

News Bulletin from Aeromatic-Fielder

NICA™ System - Pellet Production

Aeromatic-Fielder has seen a resurgence in the level of enquiries and sales of the NICA™ System, particularly the Extruder and Spheroniser for production of pellets for controlled release medication.

Exploration of improved production techniques and drug release profiles can be critical to continued product development and subsequent patent and life cycle extensions. With the Nica System, Aeromatic Fielder have been particularly successful in recent times in providing major multi-national organisations with pellet production suites capable of manufacturing superior pellets

The following typical case study identifies the benefits that can be achieved.

The product was developed in the US using an alternative Extruder and Spheroniser combination which produces an oval pellet with a rough surface.

The benefits of the Nica System as explained by the customer are that the pellets are spherical and with a smooth surface which improves the reliability of the polymer coating process and also gives a more consistent fill by weight of the coated pellets into hard gelatine capsules.

Although there are many competing alternative processes for pellet production, namely rotary processing in a fluid bed and in a modified high shear mixer, the extrusion and spheronisation route, albeit traditional, still has many advantages in that it is:

- Flexible
- Capable of handling difficult products
- The most robust process

Graphic 1. - An example of produce quality

Spheronisation from well formed extrusions: 90% lactose, 10% MCC, 22% water (LOD), 1.0 dia. profile screen.



#14



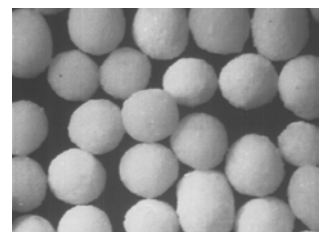
#14 - 1 min



#14 - 3 min



#14 - 5 min



#14 - 7 min

Graphic 2 - NICA™ System combined units

Scale	Equipment	Typical production of wet pellets
Pilot	E140/S450	30kg/hr }
Small	E140/two x S450	60kg/hr } <i>Sometimes less, often up to twice as much</i>
Intermediate	E220/two x S450	60kg/hr }
	E220/S700	90kg/hr }
Large	E220/two x S700	180kg/hr}

The typical outputs of the various equipment combinations within the Nica programme are given in graphic 2 which should be used as a guideline only. It is recommended that if specific output capacity figures are required, then trials are carried out.

An example of an Integrated E140 with a Shuttlebox and 2 off S450 Spheronisers with an output of around 60 kgs/hr is shown in graphic 3.

Process Solutions

When customers have a requirement for the production of pellets, there is considerable scope for Aeromatic-Fielder and NPS in providing a complete process line because invariably the process requires materials handling equipment, wet massing either batch or the continuous Nica M6 Mixer, extrusion and spheronisation, followed by drying and subsequent coating - see graphic 4.

Trials

Aeromatic-Fielder has the capability to undertake trials in its test laboratories at either the UK, Switzerland or the US and there is also equipment available for rental by those customers who wish to carry out extended trials in-house prior to purchase of equipment/systems.

Graphic 3 - Combined NICA™ System Production plant - E140 / shuttle box / S450 x 2

- Control options:**
- Manual Push-button
 - PLC & OIT (Allen Bradley or Siemens)
 - SCADA compliant with 21 CFR part II



Graphic 4 - Pelletising plant using NICA™ System

