prati donaduzzi

Prati-Donaduzzi, the most widely consumed generic in **Brazil**

Founded on December 1993, **Prati-Donaduzzi** Industry stands out for its production of **12 billion** therapeutic doses / year. With more than **4,500 employees** and **300 presentations** in its portfolio, it is the largest supplier of medicines for public agencies and the most consumed generic in **Brazil**.

API business

Specialità Fine Chemicals was established in October 2013, through an initiative of Prati-Donaduzzi Group, aiming at the development of the manufacturing process of Active Pharmaceutical Ingredients (APIs) considered strategic for the company's business.

For the development of the manufacturing processes of these products, a state-of-the-art organic synthesis laboratory with a total of 250 m^2 built-up area has been structured and equipped in order to allow the synthesis of organic compounds from the scale of units of grams up to the scale of hundreds of grams.

Specialità's R&D team is highly qualified, and is responsible for both development of manufacturing processes, as well as for development and validation of analytical methods of APIs and raw materials used in its manufacturing processes. In 2015, the company started the development of manufacturing process of Cannabidiol API through chemical synthesis, reaching the product of interest with high purity content.

The manufacturing process of Cannabidiol API is based on chemical synthesis, that is, the product is obtained through chemical reactions that modify the structure of simpler substances, so-called starting materials, until it reaches the chemical structure of the API. The starting materials were defined in accordance with the ICH Q11 guideline.

Cannabidiol API manufacturing process was transferred to Prati-Donaduzzi API production unit, which, after inspection by the Brazilian Health Authority (Anvisa) in November 2018, was approved for the beginning of the industrial production. It is noteworthy that Anvisa has been accepted as a new member of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) since August 2016.

There is no monograph for Cannabidiol API in the European and US pharmacopoeias until now; for this reason, the quality attributes were defined in accordance with the ICH Q6A guideline. The quality attributes and their specifications are available for viewing at www.pratidonaduzzi.com.br (there you should see the "Products" tab; click the tab, then "Active Pharmaceutical Ingredient" and follow the instructions).

The technical dossier for the product (DMF - Drug Master File) is being prepared in accordance with the M4Q guideline. Stability studies are being conducted in order to address climatic zones I and II, as well as IV-B, in accordance with ICH Q1A and Q1B guidelines.