

How Mylan Drugs are Made

Welcome to Mylan (0:57)

Welcome to a company that produces the highest quality generic and specialty pharmaceuticals in the world. A company that is anything but generic.

Welcome to Mylan.

My name is Tracy Sylvester, and I am one of the more than 15,000 proud members of the Mylan family. As any one of us can tell you, Mylan is a company that is obsessed with quality, and each one of us is energized by the singular purpose of helping to provide the world's 7 billion people with access to medicine.

We do this by producing high quality, affordable medications to be made available everywhere, every day.

With this video, we'd like to give you a look inside our production processes. So please sit back, relax and get a glimpse of what makes Mylan one of the world's leading providers of generic and specialty pharmaceuticals of the highest quality.

Mylan's Largest Facility (0:53)

Mylan's largest finished-dose manufacturing plant, located in Morgantown, West Virginia, reflects the highest quality industry standards and represent the cornerstone of Mylan's overall strategy to meet market needs through innovation in pharmaceutical technology.

With more than 1.4 million square feet of research, laboratory, manufacturing and office space, Mylan's Morgantown plant routinely produces more than 60 million high quality tablets and capsules each day and is one of the largest pharmaceutical manufacturing facilities under one roof in the entire world.

We produce hundreds of different products, in multiple strengths and package sizes, that are made in full compliance with all FDA mandated Good Manufacturing Practice regulations and stringent Quality Assurance and Quality Control procedures.

Innovation Starts Here (1:10)

The innovation of our high quality products starts in Mylan's Product Development, Chemistry and Bioanalytical Laboratories. 36 Product Development suites allow us to develop a wide variety of immediate-release, controlled-release, transdermal and specialty drug products quickly and efficiently.

In addition, two specially designed potent-substance containment suites with three air-locked chambers and negative air pressure allow for the safe and efficient development of hormonal, teratogenic and cytotoxic drug products—much like the large scale potent-substance operations that are housed at Mylan’s Caguas, Puerto Rico manufacturing facility.

The Chemistry and Bioanalytical Laboratories feature extensive and modern chromatography labs, thermal characterization instrumentation, nuclear magnetic resonance and mass spectrometers in addition to a bioanalytical robotics lab. The use of such cutting edge technology allows Mylan to continually improve R&D productivity as well as our innovative development processes.

It Begins with Dispensing (0:55)

After our highly trained scientific staff develops and gains approval for new products, Mylan’s extensive and modern manufacturing process can begin.

First, raw materials, both active and inactive, are received and assigned lot numbers. They are sampled, quarantined and tested at our Quality Control Laboratory. If they meet all specifications, we take them out of their containers, weigh them, and place them into Mylan containers.

The active and inactive ingredients are then processed and blended to the exact, appropriate consistency for the processing machinery.

The blending operation at Mylan’s Morgantown facility uses “V” Blenders that range in size from 5 to 125 cubic feet. Blenders are loaded with various materials and then rotated to produce a homogeneous blend.

Next Step, Granulation (1:12)

Once the powders are blended, we use either wet or dry granulation techniques to further process the ingredients.

Mylan’s wet granulation process includes three-story fluid bed dryers and high shear granulators.

Wet granulation in the fluid bed dryers, for example, features a high-tech process where the dry powders are suspended in mid-air by high volume airflow. A spray ball is located in the middle of the air chamber and sprays a granulating solution onto the suspended powder. Then the temperature of the air stream is increased to dry the wet granulation.

Strict, product specific processing parameters are utilized to produce an efficient and controlled process, which produces consistency from batch to batch and adheres to Mylan’s high quality standards.

The dried granulation is then milled to produce a subsequent granulation within a specific size range.

In a dry granulation method called roller compaction, powders are directed between two tightly compressed rolls, producing a ribbon of pressed powder, which is then milled. Machine parameters are controlled throughout the process to produce a granulation of specific size and density.

Tablets and Capsules (1:37)

A final blending step ensures uniformity of the powder blend. This blend is then sampled by Quality Assurance and tested by the Quality Control laboratory to ensure that it is uniform.

At this stage the materials are either compressed into tablets or filled into capsules.

A tablet press consists of a rotating die table, where upper and lower punches are brought together within a die to form tablets. Mylan's high-speed presses can produce up to 10,000 tablets per minute, and can be fed via scoop, drum or gravity feed from large overhead hoppers. During the compression process, an operator uses a state-of-the-art Laboratory Information Management System to monitor tablet weight, hardness and thickness. Test results are compared against product specifications, resulting in a tightly controlled compression process. Tablets, which require coating, are then placed into coating pans.

Capsules are made by placing empty shells into an encapsulating machine where they are filled with the final blended product. The bottom half is filled with the drug, which can be in one of several forms including powder, beads or even a tablet. The top half is then placed onto the bottom and locked into place.

Each capsule goes through a weight check step where it is weighed and compared to the product specification. The capsules are also visually checked to ensure that there are no physical defects.

These are just two examples of how we build quality into every step of the manufacturing process at Mylan.

High-tech Packaging (1:05)

Once the tablets and capsules are manufactured, they are sent to the Packaging Department to be placed into bottles on any one of 12 packaging lines. Nine of Mylan's 12 lines are standard and three are high speed.

On the high-speed lines, tablets or capsules are placed in bottles electronically; on a standard line, they are fed into compartmented slats. Both types of lines are

configured to deliver a precise quantity of medication into each bottle as it moves along a conveyor belt.

A foil-lined lid is then placed on the bottle and a heat induction sealer seals the foil lining to the top of the bottle. A patient information packet is glued to the lid and the bottles move to be labeled.

Quality Assurance, or QA, sets the lot number and expiration date for each label, and appropriate lot numbers and expiration dates are printed on each one.

Each label is checked and reviewed through a high tech optical inspection system, which photographs every label produced; any label deviating from set parameters automatically shuts down the line.

Shipping Quality Medicine (0:27)

Finally, the shrink-wrapped bottles are placed in shipping cartons according to lot number and, based on the packaging order for the customer, placed on pallets for shipment out of the house.

After our high quality products are wrapped, banded and prepared for shipment, trucks arrive every day at Mylan to deliver them to our distribution center in Greensboro, North Carolina. The medications are then on their way to getting to the people who need them most at an affordable price.

Thank You (0:40)

We hope you've enjoyed your virtual tour of Mylan's finished dose production facility in Morgantown, West Virginia.

Our employees and our facilities are dedicated to high quality and operational excellence, and our rigorous quality control testing and quality assurance procedures further exemplify this dedication.

This commitment to producing high quality, affordable medicine is what will help us reach our goal of helping to provide the world's 7 billion people access to medicine everywhere, every day, no exceptions.

Thank you.