

## Manufacturing Facilities in Italy

### Multipurpose Manufacturing Plants

- 3 Manufacturing multipurpose facilities with reactors ranging from 800 to 6000 lt volume
- 140,000 litres of total glass lined and stainless steel (AISI 316 and 304) reactor capacity
- Operation conditions -10°C to +250°C
- Solvent recovery
- 12 Stainless steel, glass lined or ebonised pressure filters and centrifuges

### Finishing Bulk Facilities

- 7 fluid bed and rotative vacuum dryers; finished bulk APIs dryer in clean room
- Separated finishing areas for micronising, blending and sieving operations in clean rooms

### Multipurpose Pilot Plant

- 4 glass lined and stainless steel reactors ranging from 250 to 1.000 lt capacity
- 1 glass reactor (50 lt) equipped with distillation system.
- 1 glass lined Comber dryer-filter (500 lt)
- Distributed process control systems (DCS)
- Operative conditions: -20°C to +250°C

### Process R&D Capabilities

- 3 organic synthesis laboratories operating up to 20 lt volume.
- 1 FDA inspected Kilo Lab
- Micronisation equipment
- Auto-Mate H.E.L. (calorimeter for Hazard Evaluation)

### Analytical R&D and QC Services

- Titrimetry, potentiometry, gravimetry
- Elemental analysis (C, H, N, S)
- Chromatography (TLC, HPLC, GC)
- Capillary electrophoresis
- Spectrophotometry UV/VIS and FT-IR
- Nuclear Magnetic Resonance for 1H and 13C
- Mass spectrometry (GC, LC coupled with APCI) and electrospray interfaces
- Differential scanning calorimetry (polymorphism and purity studies)
- Melting/boiling point equipment (Büchi, Mettler, Kofler)
- Particle size measurement (Sonic Sifter, Malvern Mastersizer)
- METAMORPH® image analyzer
- Environment chambers for ICH stability conditions
- Computerized QC data processing

### Regulatory

- FDA inspected since 1979
- Validation master plans
- Process validations
- ICH stability studies
- DMF preparation and filing

### Environmental Capabilities

- Physicochemical and Biological WW Plant
- Contract WW treatment
- Gases emission control system

### Work Force

- 97 employees

