

Press Release

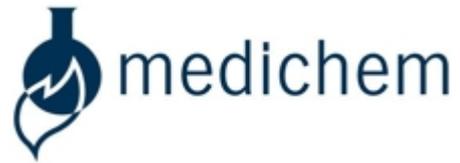
Medichem opens High Potency API unit in Malta

The Spanish manufacturer of Active Pharmaceutical Ingredients announces the set-up of its new Highly Potent Active Pharmaceutical Ingredients unit in its Maltese manufacturing plant

Barcelona, Spain, July 1st, 2014 – Global Active Pharmaceutical Ingredients (API) manufacturer Medichem opens today a brand new High Potency API unit (HPAPI) in its Maltese plant, located in Hal Far (Malta). With this new offering, Medichem wants to consolidate its presence in the generic pharmaceutical industry. “Our expansion to HPAPI field will allow Medichem to offer a broader product portfolio to our customers. Today, 25% of new drugs in development are highly potent, and we expect this tendency to keep growing”, explains Ervin Veszprémi, CEO of Medichem.

The HPAPI modular laboratory is a multipurpose facility that is fully equipped for the synthesis of HPAPIs from the very early R&D phases, through process development and to manufacturing allowing Medichem to produce Class 4 HPAPIs with OEL down to 40 ng/m³. It is composed of different areas dedicated to R&D and Kilo-lab activities. The Kilo-lab unit is equipped with 10-20L reactors, filtering, drying, milling and micronizing equipment. R&D work and production are expected to begin in the second half of 2014.

The global demand for HPAPIs is growing due to the ability of this class of molecules to target diseases while being more effective at very low doses. They are usually used in therapies such as oncology and musculoskeletal treatments among others. Typical highly potent compounds are hormones, narcotics and retinoids. Many generic companies are looking for partners who can provide a high quality and reliable supply of highly potent products within current Good Manufacturing Practices (cGMP) and FDA inspected environments and Medichem is able to fulfill these requirements. Moreover, the unique patent situation of Malta allows Medichem to develop and produce HPAPI in advance of patent expiry. This legal /IP framework allows Medichem to offer first-to-market opportunities to its customers worldwide.



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About Medichem

Medichem is an independently-owned API manufacturer, headquartered in Barcelona (Spain) and has 40 years of experience in this market. Medichem has two FDA inspected plants (Spain and Malta) and 3 R&D centers located in Spain, Malta and China.

Medichem has more than 250 people working at various locations (Spain, Malta and China) and delivers products to more than 60 countries. This includes generic and pharmaceutical companies in the United States, the European Union and Japan among others.

Over the last years, Medichem has developed a broad pipeline of new products to meet its clients' needs. These products are indicated for the treatment of diseases in many therapeutic areas, such as Central Nervous System (CNS), Cardiovascular, Gastrointestinal, Ophthalmic, Urinary tract, etc... We also offer Contract Manufacturing services, both for regular and High Potent APIs.

Medichem's main goal is to provide non-infringing processes and products from its two US-FDA inspected plants to its customers. Currently, Medichem has more than 70 products in pipeline and portfolio. Medichem has a sister company, Combino Pharm, which manufactures, develops and markets generic pharmaceutical products.