

MEDICHEM MALTA:

FIRST-TO-MARKET OPPORTUNITIES

Medichem API plant in Malta takes **advantage of the country's unique patent situation** as an attractive option for generic pharmaceutical companies.



MALTA OFFERS MANY ADVANTAGES FOR THE PHARMACEUTICAL INDUSTRY BECAUSE OF ITS PATENT HISTORY AND FRAMEWORK

As a consequence of this, many companies in the pharmaceutical industry have established operations in Malta over the last decade. They can take advantage of the absence of number of patents which were not registered in Malta and thus develop and launch product batches to **be the first on the market immediately** when a patent expires in a given country.

Medichem and Combino Pharm (its sister company) can benefit from this unique patent situation and are able to do **R&D work and produce generics drugs in advance of patent expiry.**

Medichem can offer unique non infringing processes and products from its USFDA (US Food and Drug Administration) inspected plant in Malta. This legal / IP framework allows us to offer **first-to-market opportunities to its customers worldwide.**

MEDICHEM

IN A FLASH

- > 40+ years in the industry
- > cGMP company
- > FDA inspected since 1985
- > Both plants (Spain and Malta) are no "Form 483"
- > ISO 9001 & ISO 14001 certified

OUR TECHNICAL

INFRASTRUCTURE AND EQUIPMENT

PILOT PLANT

| QTY | EQUIPMENT DESCRIPTION |
|------------------|--|
| Reactors: | |
| | Total number: 4 |
| | Total capacity: 1.5 m³ |
| 2 | Glass-lined |
| 2 | Stainless-steel |
| Filters: | |
| 1 | Stainless-steel centrifuge |

Our Pilot Plant is used for process validation, process scale-up and also for some small scale pilot production for lots ranging from 5 to 50 Kg.

PRODUCTION PLANT

| QTY | EQUIPMENT DESCRIPTION | REACTION CAPACITY |
|------------------------------|--|--------------------------|
| Reactors & tanks: | | |
| | Total number: 3 | |
| | Total capacity: 9 m³ | |
| 2 | Glass-lined | 6.5 m³ |
| 1 | Stainless-steel | 2.5 m³ |
| Filters: | | |
| 1 | Stainless-steel centrifuge | |

Our Production Plant is a multipurpose facility that is fully equipped for the synthesis of APIs. Reaction capacity 9 m³ easily expandable to 30 m³.

THE FINISHING AREA

| QTY | EQUIPMENT DESCRIPTION |
|---|------------------------------|
| Dryers: | |
| 2 | Stainless-steel vacuum dryer |
| Milling & sieving equipment: | |
| 1 | Pin mill |
| 1 | Centrifuge sift |
| Blenders: | |
| 1 | Stainless-steel V blender |
| 1 | Stainless-steel drum blender |

The Finishing Area is where the last steps of the process are performed. It is equipped with HVAC, air filtration, differential pressure, air locks, etc. to prevent cross-contamination.



Medichem S.A.

Fructuós Gelabert, 6-8. 08970 Sant Joan Despí (Barcelona) SPAIN

Medichem Manufacturing (Malta) Ltd.

HF 61, Hal-Far Industrial Estate. BBG 3000 Hal Far MALTA

Tel: + 34 93 477 64 40 :: Fax: +34 93 477 64 44 :: info@medichem.es :: www.medichem.es