

Helsinn Chemical Ireland Ltd (Ireland)

Small Scale Manufacturing Plant upgraded to full cGMP

DUBLIN, IRELAND, December 17th 2007

Helsinn Chemicals Ireland Ltd. (HCI) is pleased to announce the opening of a Small Scale cGMP Manufacturing Plant at its Dublin site.

The new GMP Pilot Plant will complement the existing Helsinn Chemical Operations capabilities by providing the additional ability to run small scale processes (0.5 - 2kg) under full cGMP, which is particularly relevant for the production of small clinical and/or registration batches.

The Small Scale Manufacturing Plant will be fully supported by the site Process Implementation and Quality Units.

The GMP Pilot Plant consists of

- ✓ 2 x 30L glass reactor trains
- ✓ 1 x 20L glass filter-dryer unit
- ✓ 1 x 20L vacuum drier.

The typical operating ranges for the reactors are -20 to 140°C, and full vacuum up to maximum pressure of 0.5 bar with the option to upgrade to higher pressures for catalytic hydrogenations.

Wet processing is carried out in a reactor room while dry processing is performed in a separate finishing area.

The Small Scale Manufacturing Plant is separated from the main Production plant and can only be accessed via a dedicated lobby. The whole area is designed to full cGMP and is supplied with dedicated utilities. Full flexibility has been considered in order to be able to introduce additional technologies in the future, for example column chromatography for purifications or chiral resolutions.

With this addition, Helsinn Chemical Operations is capable of providing clinical batches of classical API ranging from 0.5 kgs up to 1,000 kgs thus fulfilling the needs of all clinical phases. Commercial production is also starting from kgs per year up to multi-tens of tons on both sites, Irish and Swiss.

Helsinn Chemicals Ireland Ltd. has a long history of manufacturing advanced intermediates and API's at large scale (up to 8,000L) in its dedicated GMP plant since 1993. This is coupled with extensive experience in developing processes for plant scale.

Helsinn's Chemical Operations is well known world-wide as exclusive partner for contract development and manufacturing of API, High Potency Active Ingredients and cGMP Advanced Intermediates for the Pharmaceutical Industry, with several active DMFs in the USA, CTDs in Europe and pending DMFs in Japan.



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Exclusive Manufacturing Solutions

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