Phoenix

This project received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 953110.

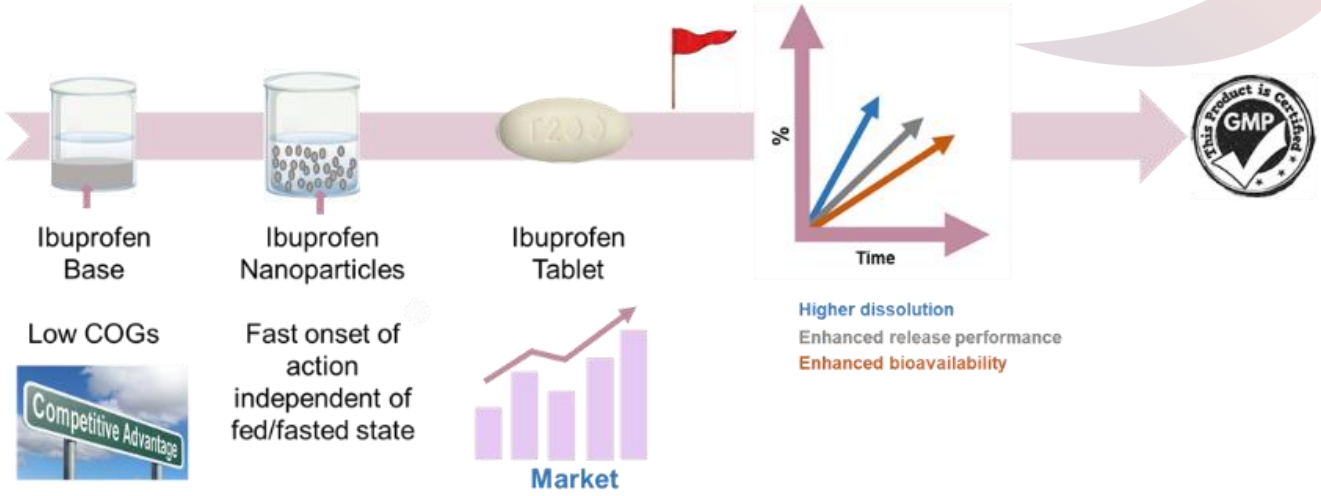
Phoenix

Demo Case 1

Nanolbu

MyBiotech

Nano-Ibu: Innovation Beyond the State-of-the-Art



State-of-the-art

Medication in the NSAID class used for treating pain fever and inflammation

60 minutes delay in onset of action after meal

- Slow onset of action
- Fed/fast state difference
- Tabletting problems

Long-term treatment of chronic conditions

Spondylitis,
Rheumatoid arthritis
...

Relieve mild to moderate pain and inflammation

Headache
Muscular aches
Toothache
Fever
Redness
Swelling
...

MyBiotech

PHOENIX services

- ✓ Advance physico-chemical characterization
- ✓ Chemistry-Manufacturing-Control (CMC)
- ✓ Pre-clinical *in vivo* testing
- ✓ Stability confirmed under ICH stability conditions

✓ IMPD related sections

State-of-the-art Ibuprofen medicaments

The path towards TRL 6

- ✓ **Production of nanoparticle suspension using proprietary microreactor technology**

  Nanoparticle suspension production using MyB proprietary technology: reproducibility (i.e. assay, impurity, particle size) confirmed

- ✓ **Granulation with further excipients and capsule filling**

  Wet granulation achieved

  Capsule filling with homogeneity of batches achieved with good flow properties of the ibuprofen granule powder

- ✓ **Scale up**

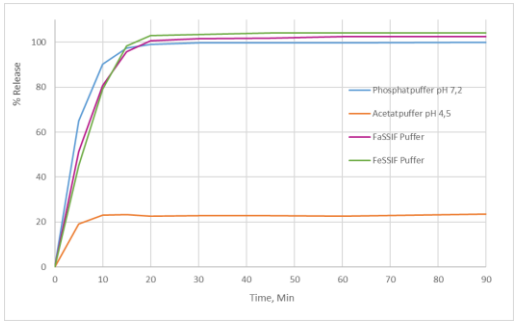
  Proprietary continuous method with production volume of 185 mL/min confirmed

- ✓ **End product**

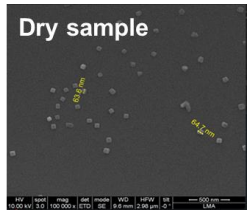
  Three technical batch size NanoIbu capsule produced. Specifications were compliant and stability studies indicate minimum of 12 months shelf stability

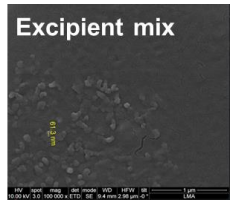
The path towards TRL 6

- ✓ Manufacturing method established
- ✓ Process validation completed
- ✓ IPC an batch release analytical method set ready
- ✓ GMP compliant equipment ready and qualified

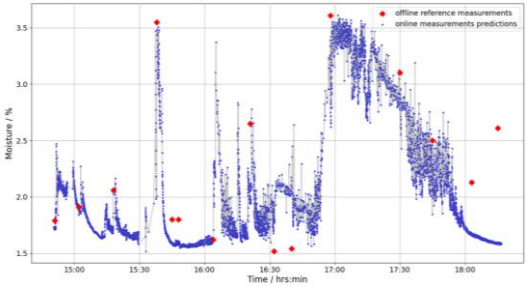


- ✓ 100% Ibu release both in the fasted and fed state.
- ✓ No food effect on the release of nanoIbu





- ✓ in vivo pharmacokinetics profile of different Ibuprofen formulations showed comparable results in all tested conditions (e.g. male/female, fed/fast)
- ✓ in vivo 7-day toxicity in rat model showed no toxicity in the tested conditions



- ✓ PAT: Successful online monitoring of drying process/moisture content (measurement frequency ~ 1 Hz)

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