Sun Pharma's bulk active and tablet manufacturing factories are cleared by USFDA

May 26, Mumbai: Two of Sun Pharma's factories recently received clearance from the USFDA without a single adverse remark or observation (technically called a 483 observation). Both the Panoli bulk active and Halol tablet manufacturing factories were inspected and cleared by the USFDA. With this addition, now three of the company's factories including the Ahmednagar site can be used for the US market.

This USFDA approval is the second major international approval for the Panoli factory. European regulatory authorities have earlier approved this factory. Large innovator companies across Europe have been sourcing material from here.

The clearance for formulations at Halol is the company's first USFDA clearance for an Indian tableting facility. The Halol factory has approvals from regulatory authorities like the UKMCA, Brazilian ANVISA, Columbian INVIMA, and South African MCC.

Sun Pharma will participate in the $16 billion US generic market both through the 63% subsidiary Caraco Pharmaceutical Labs (Amex: CPD) and this Indian factory.
"This approval significantly strengthens the company's international dosage form plans," said Dilip Shanghvi, CMD, Sun Pharma.

Sun Pharma is ranked 5th among all Indian pharma companies with a 3.12 %MS (IMS-ORG Retail Chemist Audit, April 2004). International markets account for 30% of turnover (with Caraco turnover) In niche therapy areas such as psychiatry, neurology, cardiology, diabetology, gastroenterology, orthopedics, Sun Pharma ranks among the top 3 companies (CMARC Nov 03- Feb 04).

The company has strong initiatives planned in research, with additional 250,000 sq ft of research floor area across 2 new sites added this year, 320 strong scientist staff, projects in human trials and continuing commitments of $15 mill to R&D for each of the next two years.

Mira Desai, Corporate Communications
Phone :022-28212128/ 28230102/8211961 ext 243
E mail: miradesai@sunpharma.com, corpcomm@sunpharma.com