

June 13, 2016

Nagase Medicals will strengthen the production capabilities for high potency injection drug
~Construction of new building and introduction of freeze dry production line ~

Nagase Medicals Co., Ltd. (Nagase Medicals, Head office: Osaka, factory: Hyogo), President : Mitsuru Akasaka), a wholly owned subsidiary of NAGASE & CO., LTD. (Head office: Tokyo, President: Kenji Asakura) will add a new building to the injection production building dedicated for high potency pharmaceuticals(*1) (2nd Injection Building), which was completed in February 2013 to strengthen the production capacity.

Based on the production technology of sterile product, mainly injection liquid formulation, Nagase Medicals serves as the core of the NAGASE Group's pharmaceuticals business.

Traditionally, Nagase Medicals has been managing contract manufacturing of high potency injection drug, mainly oncology injection. In order to further enhance its production capabilities, Nagase Medicals had built 2nd Injection Building dedicated for the production of vial injection liquid formulation of high potency in February 2013. Since then, Nagase Medicals expanded in-house development and production of high potency generic injection drug and contract manufacturing of investigational product and commercial product.

In order to further increase manufacturing items and reinforce in-house development items, Nagase Medicals will build a new building next to 2nd Injection Building, which will be connected to 2nd Injection Building. With the completion of this new building, production function of injection drug for high potency drug will expand significantly.



Image of the new building

【Brief overview of the new building】

Location	4-323, Senzo, Itami, Hyogo, 664-0898
Building Area	1,582 square meter
Building structure	Steel-framed structure, 4 floors
Main purpose	Lyophilized and liquid formulation of ethical drug and investigational drug including high potency drug
Main equipment	Sterile isolator at filling section, Freeze dryer (suitable for high potency drug), Filling line suitable for single-use system
Completion and Commencement of operation	Completion of the building in August, 2017 Commencement of operation at the end of 2017
Investment amount	JPY 2.5 Billion

【Aim of construction】

The original concept of the 2nd Injection Building; that is, preventing cross contamination and handling multiproduct by utilizing single-use system(*2) ; advanced sterile assurance by the introduction of sterile isolators(*3) ; and installation of advanced containment system will be maintained. Meanwhile, due to the expansion of the new building, new function will be acquired and existing function will be enhanced such as 1) acquisition of freeze dry function, 2) significant expansion of the production capacities (more than 2.5 times compared with the current capacity) and 3) improvement and expansion of inspection and packing function. Moreover, in this new building, we will secure the space for new equipment as we plan to introduce small-scale production line for high potency drugs suitable for investigational drug in the new future.

As for high potency injection business focusing on oncology drug, we will promote the business by utilizing the comprehensive strength of the NAGASE group from sourcing active pharmaceutical ingredients to producing final drug products.

- *1) High potency injection product: Injection product such as oncology drug that is highly active and requires containment
- *2) Single-use system: Disposable production line, where contact section with the liquid is single-use per lot from solution preparation to the needle of filling device.
- *3) Sterile isolators: Isolator system that can maintain sterile environment. This system is used when aseptic filling of drug solution is performed.

【Summary of Nagase Medicals Co., Ltd.】

Representative : Mitsuru Akasaka
Head Office : 1-1-17 Shinmachi Nishi-Ku Osaka, Japan
Foundation : July 1, 1972
Type of Business : Manufacture and sale of pharmaceuticals, animal drugs, health foods, and cosmetics
Capital : 498 million yen
URL : <http://www.nagase-medicals.co.jp/>

【Contact for this information】

NAGASE & CO., LTD.

Life & Healthcare Product Department, Pharma-Medicals Division, Sales 2nd Section

Tel : +81-3-3665-3333 FAX : +81-3-3665-3940

Finance Division, Public & Investor Relations Section

Tel : +81-3-3665-3028 FAX : +81-3665-3930

URL : <http://www.nagase.co.jp/>