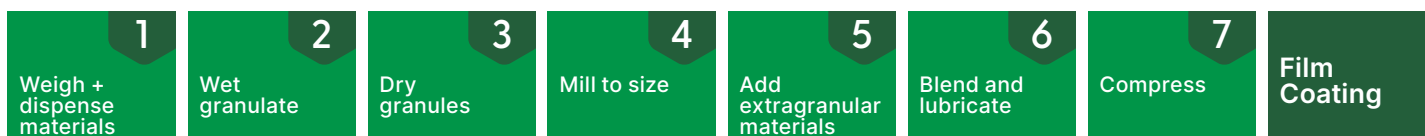


Direct Compression with StarTab Overcomes Formulation Challenges with High Dose, Poorly Flowable & Poorly Compressible Ibuprofen

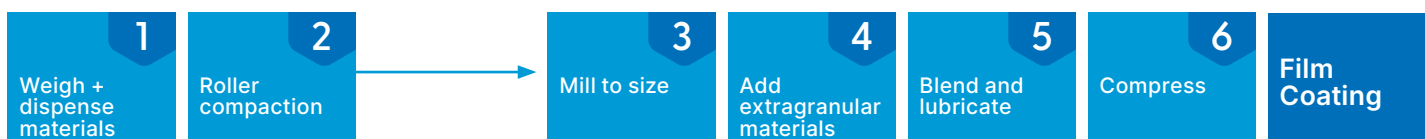
Formulation Simplification

Use of StarTab®, Directly Compressible Starch enables simpler manufacturing, limiting process steps to reduce manufacturing time and overall cost.

Wet Granulation



Dry Granulation



Direct Compression with StarTab



The Challenge

Ibuprofen provides significant formulation hurdles given its high dose, poor flow and compressibility. It has a low melting point of ~75°C which can present compression challenges e.g. tablet sticking to the punch, especially during the scale-up process. This study demonstrates the use of StarTab to simplify formulation and process leading to successful scale-up of immediate release tablets of ibuprofen.

Materials and Methods

Robust film coated immediate release tablets of ibuprofen, at a high dose of 50% w/w, were developed (Table 1). Compressed tablets were coated with pigmented Opadry® QX, quick and flexible film coating at 3% weight gain (w/w).

Table 1: Composition of Immediate Release Tablets of Ibuprofen

Core Tablet Ingredients	% w/w	mg / tablet
Ibuprofen	50.0	200.0
StarTab	49.0	196.0
Stearic Acid	1.0	4.0
Final Core Tablet Weight	100.00	400.00

The properties of ibuprofen formulation blend were evaluated prior to compression. When mixed with StarTab, the ibuprofen formulation demonstrated improved powder flow (Table 2).

Table 2: Powder Properties of Individual Materials and Final Core Tablet Blend

Property	Ibuprofen	Formulation Blend
Bulk density (g/mL)	0.49	0.58
Compressibility index (%)	31.0	24.0
Particle size d (0,5) (µm)	22.1	66.5
Flow rate (g/min)	No Flow	19.3
Overall Flow	Very poor	Good

Results

Successful Scale-up

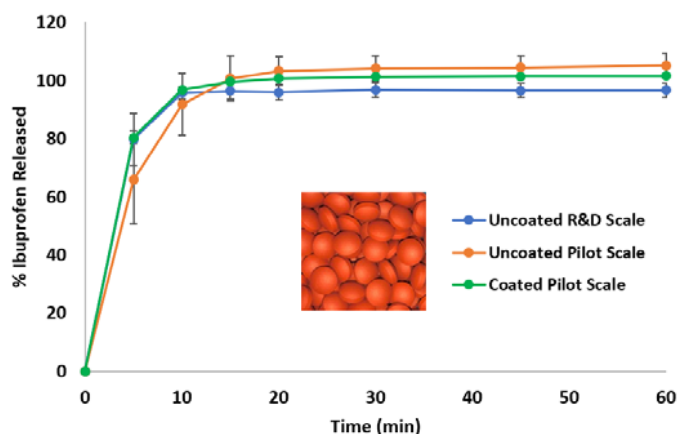
Ibuprofen formulation blend was seamlessly compressed on both R&D scale, using Piccola (4 station, single rotary tablet press) at 12,000 tablets/ hr and pilot scale Manesty TPR 200 (25 station, single rotary tablet press) at 138,000 tablets/ hr rotary tablet presses using a range of compression forces (9-18 kN). Tablets with good physical properties and free from defects were produced. Tablets compressed at 12 kN were successfully coated using a pigmented Opadry QX formulation, similar to marketed products (Table 3).

Table 3: Physical Properties of Ibuprofen Immediate Release Tablets Compressed at 12kN

Property	Uncoated R&D scale	Uncoated Pilot scale	Coated Pilot scale
Weight (mg)	412.3 ± 1.1	413.5 ± 14.1	415.8 ± 12.5
Hardness (kP)	8.2 ± 0.7	6.9 ± 2.4	9.9 ± 1.5
Friability (%)	0.76	0.53	<0.01
Disintegration time (sec)	93 ± 10	58 ± 19	68 ± 14

Drug Release

Both uncoated and coated ibuprofen tablets provided immediate drug release with > 80% drug released in <10 minutes:



StarTab Overcomes Challenges of Poorly Flowing and Poorly Compressible Drugs

Use of StarTab, directly compressible starch, in formulation of immediate release ibuprofen tablets shows simplicity of formulation and process, which is easily scaled up on high speed tablet press, with good weight uniformity and physicochemical properties. Tablets are easily coated with Opadry QX, quick and flexible film coating for a perfect finish.

Think Direct Compression, Think StarTab.

- Elimination of glidant and superdisintegrant in tablet formulation
- Excellent powder flow, blend uniformity and tablet weight uniformity
- Superior compressibility with fast disintegration
- Simplified formulation and process

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