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Our Bureau, Hyderabad

The Hyderabad-based MSN Laboratories Limited, the flagship company of the Rs 150 crore MSN Group of Companies, has successfully completed US FDA and EU GMP audits.

Commenting on the development, Dr M S N Reddy, chairman and managing director, MSN Laboratories, said, "It is a major achievement for us. We have achieved successful recognitions and approvals within a short span of four years of operations. Crossing this audit process has reiterated our belief in quality management and continuous process of innovation. It would help us in making a foray into the US and other regulated markets in the coming years."

According to the company, it has filed over 14 drug master files (DMFs) in both US and Europe and four CEPs in Europe. It is also planning to file another 14 over the next 12 months. It has also filed over 57 intellectual property rights (IPR) applications including over 14 under patent cooperation treaty (PCT) of which over 7 have been published.

The company stated that two of its manufacturing plants have been recently certified by the MOH of a European nation for Good Manufacturing Practices (GMP). In addition, European Directorate for Quality of Medicines (EDQM) has also approved MSNs Terbinafine CEP. Over 40 per cent of its present revenues are generated from international markets, more specifically from semi-regulated markets. With the approvals from US and European regulatory authorities, the company hopes to increase its revenue potential from its international endeavors more specifically the regulated markets, where the margins are higher.