



PHARMACEUTICALS EXPORT PROMOTION COUNCIL

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Karnataka drug dept detects 9 drugs including 4 brands of diclofenac injections as not-of- standard quality

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Direct link to the News/Story:- <http://www.pharmabiz.com/article/detnews.asp?articleid=56166§ionid=>

Karnataka drugs control department carried out a series of raids on pharma companies for producing not-of-standard quality medicines during this month. Nine such drugs manufactured across the country and sold at chemist outlets in the state were detected. Of the nine drugs, four brands are diclofenac injections failing the quality test.

In an inspection drive carried out early this month, the Karnataka drugs test lab which has received the samples identified nine drugs to be not-of-standard quality. The drugs have failed the stability tests and are found to disintegrate. There were also instances of damaged packs.

The findings from the Drug Test Lab have indicated that of the nine drugs, four were diclofenac injections manufactured by four different companies in the country, found to be not-of-standard quality. The companies are Akums Drugs & Pharmaceuticals Limited in Haridwar, Win Drugs on Bhiwani Road, Jind, Regain Laboratories in Hissar and Embiotic Laboratories in Bangalore.

Other drugs included a surgical spirit produced by Kakatiya Pharma in Hyderabad, Oscadine Povidone Iodine by Oscar Remedies in Himachal Pradesh, albendazole tablets by Karnataka Antibiotics Pharmaceutical Limited, Ciflomit which is a ciprofloxacin tablet by Mars Remedies at Vadodara and Nervengine capsules by Eastern Healthcare in Haridwar.

The department has been carrying out regular surprise checks across the state. The drugs samples which are picked up from the chemist outlets are sent in for testing. Efforts are made to inform the healthcare providers and the chemists to refrain from prescribing and stocking these drugs. Going by the over-the-counter sales, public have been also alerted not to purchase these drugs, according to Dr. BR Jagashetty, Karnataka Drugs Controller.

Diclofenac injections are pain killers prescribed for arthritic conditions among others.

Experts point out that a drug is categorized as being not-of-standard quality or spurious when it resembles another popular drug brand, has less amount of active pharmaceutical ingredient, grossly sub-standard if its below 70 percent for thermo liability and below 5 percent in terms of the permitted limits for thermo stable products.

Further, it is also considered to be not-of-standard quality if the tablet or capsule fails disintegration of dissolution tests, presence of fungus in liquid preparations contains adulterants injurious to health.

In the case of small volume parenterals, not-of-standard quality is decided when product fails in tests for sterility, pyrogen/endotoxin test or is known to indicate undue toxicity. Vaccines failing in potency, sterility, toxicity or moisture content are considered to be not-of-standard quality.