India tightens drug quality norms with new pharmacopoeia standards

The changes have implications for India's roughly $250 million veterinary vaccine market.

NEW DELHI : New Delhi: India has introduced stricter testing and observation requirements for veterinary medicines, including biological products, with a particular focus on inactivated foot-and-mouth disease vaccines, according to two officials and a document reviewed by *Mint*.

Under the revised norms, manufacturers must administer a double dose of the vaccine to pigs and observe them for 14 days to detect any adverse reactions or contamination. The rules also introduce the monocyte activation test for biological products to detect pyrogens—substances that can trigger fever and signal contamination—during the manufacturing process.

The changes are part of the 10th edition of the Indian Pharmacopoeia, which came into effect on 1 July. The Indian Pharmacopoeia is the country's official book of quality standards for medicines, vaccines, biological products, and pharmaceutical ingredients.

News Source:

https://www.livemint.com/industry/india-indian-pharmacopoeia-10th-edition-drug-quality-standards-veterinary-vaccines-testing-rules-11783338364731.html