Piramal
Pharma Solutions

DELIVERING AT TIGHT TIMELINES

CUSTOMER NEED

Generic product development for EU and US with a Para IV certification where "First to file" is important. Product development at NCE-1 stage in market for 3 strengths was required along with final eCTD dossier compilation

CHALLENGES

The molecule to be developed was a BCS class II required in 3 different strengths. The formulation for 2 strengths was dose proportional, lowest strength stand alone formulation with different dissolution media. Extensive work on analytical method development and transfer was critical factor. Technically, polymorphic stabilization of molecule was a challenge along with tight timeline with just in time supply of the API. From regulatory perspective, an Orange Book non-infringement patent formula and process was required to be developed!

WHAT WE DID

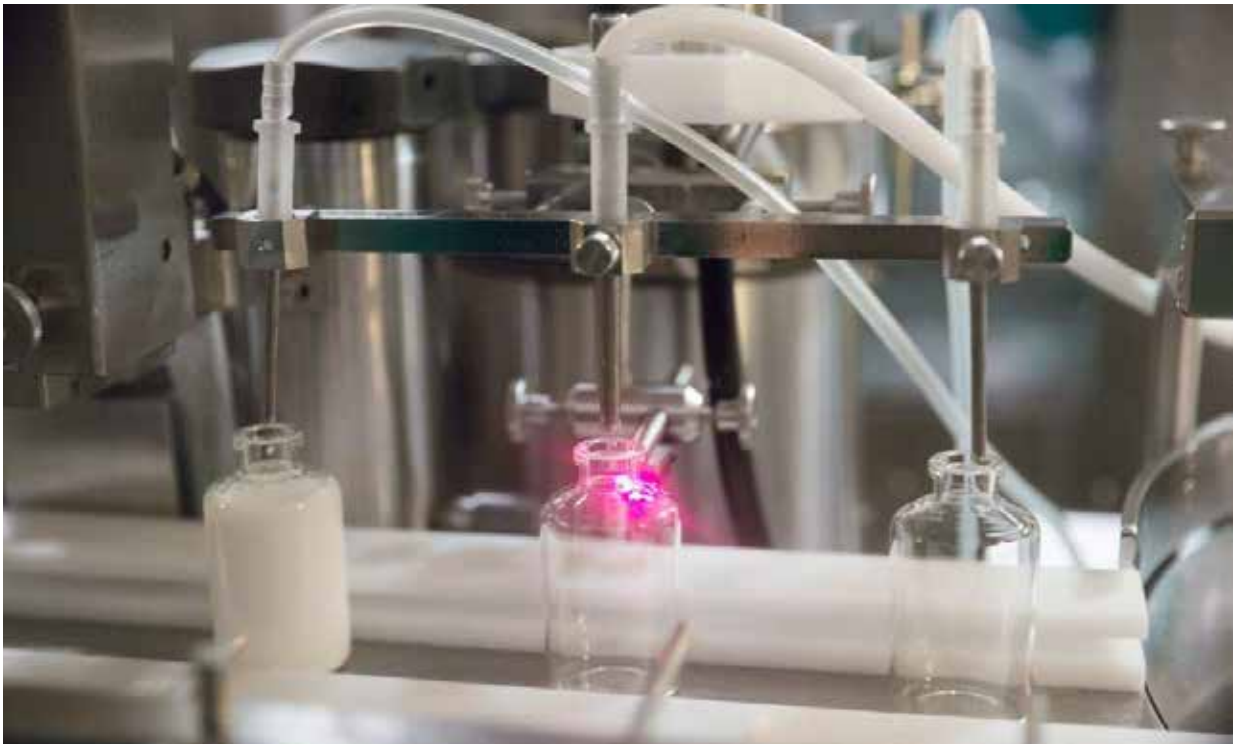
Meticulous study of Innovator API and careful optimization of API particle size was carried out. Formulation and process development was done with respect to reference drug which involved dissolution development and selection of surfactant in dissolution media. All 3 strengths were matched with corresponding strengths of innovator (in vitro). All studies right from Pre-formulation, Formulation Development, analytical method development and validation to scale –up and

stabilities was carried out developmental site. We had successful BE studies before tech transfer to commercial site.

Tech transfer was followed by exhibit batch manufacturing at commercial site. The strong base was built by optimization of various process parameters for pivotal Batch. 6 bio studies were performed for US & EU market .Pivotal bio passed for all 6 studies. Also from regulatory stand point, timely submissions were done to achieve a successful Para IV filing!

VALUE DELIVERED TO CUSTOMER

End to End Solutions delivered from development, exhibit batch manufacturing and regulatory filling. Delivery under tight timelines along with “First to File” achievement. We overcame the patent challenge and supported client to get marketing exclusivity as planned. Expertise along with dedication defines the Piramal way of serving customers!



Piramal Pharma Solutions is a contract development and manufacturing organization (CDMO), offering end-to-end development and manufacturing solutions across the drug life cycle. We serve our clients through a globally integrated network of facilities in North America, Europe and Asia. This enables us to offer a comprehensive range of services including Drug Discovery Solutions, Process & Pharmaceutical Development services, Clinical Trial Supplies and Commercial supply of APIs and Finished dosage forms. We also offer specialized services like development and manufacture of Highly Potent APIs, Antibody Drug Conjugation and are well versed in technologies such as Bio-catalysis, Route Scouting etc. Our capability as an integrated service provider & experience with various technologies enables us to serve Innovator and Generic companies worldwide.

Piramal Pharma Solutions

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