# High Dose Formulation

atacama Labs

**IBUPROFEN**

# Ibuprofen trial set-up

Pre-blend (before PD-Granulation)

- 95.0% Ibuprofen
- 5.0% Ac-Di-Sol

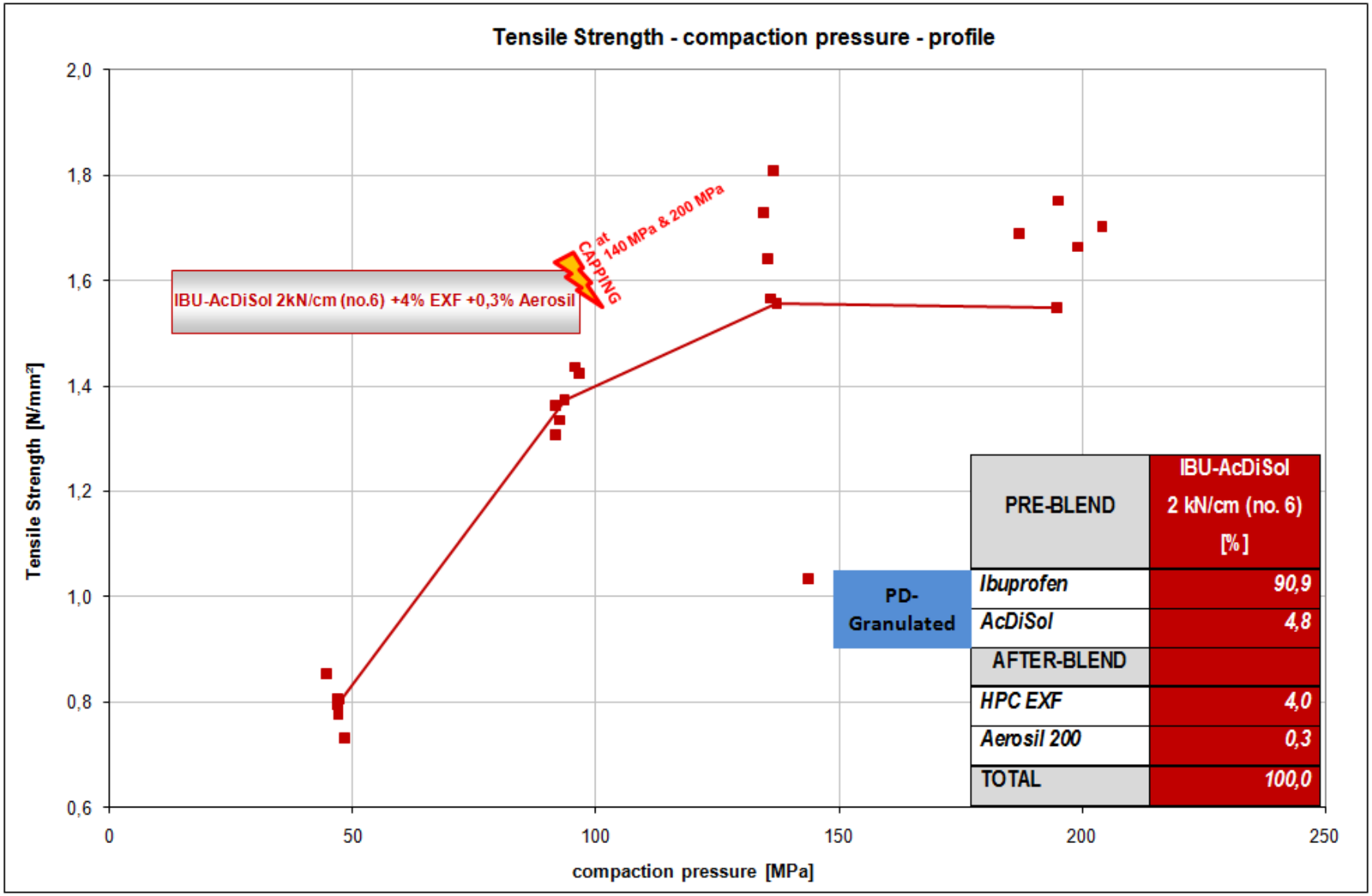
Final blend*

- 95.7 % Pre-blend
- 4.0 % Klucel EXF
- 0.3 % Aerosil 200

Final tablet contains 90.9 % of Ibuprofen

* Externally lubricated with Magnesiumstearate

# COMPACTIBILITY of PDG-Ibuprofen



# Properties of PDG-Ibuprofen tablets

| aspect | |
|---|---|
| Crushing Force (9mm concave tablets (rc=15 mm), 312.5 mg) | 104 N |
| Tablet Strength | 1.66 MPa |
| Friability | 0,32 % |
| Disintegration | < 15 min |
| Dissolution | not yet tested, but is not expected to be a problem |

simulated tableting speed: 43000 tablets/hr (Fette 102i, 30 rpm), no sticking to punches observed

# Conclusion PDG Ibuprofen

So, a rather difficult-to-process material like Ibuprofen

results in

**a well flowable granulate/tableting mix**

and tablets, which

| | |
|---|---|
| **are strong enough:** | 104N (= 1.66 MPa), low friability, no capping, no sticking to punches |
| **disintegrate witin:** | 15 minutes |
| **dissolution:** | probably OK |
| **have high drug load:** | 90.9 % |

# PDG summary

Pneumatic Dry Granulation results in

**Avicel PH105**

- excellently flowable granules
- obtained by roller compaction to low density ribbons
- thus ensuring optimal recompaction properties

**Paracetamol**
**Ibuprofen**

- enables tablet formulations with difficult to compact API's
  - hardness OK, friability OK, no capping
  - disintegration and dissolution OK
  - high drug loads

# PDG summary

Virtually every API, that in principle can be compacted, can also be **PD-G**ranulated !

The result is a flowable and compactable granulate !

This extends the application of dry granulation enormously:

**PDG**-technology now provides you with
an excellent alternative to wet granulation
without the disadvantages and
being far more economical

**Contact us at www.atacamalabs.com for more results**