



NANOGEN
B I O P H A R M A C E U T I C A L

*Live Well*_____

About **NANOGEN**

COMPANY PROFILE

Nanogen Pharmaceutical Biotechnology is Vietnam's a research and Innovation driven Biotechnology Company.

In 1997, our journey began with manufacturing unit of three production lines for lyophilized powder, vials, and prefilled syringe. Following our early accomplishments, we set out to complete the other phase of our growth in the form of state-of-the-art manufacturing facilities, which are designed to comply with EU GMP and TGA Australia. These facilities are dedicated to manufacture Biological, Oncological and other parenteral products.

With this substantial upgrade, we will be able to share our high-value products with affordable price to countries in need.

With a vision to conquer new horizons of excellence, Nanogen's strength lies in its use of top quality facilities with its internationally experienced R&D professionals and with continues guidance of collaborated research institutes and universities across the globe.



VISION

To become the world-class pharmaceutical and Biotechnology organization in Asia

MISSION

To become **world-class, innovative** biotechnology company in the **pharmaceutical** industry. We take pride in the quality, **safety and efficacy** of the innovative products, manufactured by **propose-driven** individuals in an energized workplace. We are committed to continuously delight our customers and stakeholders with our **exceptional service** and **unwavering integrity**. We **continuously improve** our standards and **strive for excellence** in all aspects of our business



MILESTONE



2018

Introduced 34 000 sq.m unit for Infusion solution, beta lactam, solid, oncology products

2018

Introduced 24,000 sq.m TGA compliant unit for large scale Biological production

2017

Invested by STIC Private Equity Fund (USD 20 Million)

2015

Inaugurated second 10,000 sq.m facility with state-of-the-art R&D and Biological API manufacturing

2013

Received U.S Patent approval for Peg-Interferon Lambda 1 Conjugates

2012

Rolled out International business operation

2011

Launched Erythropoietin, Filgrastim, Peg Filgrastim

2010

Launched first Biosimilar of Peg-Interferon α 2a (Pegnano) in Asia

2009

Established first 5,000 sq.m biological manufacturing unit, consists of three production lines

2006

Changed over the name to NANOGEN

1997

Company incorporated as a Viet Co Co Ltd

FACILITIES

FACILITY I: Cytotoxic products / Biological products

Located : Saigon Hi-tech Park of Hochiminh City, Vietnam

Total area: 15 000 m²

Factory 1: WHO-GMP compliant: 5 000 m² (Biological products)

Factory 2: On process for TGA- GMP, compliant: 10000 m²
(Cytotoxic Products)



FACILITY II: Biological products / R&D Center

Located: Saigon Hi-tech Park of Hochiminh City, Vietnam

Total area: 24 000 m²

Business: API large-scale production & Tech- transfer service



FACILITY III: Infusion products

Located: Phu Hoi Industrial Zone, Lamdong Province, Vietnam

Total area: 34 000 m²

Business: Infusion solution, beta lactam, solid products,
oncology tablets Under construction, business start
in 2019 with Infusion solution



HA NOI BRANCH OFFICE
Ha Noi City, Vietnam

TECHNOLOGY DEVELOPMENT

Nanogen's Formulation & Development teams are geared up to meet the new challenges to develop next generation biosimilars.



MANUFACTURING FACILITIES

PRODUCTION LINES

Formulation Capacity: Fill & Finish

Formulation type	Fill Volume (ml)	Filling speed/h	Output/batch
Vials (Liquid & Lyophilized)	1	6.000	60.000
	5	6.000	60.000
	10	6.000	60.000
	15	5.000	50.000
Prefilled syringes	20 – 30	3.600	36.000
	40 – 50	1.200	120.000
Lyophilized	0.5 – 3.0	8.000	12.000
	1	6.000	20.000
	5 – 10	6.000	10.000
	15 – 20	1.200	4.500

Prefilled syringes



Liquid & Lyophilized vials



KEY SUPPORT FUNCTIONS

► Packaging



► Warehouse

- Segregated controlled area of 600 m² for RM, Primary PM & Secondary PM
- GSP controlled system for cold storage and freezer
- Equipped with refrigerated truck



QUALITY CONTROL

☞ Biochemical-Physicochemical Team:

- ▶ **Biochemical:** Antiviral assay, Cell Proliferation assay of APIs, Finished products, Stability Testing, Process Validation.
- ▶ **Physicochemical:** test Raw materials, Packaging materials, APIs, Finished products, water system, In-process Control, Stability Testing, Process Validation, Cleaning Validation and Validation support testing.
- ▶ **Calibration:** calibration & maintenance all of the equipment in QC dept.

☞ Microbial-Pharmacological Team:

- ▶ **Microbial:** Microbiological Limit Tests, Bioburden, Sterility testing, Bacterial Endotoxin Test, Environment Monitoring, Water system Monitoring.
- ▶ **Pharmacological:** in vivo assay, abnormal toxicity test



RESEARCH AND DEVELOPMENT OF FINISHED PRODUCT

- ▶ Research and development of formula/manufacturing process/ analytical method of new finished products: chemical/biopharmaceutical, including solid, injection and infusion for on-time launching to market
- ▶ Improving and optimizing formula and manufacturing process of existing finished products: chemical/biopharmaceutical, including solid, injection and infusion. Support to solve technical problems arising in production
- ▶ Technology transfer of scale-up to Production and Quality Control department and other relevant activities

MEDICAL SUPPLY

- ▶ Edit and develop product package insert for registration
- ▶ Implement and review Pharmacovigilance
- ▶ Provide medical advices of all products

CLINICAL SUPPLY

- ▶ Develop clinical trial documents compliance with ACTD
- ▶ Incorporating with the other clinical related organizations in conducting clinical trials of products
- ▶ Inspect clinical trial projects throughout the execution procedure



QUALITY ASSURANCE

- ▶ Validated document management system
- ▶ Ensure medical products compliance with internal and national GMP
- ▶ Production and Operation control via PIC/SGMP
- ▶ Periodic review products quality and manufacture inspection
- ▶ Vendor and Material management by GMP, GLP, GSP
- ▶ ERP system- cGMP documentation
- ▶ Quality improvement via continuous audits
- ▶ Internal self-assessment audits and annual internal training



CERTIFICATES

Nanogen's facilities have been designed to comply with EU GMP and TGA Australia.



Nanogen can help broaden your business!

SERVICES

Nanogen offers a variety of contract services to support technical expertise and market expansion with our partners by cooperating in Contract Manufacturing and Technology Transfer.

WHAT WE OFFER

- ▶ Proven technology with successful reproduction track record
- ▶ Complete data package, including safety and efficacy data
- ▶ Established in-house R&D, RA, QA, and Tech Transfer teams
- ▶ Complete Formulation & Filling manufacturing, QA/QC, Bioassays & IPC
- ▶ Full Drug Master File (DMF)
- ▶ GMP Process and Analytical Validations Clinical data



PRODUCTS

FINISHED PRODUCTS BIOPHARMACEUTICAL



NANOKINE

Erythropoietin α

2,000 IU/0.5 ml

4,000 IU/0.5 ml

10,000 IU/1 ml

EPO is used to treat anemia in patients with chronic kidney failure, patients receiving HIV treatment, and patients receiving chemotherapy for some types of cancer. It is also used in anemic patients to reduce the need for blood transfusions during surgeries that have a high risk of blood loss.



FICOCYTE

Filgrastim

30 MU /0.5 ml

It is a synthetic version of a certain natural substance made in the human body. It helps the bone marrow to produce new white blood cells. Filgrastim is given to people whose ability to produce white blood cells is reduced, due to chemotherapy, chronic neutropenia, or exposure to large amounts of radiation. It is also used in certain treatment procedures such as bone marrow/stem cell transplant.

PRODUCTS

FINISHED PRODUCTS BIOPHARMACEUTICAL



PEGCYTE

Peg Filgrastim

6 mg/ 0.6 ml

Pegfilgrastim has a polyethylene glycol, "PEG," unit added to it, which makes the molecule larger so that it stays in your system longer than filgrastim.



PEGNANO

PegInterferonapha-2a

PFS 180 mcg /0.5 ml

It is an antiviral for the treatment of chronic hepatitis B virus (HBV) infection and chronic hepatitis C virus (HCV) infection. HBV and HCV infections are HIV-related opportunistic infections. Peg INF is given alone or in combination with other medications.

FINISHED PRODUCTS

PHARMACEUTICAL

Name	Ingredients	Indications	Administration	Strength
GLURINAX 600	Glutathione		IV Infusion/ IM Inj.	Lyophilized powder for Inj. Box of 1 vial of Lyophilized powder for Inj. and 1 vial of water for Inj. of 5mL
NECROVI	Iron Sucrose			Solution for Inj. Vial 100mg/5mL Box of 5 vials of solution for Inj. x 5 mL
EMILOX	Doxorubicin HCl			Concentrate for solution for infusion Vial 50mg/25mL Box of 1 vial x 25mL
CALITAXEL	Paclitaxel			Concentrate for solution for infusion Vial 30mg/5mL, 100mg/16.7mL, 150mg/25mL Box of 1 vial x 16.7mL

ACTIVE PHARMACEUTICAL INGREDIENT (API)

BIOPHARMACEUTICAL

Ingredients	Indications	Strength
Bevacizumab	Colorectal cancer, Lung cancer, Renal cancer	SI 400mg/16mL, 100mg/4mL
Darbepoetin	Anemia associated with chronic renal failure Chemotherapyinduced anemia	PFS 25mg/mL, 40 mg/mL, 60 mg/mL, 100 mg/mL, 300 mg/mL, 500 mg/mL
Etanercept	Rheumatoid arthritis, Plaque psoriasis	LPI 25mg/ 0.5mL
Factor VIII	Hemophilia	LPI 1000IU, 250IU, 500IU
Granulocyte Colony Stimulating Factor	Neutropenia	PFS 30 MU /0.5 mL, 48 MU /0.5 mL
Pegylated - Granulocyte Colony Stimulating Factor	Neutropenia	PFS 6 mg/ 0.5 mL
Pegylated - Interferon Alfa 2a	Chronic Hepatitis B, C	PFS 180 mcg /0.5 mL
Pegylated - Interferon lambda 1	Chronic Hepatitis B, C	PFS 180 mcg /0.5 mL
Trastuzumab	Breast cancer, Gastric cancer	LPI 440mg, 150mg
Recombinant human Erythropoietin Alfa	Anemia associated with chronic renal failure Chemotherapyinduced anemia	PFS 2000 IU /0.5 mL, 4000 IU /0.5 mL, 10000 IU /0.5 mL
Recombinant human Interferon Alfa 2a	Chronic Hepatitis B, C	PFS 3 MIU /0.5 mL
Rituximab	Lymphoma, Rheumatoid arthritis, Wegener's granulomatosis	SI 100mg/10mL, 500mg/50mL

UNDER REGISTRATION PRODUCTS

BIOPHARMACEUTICAL

Name	Ingredients	Indications	Strength
Vinoxrin	Enoxaparin	Venous thromboembolism	PFS 20, 40, 60 mg
Fibricin	Heparin Sodium	Deep vein thrombosis	SI 5000IU/5mL, 10000IU/5mL, 25000IU/5mL
Nanokine	Recombinant human Erythropoietin alfa	Anemia associated with chronic renal failure Chemo therapy induced anemia	Solution for injection PFS 3000 IU /0.5 mL, Vial 3000IU/1mL
Maropin 30/70	Human insulin		Suspension for injection Vial 300IU/3mL Vial 1000IU/10mL
Maropin N	Human insulin		Suspension for injection Vial 300IU/3mL Vial 1000IU/10mL
Maropin R	Human insulin		Suspension for injection Vial 300IU/3mL Vial 1000IU/10mL
Maropin 30/70 Pen	Human insulin		Suspension for injection Prefilledpen 300IU/3mL

UNDER REGISTRATION PRODUCTS

PHARMACEUTICAL

Name	Ingredients	Indications	Strength
Lycograp	Sodium hyaluronate	Osteoarthritis	SI 20mg/2mL
Calitaxel	Paclitaxel	Ovarian Cancer, Breast cancer, Lung cancer	SI 260mg/43.3mL, 300mg/50mL
Xalilatin	Oxalilatin	Colorectal carcinoma	SI 50mg/10mL, 100mg/20mL
Glurinax	Glutathione	Antioxidant Detoxification	LPI 300 mg
Leurenat	Calcium folinate	Antidote for folic acid, Antagonists	SI 50mg/5mL, 100mg/10mL
Emilox	Doxorubicin hydrochlorid	Acute leukaemia, Breast cancer, Hodgkin and Non Hodgkin Lymphoma	SI 10mg/5mL,
Pegruylx	Doxorubicin liposome	Small-cell lung cancer, Breast cancer, Ovarian carcinoma, Bladder carcinoma, Osteosarcoma	SI 20mg/10mL,
Voposid	Etoposide	Prostate cancer, Lung cancer, Hodgkin and Non Hodgkin Lymphoma	SI 100 mg/5mL, 200mg/10ml
Zoluptas	Pantoprazole sodium	Reflux oesophagitis, Zollinger-Ellison syndrome, Helicobacterpylori infection	LPI 40mg

UNDER REGISTRATION PRODUCTS

PHARMACEUTICAL

Name	Ingredients	Indications	Strength
Petrexum	Pemetrexed	Lung cancer, Mesothelioma	LPI 500mg
Dorubex	Docetaxel	Lung cancer, Prostate cancer	SI, 20mg/mL, 80mg/4mL, 160mg/8mL, 20mg/0.5mL, 80mg/2mL
Nanotecan	Irinotecan hydrochloride	Advanced colorectal carcinoma	SI 40mg/2mL, 100mg/5mL
Forespi	Epirubicin	Bladder cancer, Breast cancer, Gastro-esophageal cancer	SI 10mg/5mL, 50mg/25mL
Apogem 2f	Gemcitabine hydrochloride	Ovarian cancer, Pancrea cancer	LPI 200mg, 1000mg
Anolif	Zoledronic monohydrate	Skeletal related diseases, Tumour-induced hypercalcaemia	Concentrate for solution for infusion 4mg/5mL
Mediplatin-BP	Carboplatin	Ovarian cancer, Head&Neck cancer, Lung cancer	SI 50mg, 150mg, 450mg
	Bortezomib	Multiple Myeloma, Mantle cell lymphoma	LPI 3.5mg
Inoplatin-CP	Cisplatin	Ovarian cancer, Head & Neck cancer, Bladder cancer	SI 10 mg/10mL, 50mg/50mL

PIPELINE PRODUCTS

BIOPHARMACEUTICAL

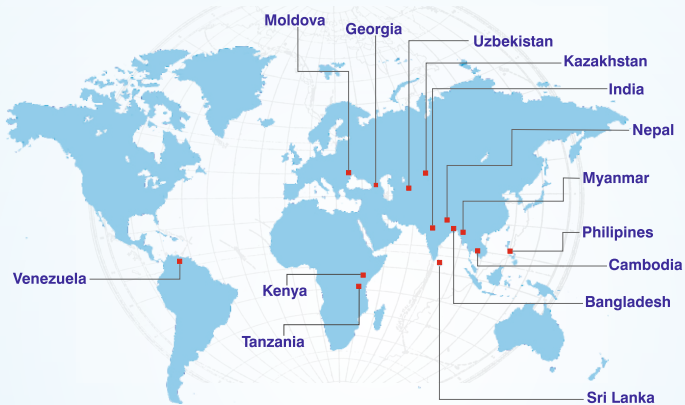
Name	Ingredients	Indications	Strength
Faceptor	Trastuzumab		Lyophilized powder for infusion - Vial 150mg, Vial 440mg
Rixumab	Rituximab		Concentrate for solution for infusion Vial 100mg/10mL, Vial 500mg/50mL
Astapen	Bevacizumab		Concentrate for solution for infusion Vial 100mg/4mL, Vial 400mg/16mL
Himumab	Adalimumab		Solution for injection - PFS 40mg/0.8mL
Novumab	Nivolumab		Concentrate for solution for infusion Vial 40mg/4mL, Vial 100mg/10mL
Limumab	Ipilimumab		Concentrate for solution for infusion Vial 50mg/10mL, Vial 200mg/40mL
Stimus	Darbepoetinalfa		PFS 20mcg/0.5mL, PFS 40mcg/0.4mL PFS 60mcg/0.3mL, PFS 100mcg/0.5mL, PFS 200mcg/1mL
Nanofactor	Factor VIIa, VIII, IX		Lyophilized powder for injection - Vial 500IU
	Cerebrolysin	Alzheimer's disease, Cerebral disorders	SI 215.2mg/mL

PIPELINE PRODUCTS

PHARMACEUTICAL

Name	Ingredients	Indications	Strength
	Choline alfoscerate	Alzheimer's disease, Dementias	SI 1000mg/4mL
EZOMES	Esomeprazole sodium	Gastroesophageal reflux disease Acute bleeding gastric or duodenal ulcers	LPI 20mg, 40mg
RAFAGUZ	Rabeprazole sodium	Gastroesophageal reflux disease, Active duodenal ulcer, Active benign gastric ulcer, Zollinger-Ellison syndrome	LPI 10mg, 20mg

GLOBAL PRESENCE







Lot I-5C Saigon Hi-tech Park, Tang NhonPhu A Ward,
District 9, Ho Chi Minh City, VIETNAM

✉ Email: info@nanogenpharma.com 🌐 www.nanogenpharma.com