









# **Case Study**

# Best of Breed in Solid Dosing Manufacturing





# Kotra Pharma Malaysia

### Best of Breed in Solid Dosage Manufacturing





Kotra Pharma (M) Sdn. Bhd. is located in Melaka, Malaysia and is a wholly owned subsidiary of Kotra Industries Berhad a company listed on the Main Board of the KLSE.

Kotra has 172 products registered with the National Pharmaceutical Control Bureau covering various dosage forms, which include sterile gels, liquids and powders in vials. Prescription and OTC Brands such as Axcel, Vaxcel and Appeton are household names in Malaysia.

Kotra's foreign market has expanded vigorously to cover more than 12 countries beyond ASEAN nations. This has led to Kotra's required expansion of their manufacturing facility in Melaka.

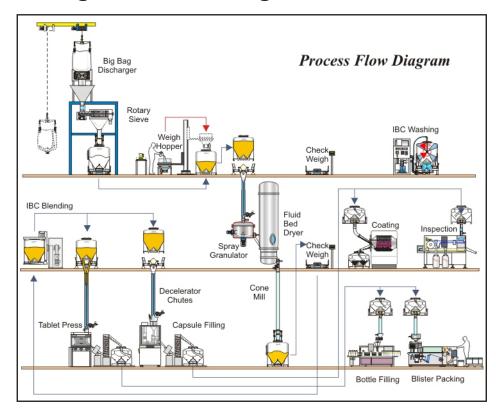
Matcon has recently been awarded a substantial contract for the supply of the Materials Handling System for Kotra's new Solid Dosage manufacturing facility that will be completed during the 3rd quarter of 2008.

#### **Equipment Selection**

Matcon was selected as a "Best of Breed" supplier for the facility due to their extensive experience in the supply of Materials Handling systems



IBC Batch Blender



in the Global industry and the level of value engineering applied to each process interface.

The Best of Breed approach follows Kotra's philosophy in the equipment selection in other process areas such as granulation, compression, capsulation etc where other quality European vendors have been selected.

#### Process steps and benefits

The solid dosage manufacturing process is batch based and utilises Matcon's Intermediate Bulk Container technology (IBCs) to transfer batches between the process steps, which include;

- Bulk and minor Raw Material dispensing to an IBC
- Granulation
- IBC Blending
- Compression of batch into tablets
- Controlled feed of tablets into Coaters and Packers
- ■IBC Cleaning off line

The IBC system is a new system implemented by Kotra, which allows them to maximize the design flexibility. As a result of careful evaluation Kotra decided to use gravity flow for the material handling system which helps

to simplify the process handling, facilitate automation and minimise product wastages.

#### Contained Transfer System

The IBC system is a closed transfer system and prevents the risk of contamination i.e. operators exposure airborne dust or fumes from potentially hazardous or potent, materials (such as penicillin), therefore improving the Health & Safety issue (contaminate getting out) considerably. Also the IBC system prevents contamination of product quality which is a GMP issue (contaminate getting in).

## Increased automation utilising IBCs

The IBC system allows for a higher level of automation which will have the benefit of increased productivity, improved product quality, batch traceability, improved process efficiency and a more economic production in \$ per tablet. One example of the increased automation provided is in the compression process area where the IBC provides an automatic controlled discharge feed directly to the tablet press without the need of operator intervention.

#### **CASE STUDY**



IBC & Discharge Station

#### Plant Design Philosophy

The criteria of both Kotra and Matcon projects team have been to collaborate closely to design the most ergonomic, safe and GMP compliant Materials Handling system anywhere in Malaysia or in the ASEAN region.

The emphasis on the process design has been to;

(i) maximise the efficiency of bulk handling of powders and tablets throughout the process, (ii) ensure the process is flexible to suit the clients needs & manufacturing demands, (iii) ensure interfacing with other process equipment is adopted in the most efficient way possible, (iv) ensure operator safety, ease of operation and cleaning, (v) ensure low risk of cross contamination, (vi) ensure containment of dust, (vii) ensure

guaranteed discharge of all dry solids now and in the future, (viii) reduce the risk of segregation in powdered products. Matcon is a proud partner to Kotra and is looking forward to gaining a world-class reference in Malaysia that will be the showpiece for the ASEAN region.

#### Matcon IBC systems

Matcon IBC solutions are widely used in the Solid Dosage industry, where we are able to provide solutions for blending powders within IBCs, handling blended powders without segregation and tablet handling in bulk without damage. As a result Matcon has many successful installations in major blue-chip pharmaceutical and generic manufacturing companies.



Direct Compression Feed



Matcon offers the full range of IBC solutions for the industry, including formulation systems and blenders as well as having the in-depth knowledge and experience to successfully interface with wet granulation, dry granulation/roller compaction, milling, blending, compression, coating, and packing.

Matcon has considerable experience in providing solutions for:

- Containment
- Nitrogen Purging
- CIP (Clean In Place)
- Preventing segregation of blended materials
- •Gentle handling of delicate materials, such as tablets.

For further information contact: Matcon: www.matconibc.com Kotra: www.kotrapharma.com