel and they are asked to identify whether the specific vial contains any anomaly. "There are more than 40 different types of contamination sources we have come across. Our experience to handle such cases has made it possible to come out as making

Knapp test Kits as per regulatory requirements," said Prof Sarvaiya.

Dr J M Vyas, vice-chancellor of NFSU, said that they are receiving four times more contamination investigation assignments compared to past couple of years. "It's a matter of pride for us that the kit and our method has got global recognition," he said.

For the industry, it means smoother process with international agencies. Manthan Trivedi, general manager with an MNC pharma company, said that the tests and training improve the compliance rate and reduce rejection rates in overseas market.

For the personnel, it's the battle of survival. "If they can detect the contamination, they can retain their job against the machines that do the same job," said another pharma company official.