



LEVERAGING
NETWORK
TO DELIVER
CUSTOMER VALUE

CUSTOMER NEED

NCE Product development from early phase to Phase III along with registration batch manufacturing

CHALLENGES

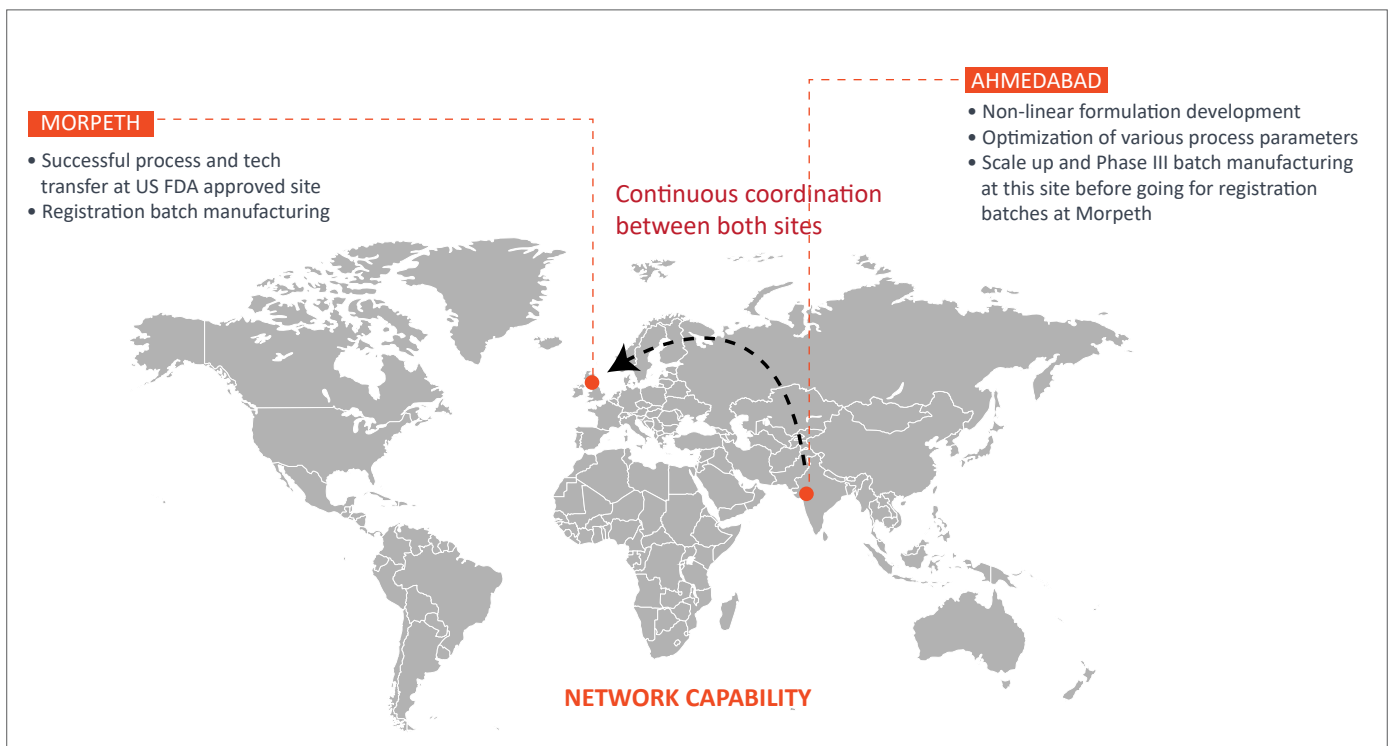
The product development was complex as there was a need to develop non-linear formulations with 9 strengths. The hurdle of formulating from a very early phase poses a challenge of uniformity and segregation. An intricate developmental case where the oral solid was to be developed was in the form of non-conventional tablet shape, i.e. Hexagonal, adding up to compression challenges. The NCE molecule was also quite unstable in nature!

WHAT WE DID

Development of all the mentioned strengths was done with rigorous optimization within stipulated period of time. A selectable excipient approach was followed where specific and suitable grades of excipient were chosen for development of formulation. Particle size assessment was done thoroughly to attain an acceptable level of uniformity, which in turn solved the issue of segregation. To build the tablet in required hexagonal shape, we evaluated various size tools to appropriately select the punch size. This precision achieved helped in finalizing the shape with less amount of yield loss. The stability challenges were overcome by use of suitable packaging system, in which the formulation stored attained an impeccable levels of purity!

VALUE DELIVERED TO CUSTOMER

The NCE formulations was successfully developed as per requirements and was transferred to FDA approved manufacturing site in Morpeth, UK. A high level of confidence was achieved by manufacturing late phase batch at development center before exhibit batch manufacturing. Root cause analysis for impurity generation was done at Morpeth and a mitigation plan was put in place for impurity identification and characterization. Piramal becomes a “One-stop Shop” for customers with need from development to manufacturing by leveraging network across globe!





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