



Biocon Biologics in Malaysia: Factsheet

Biocon Biologics is a leading global biosimilars company committed to addressing patients' needs for cost-effective, high-quality biosimilars.

VISION

To be a global leader in biologics, delivering affordable access to innovative and inclusive healthcare solutions, transforming patients' lives.

VALUES

- Innovation & differentiation
- Quality through compliance & best practices
- Integrity and ethical behaviour
- Collaboration, teamwork and mutual respect
- Performance-driven culture

Company Profile

Biocon Biologics is a unique, fully integrated, global biosimilars company with world-class 'lab to market' capabilities across development, manufacturing, and marketing. It is present in over 120 countries, including over 80 Emerging Market countries, where it is providing sustainable solutions for a healthier world through its cost-effective, high-quality biosimilars.

Biocon Biologics has created a Center of Excellence (CoE) for insulins in Malaysia with end-to-end capabilities for manufacturing a robust portfolio of human insulin and insulin analogs. The state-of-the-art integrated insulin manufacturing facility was set up with an investment of over USD 350 million (MYR 1,543.5 million), the largest foreign investment in biotechnology in Malaysia till date. Commercial operations at the facility commenced in 2016 when Biocon Biologics' recombinant human insulin became the first locally manufactured biosimilar product approved for sale in Malaysia. The company has been working closely with the Ministry of

Health, Malaysia (MoH) to cater to the growing needs of diabetes patients in the country and reducing the dependency on insulin imports. Biocon Biologics has provided the MoH over 87 million insulin cartridges and has served nearly 300,000 people with diabetes in Malaysia since 2016. Following Biocon Biologics' entry into Malaysia, prices of human insulin have dropped by over 40% and insulinization has improved by 30%, according to a market study.

Beyond insulins, Biocon Biologics also serves the needs of cancer patients in Malaysia through its Trastuzumab, Bevacizumab, and Pegfilgrastim biosimilars..

World-Class Facility

Biocon Biologics' commercial scale, globally compliant facility in Iskandar Puteri, Johor, has integrated capabilities for manufacturing drug substance, drug product and devices for human insulin and insulin analogs. It is the first and only biopharmaceutical sterile injectables facility in Malaysia to

receive approvals from the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA). In 2021, Biocon Biologics' biosimilar Insulin Glargine manufactured at the Malaysia facility received a historic U.S. approval as the first interchangeable biosimilar under the 351(k) regulatory pathway. Today, the company's biosimilar Insulin Glargine has a strong double-digit market share in the U.S., serving a very large pool of patients in the country. Insulin products manufactured at this facility are also serving a majority of the need for cost-effective, high-quality insulins in several Emerging Market countries.

This manufacturing facility is approved by U.S. FDA, EMA, NPRA (Malaysia), as well as several international regulatory agencies like TGA (Australia), ANVISA (Brazil), etc. The facility has state-of-the-art R&D, Quality Assurance, Quality Control labs and a very robust Quality Management System, which ensures the quality of products manufactured at the facility. The facility has been recognized as the first and largest integrated insulin manufacturer in Malaysia by the prestigious Malaysia Book of Records, which officially recognizes record-creating and record-breaking achievements in the country.

Biocon Biologics is deeply committed to address patients' needs for insulins in Malaysia and other parts of the world.

Products Commercialized in Malaysia

Brand Name	Molecule*
Insugen	rh-Insulin
Basalog One	Insulin Glargine
Kirsty	Insulin Aspart
Zuhera	Trastuzumab
Krabeva	Bevacizumab

*All products commercialized by our partner Duopharma in Malaysia

Biocon Biologics in Malaysia

Business Partnership

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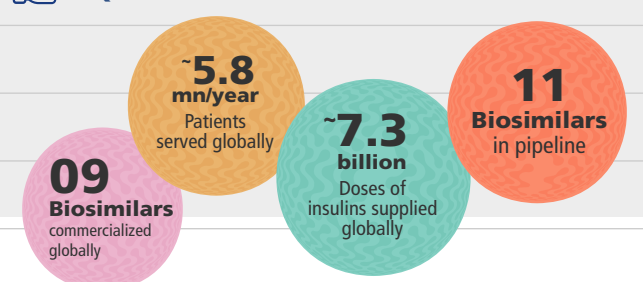
Adverse Events

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Global Portfolio

Trastuzumab	Insulin Glargine
Bevacizumab	Insulin Aspart
Pegfilgrastim	Adalimumab
rh-Insulin	Etanercept
Ustekinumab	

Quick Facts



The Biocon Biologics Advantage

- **PATIENT-CENTRICITY:** Committed to expand patient reach and generate significant saving for patients, payers, and healthcare systems.
- **LAB-TO-MARKET EXPERTISE:** Fully integrated from biosimilars development to manufacturing, distribution and commercialization.
- **LEGACY OF SUCCESS:** Cutting-edge scientific and technological capabilities leading to many 'firsts' in the industry - first to receive approvals in U.S. for biosimilar Trastuzumab, biosimilar Pegfilgrastim and interchangeable biosimilar Insulin Glargine.
- **UNIQUE PORTFOLIO:** Comprehensive and differentiated portfolio of biosimilars, including insulins, monoclonal antibodies, and recombinant proteins.
- **GLOBAL SCALE PRODUCTION:** Operates 3 large scale, globally compliant biosimilars manufacturing facilities; Among the Top 15* companies globally in terms of biomanufacturing capacity.
- **WORLDWIDE COMMERCIAL FOOTPRINT:** Commercialized products in 120+ countries through a combination of direct presence, strategic partnerships and distributors.
- **PROVEN TRACK RECORD:** 90+ cGMP approvals obtained from international regulatory agencies.

*19th Annual Report of BioPlan Associates

