

Biocon's First Overseas Insulin Unit in Malaysia receives EU GMP Compliance

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Biocon Sdn. Bhd. was issued a certificate of Good Manufacturing Practices Compliance, for its insulin manufacturing unit, said a stock exchange filing by Biocon. The facility has been inspected by the European Medicine Agency in April.



Biocon Ltd. has received a compliance certificate from the Irish drug regulator for its manufacturing and research facility in Malaysia.

Biocon Sdn. Bhd., its Malaysian subsidiary was issued a certificate of Good Manufacturing Practices Compliance, for its insulin manufacturing unit, said a stock exchange filing by Biocon. The facility has been inspected by the European Medicine Agency in April.

“Biocon’s subsidiary in Malaysia, Biocon Sdn. Bhd., has been issued a Certificate of ‘GMP Compliance’ for its Insulins manufacturing facility by the HPRA (Ireland) as the representative European inspection authority,” Biocon told BSE.

The certificate reflects that EMA considers the site to be GMP-compliant for active substances, sterile drug products, and quality control testing operations, it added.

Biocon’s Malaysia facility was inspected by the EMA in April 2017, stated the company. This Biocon’s first overseas biopharma manufacturing and research facility was set up with an investment of \$275 million and employs more than 600 professionals. It has been designed to manufacture human insulin for the treatment of diabetes.

Biocon has been developing a fast-acting oral insulin drug for a rarer case of diabetes Type 1, whose causes and preventive measures are yet not known. It has also filed an application with Drug Controller General of India for running clinical trials for a drug catering the more common type 2 diabetes.

Insugen and Basalog are the already selling insulin brands of Biocon’s Biologics division, that contributes nearly 19 percent to its total revenue.