

Company Statement on EU GMP Compliance Certificate

Biocon's Insulins facility in Malaysia Receives EU GMP Compliance Certificate

Bengaluru, Karnataka, India, Sep 07, 2017

"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. The certificate of GMP compliance reflects that the agency considered the site to be in compliance with the principles and guidelines of Good Manufacturing Practices for Active Substances, Sterile Drug Products and Quality Control Testing operations. Biocon's Malaysia facility was inspected by the EMA in April 2017.

Biocon Sdn. Bhd. (Biocon Malaysia) is one of Asia's largest state-of-the-art integrated insulins manufacturing facilities, set up with an investment of about USD 275 million, at the BioXcell Biotech Park in Johor, Malaysia. This is the first overseas biopharma manufacturing & research facility of Biocon and it employs over 600 professionals. The facility is designed to manufacture recombinant human insulin and insulin analogs to cater to the needs of people with diabetes in global markets."

-Company Spokesperson

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