COMPANY PROFILE - MAYNE PHARMA INTERNATIONAL

A leading pharmaceutical organisation, built on a heritage of 160 years of industry excellence, Mayne Pharma International is a technology-driven, drug delivery, contract development and manufacturing company for oral and topical pharmaceutical products.

Mayne Pharma International has comprehensive experience in the solid oral Drug Delivery System (DDS) market, encompassing development and manufacture of these products.

The company has:

- more than 30 years' experience in successfully developing DDS products for the global market
- a dedicated product development facility which meets cGMP standards, and includes pilot-scale plant equipment. This allows a scale-up pathway from small clinical trial batches to full commercial manufacture
- proven ability to develop and successfully transfer manufactured product and technology to other sites around the world
- formulation capababilities to help with product life cycle management.

Mayne Pharma International has been granted, or applied for, patents that protect its various drug delivery technologies. The in-market sales of products developed at the Salisbury, Australia facility using its technologies are in excess of US$500 million per year.

DRUG DELIVERY SYSTEMS

Mayne Pharma International's drug delivery systems include:

Technology to control drug release
To enable pulsed release; sustained release; modified release; and delayed release profiles (pellet/bead formulations produced using extrusion and marumerisation, or spheronisation processes).

Technology to improve oral bioavailability
Particularly for insoluble drugs (SUBA™ technology).

Technology to taste mask liquids and tablets
To improve palatability and aid swallowing (Cleantaste™ technology).

TECHNOLOGY TO CONTROL DRUG RELEASE

Pellet (or bead) technology allows a variety of different drug delivery profiles to be achieved by coating drug and excipient with various polymers. The drug cores are generally spheroidal in shape and have a diameter in the range of 300-1,700 µm.

Two types of process are used to generate the spheroidal particles (see diagram):

- The first of these processes, which allows potencies up to 90%, utilises extrusion and marumerisation to form a drug core with a polymer coat.
- The second process is known as spheronisation, where the drug particles are fixed to the outside of a seed core (typically a sugar sphere). This process provides a very tight size distribution of pellets. Drug potencies up to 60% are possible.

For both of the processes above, the desired drug release profile is achieved by coating particles with the appropriate polymer.

SUBA™

SUBA™ is a novel technology for enhancing the bioavailability of poorly water soluble drugs utilising a solid dispersion of drug in polymers having acidic functional groups.

SUBA™ has been shown to increase the oral bioavailability of itraconazole (our lead candidate) when compared with the innovator product (Sporanox®).

CLEANTASTE™

Cleantaste™ technology allows a polymer coat to be applied to produce particles (25-150 µm diameter) to improve taste. It is also possible to use this technology to improve stability or to deliver sustained release characteristics. The fine, non-gritty texture of product produced by this technology lends itself to being used in orally dispersible tablet and liquid formulations, as well as encapsulated products. Cleantaste™ acetaminophen (paracetamol) and ambroxol have been commercialised and launched in Australia, the USA and Japan.

SERVICES SUMMARY

Mayne Pharma International can develop and manufacture oral and topical formulations for clinical trials and has the ability to deliver to sites anywhere in the world. Mayne Pharma International can provide:

- **Tablets** (immediate, modified, sustained, delayed or pulse release and taste masked)
- **Capsules** (powder, pellets/beads)
- **Liquids and Creams**

Placebo formulations can be provided to match client specifications or innovator product. Packaging and labelling to suit customer requirements.

Pellet technology used for controlled release formulations

In addition to its drug delivery technologies, Mayne Pharma International offers a number of specialty services:

• **Formulation Development**

Provide solutions to a range of common formulation challenges such as poor solubility, poor bioavailability, short half life, low Cmax, poor powder flow, non-uniform crystal size and scale-up issues.

• **Analytical Services**
• **Regulatory Services**

ABOUT MAYNE PHARMA

Mayne Pharma International competes in the oral drug delivery, branded, generic and value-added API markets. The oral pharmaceutical business at Salisbury, Australia, is a GMP facility.

Annual production capacity:

• Approximately 2,500 million capsules and tablets
• 100 tonnes of bulk product
• 16 million units of liquids and creams

The site is approved by major regulatory authorities:

• FDA: United States
• MHRA: UK
• TGA: Australia
• TPD: Canada

Mayne Pharma International has generated a substantial worldwide patent estate in the drug delivery field, comprising:.

• 11 patent families
• 38 pending applications
• 76 granted

Mayne Pharma International is located in Salisbury, South Australia, approximately 19 km from the capital city of Adelaide on a 19-hectare site. There is 12,000 m^2 of manufacturing space located on the site.

Mayne Pharma International is a wholly owned subsidiary of HalcyGen Ltd, an Australian public company listed on the ASX.

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