



InstaPill® Oral Lyophilisate Technology
The ultimate Patient Centric Oral Dose Form
From Tenshi

InstaPill offers convenience & compliance



Tablets with quick dispersion time in mouth (3-10 seconds)



Tablets can be consumed without water with small volume of saliva



Vegan, Kosher, Halal, GMO Free



Ease of administration and higher patient compliance



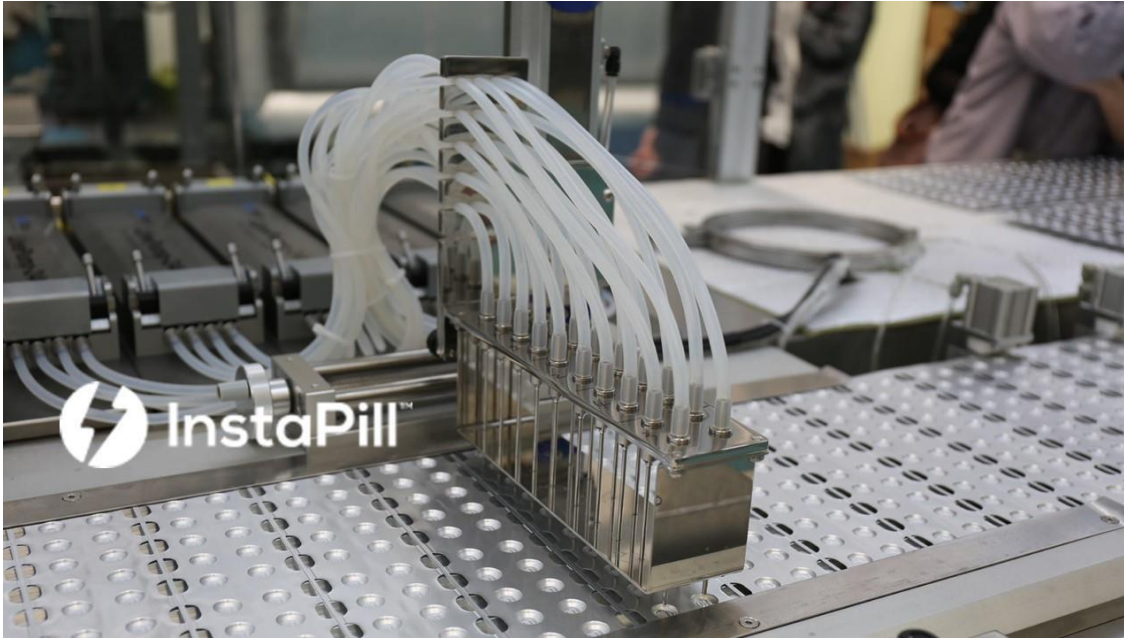
Taste-masking for bitter drugs



Offer on-the go convenient solutions



A better Oral Disintegrating Tablet by Design



Manufacturing Process

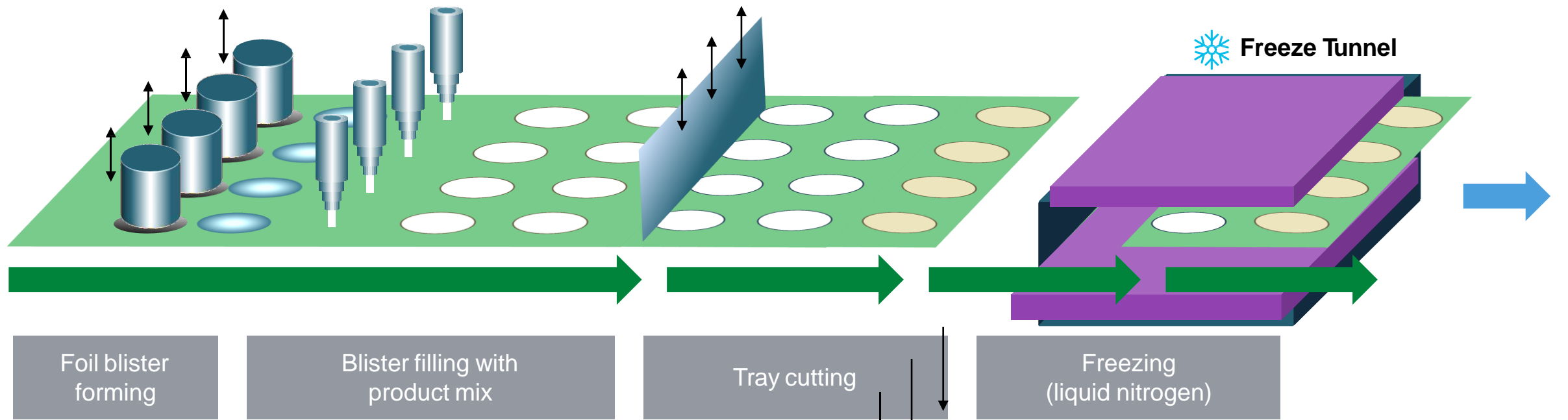
- Aqueous Suspension or Solution
- Precisely dosed into preformed Alu-Alu blister pockets
- Flash frozen
- Lyophilised
- Blister Sealing > Cartonning > Collation
- Serialisation

Formulation & Dose Form Design

- Pullulan – Matrix Former
- Mannitol or Maltodextrin– Structure Former
- Taste-masking of bitter compounds with pH adjustment, Cyclo-Dextrins or Ion Exchange Resins.
- Sweeteners, flavours (all GRAS)
- Branding with debossing and or colours

Development Status of Technology

- 16 Molecules completed Feasibility
- Loperamide & Loratadine Launched
- 3 products in EU Registration
- 3 products in development
- 8 additional POCs (prototypes)
- Technology licensed to leading global animal health company





01

UNIQUE PLATFORM FEATURES

- Proprietary formulations with taste-masking and superior dispersion
- Potential for superior Clinical claims
- Choice of specialty excipients and reduction in the number of excipients compared to conventional ODTs
- Ability to formulate RDTs to deliver as a sublingual formulation to enhance drug delivery



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DEVELOPMENT CAPABILITIES

- Full QbD approach from TPP to Validated Process
- Research and Development centre at Bangalore, India
- Expertise in clinical affairs, regulatory and analytical method development
- Lab scale studies and scale-up including GMP supplies for clinical trials and evaluations



03

MANUFACTURING

- Phase 1 manufacturing facility in Bangalore, India approved by USFDA, EMA, TGA & Health Canada
- Highly automated state-of-the-art facility in Phase 2, expected completion by Q2 2023



Fully Integrated Operations

- Limited discrete unit operations
- Integrated end to end line - from base foil introduction to case package collection
- Extensive automation to provide high cGMP compliance



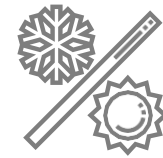
Large Scale Capacities

- Current capacity of **70 million RDTs** (Phase 1)
- Capacity to produce **200 million RDTs** annually (Phase 2)



Minimum Human Intervention

- Human intervention restricted to medicament preparation and machine settings
- Auto Guided Vehicle (AGV) system introduced for loading and unloading of blister tray to/from Lyophiliser



Process Controls

- Well established process control strategy to facilitate product movement through the integrated line
- Online Vision system before lidding operation
- AGV (Automated Guided Vehicle) on both loading and unloading equipped with Laminar Air Flow (LAF)



Compact Footprint

- Layout Design for the line occupies minimum floor area
- Lyophiliser design adapted to maximize floor space- Double deck design
- Liquid nitrogen instead of conventional chiller for cooling



Future ready Compliance

- 21 CFR Part 11 compliant line
- Global serialization requirements incorporated
- Adaptable to e-batch record manufacturing

InstaPill® significantly surpasses the existing Lyo ODT Technology



AUTOMATION

- Discrete operations with pockets of Automation

- **Fully integrated line with complete automation end to end**



CONTROLS

- Limited control on quality of Cold forming Blisters

- **Pin hole detector to check any pin hole post cold forming of the blisters**



DOSAGE UNIFORMITY

- Dosing using Positive displacement pump and Hypodermic needle mechanism



CONTAMINATION

- Potential impact on product from environment during manual loading/unloading

Experience our InstaPill® platform at:

www.insta-pill.com or [click here](#) for the platform video

For more details, please contact:

Simon Hendry VP Global Business Development
simon.hendry@tenshikaizen.com