

# What to Consider When Converting from Injectable to Solid Oral Dose

Converting an injectable to a tablet or capsule involves more than changing the dosage form. It requires understanding the API, target PK profile, formulation strategy and scale-up path.



## STAGE

## CONSIDERATIONS

## OUTPUT



### STAGE 1 Feasibility

- ✓ API property assessment (solubility, permeability, stability, dose feasibility)
- ✓ Rapid screening of enabling approaches
- ✓ Early dissolution method selection
- ✓ Initial dosage form decision (capsule vs tablet)

**Feasibility readout and candidate formulation strategy**



### STAGE 2 Prototype

- ✓ Excipient compatibility and process screening
- ✓ Prototype IR or MR systems
- ✓ Early coating selection (functional needs identified)
- ✓ Iterative dissolution/PK learnings

**Lead formulation and an early control strategy**



### STAGE 3 Scale-Up and Commercial Readiness

- ✓ Process robustness studies and scale-up planning
- ✓ Final packaging selection
- ✓ Stability and specification setting
- ✓ Technical transfer planning

**A scalable formulation and CMC package aligned with clinical and regulatory needs**



**If you're evaluating a move from injectable to solid oral dose, Colorcon can help support development through scale-up and commercialization.**

Learn more at [www.colorcon.com/injection-to-oral](http://www.colorcon.com/injection-to-oral)

