DISCOVER

The Oral Solid Dose Facility

This best-in-class facility in Research Triangle Park is a small, but robust, hub of activity within the Global Manufacturing organization. It serves as a prime example of Biogen Idec's relentless commitment to meet patient demand through continuous investment in manufacturing infrastructure.

Facility Overview

The Oral Solid Dose (OSD) facility is the only Biogen Idec site that manufactures small molecule therapies – synthetically produced medicine delivered in the form of capsules and tablets. TECFIDERA, Biogen Idec's premier small molecule therapy, is the leading oral treatment for relapsing MS. The OSD facility began manufacturing TECFIDERA in 2014 after retrofitting the Eisai plant with new equipment and partnering with Eisai to share manufacturing space.

FAST FACT

4.4 million TECFIDERA microtablets are produced per hour by the tablet press at the OSD facility

TECFIDERA production is currently in full swing at the OSD site as the new equipment is validated in preparation for FDA licensure – anticipated in the spring of 2015. Until licensure occurs, patients will receive TECFIDERA produced by contract manufacturers in Europe.

The talented team of more than 90 employees at the OSD facility also apply their vast knowledge and expertise to the production of Eisai medicines, serving as contract manufacturers for several small molecule therapies, including:

- Lunesta for insomnia (market: Japan)
- Banzel for epilepsy (markets: U.S. and Canada)
- Aciphex for acid reflux (market: U.S.)
- Aricept for Alzheimer's disease (market: U.S.)

Biogen Idec and Eisai employees have formed a true partnership – sharing resources, facilities and communal lunch rooms – to make this unique and innovative manufacturing enterprise a model for success.

FAST FACT

Biogen Idec and Eisai employees share the same facility, thereby enhancing the level of partnership and cooperation

Facility Capabilities

Step inside this small molecule manufacturing facility and you will see granulators, blenders and machines for compression and encapsulation – all the ingredients and equipment used to make millions of tablets and capsules.

The OSD manufacturing process involves several critical activities to ensure a quality tablet or capsule, such as precise measuring and weighing of dry ingredients; wetting them for proper adhesion; milling and blending the mixture, compressing it into the proper shape; applying a protective coating to the tablets; and placing the appropriate quantity of tablets into a capsule.

Small molecule production also requires world-class analytics and quality assurance to ensure the therapies have the proper chemical and physical characteristics to survive the production process while retaining optimal purity and efficacy.

FAST FACT

A batch of TECFIDERA treats 1,096 MS patients each year and the average cycle time for a batch is 35 days – best-in-class

The following seven steps ensure the purity, safety and efficacy of each and every pill produced at the OSD facility:

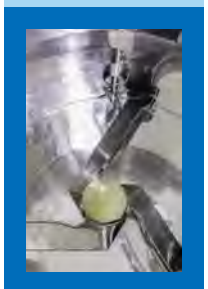
Dispensing – involves prepping and weighing the active and inactive ingredients that make up the tablets and capsules.

1

Blending and Milling – ensures consistency of the active ingredients. Milling grinds the particles to achieve the desired size while blending combines these particles to form a homogenous mixture.

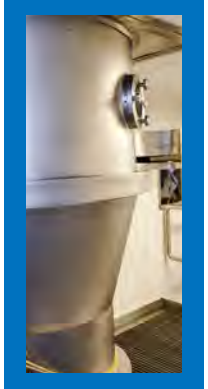
2

Wet Granulation – uses water or solvent-based solutions to create a consistent particle size and blend by placing the raw materials in a bowl, mixing them and wetting them with a solution.



3

Fluid Bed Drying of Granulation – moves warm air through the wet granulation to remove the water or solvent to ensure the blend is ready for the next step.

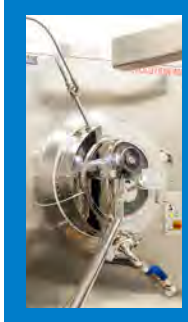


4

Tablet Compression – tablets begin to take shape during this step, which involves feeding the blend into a press, applying pressure to form the tablets, and de-dusting them to remove excess powder.

5

Tablet Coating – sprays a solution onto the tablets to enhance their flavor, appearance and efficacy; and to promote optimal absorption and to prevent stomach irritation.



6

Encapsulation – places certain formulations into capsule shells made of gelatin or similar digestible materials to ensure they are firm enough to hold the ingredients and maintain their stability.

7

FAST FACT

The OSD facility has produced 150-plus batches with a very high success rate – 97 percent of product manufactured will be suitable for release to the market

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