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**DEVELOPING AND  
MANUFACTURING  
DIFFERENT  
FORMULATION TYPE**

## CUSTOMER NEED



Customer's requirement to create a combination formulation consisting of two highly incompatible molecules with varying stability. Single product development with FDC, with desired stability and matching to corresponding innovators was of prime importance.

## CHALLENGES

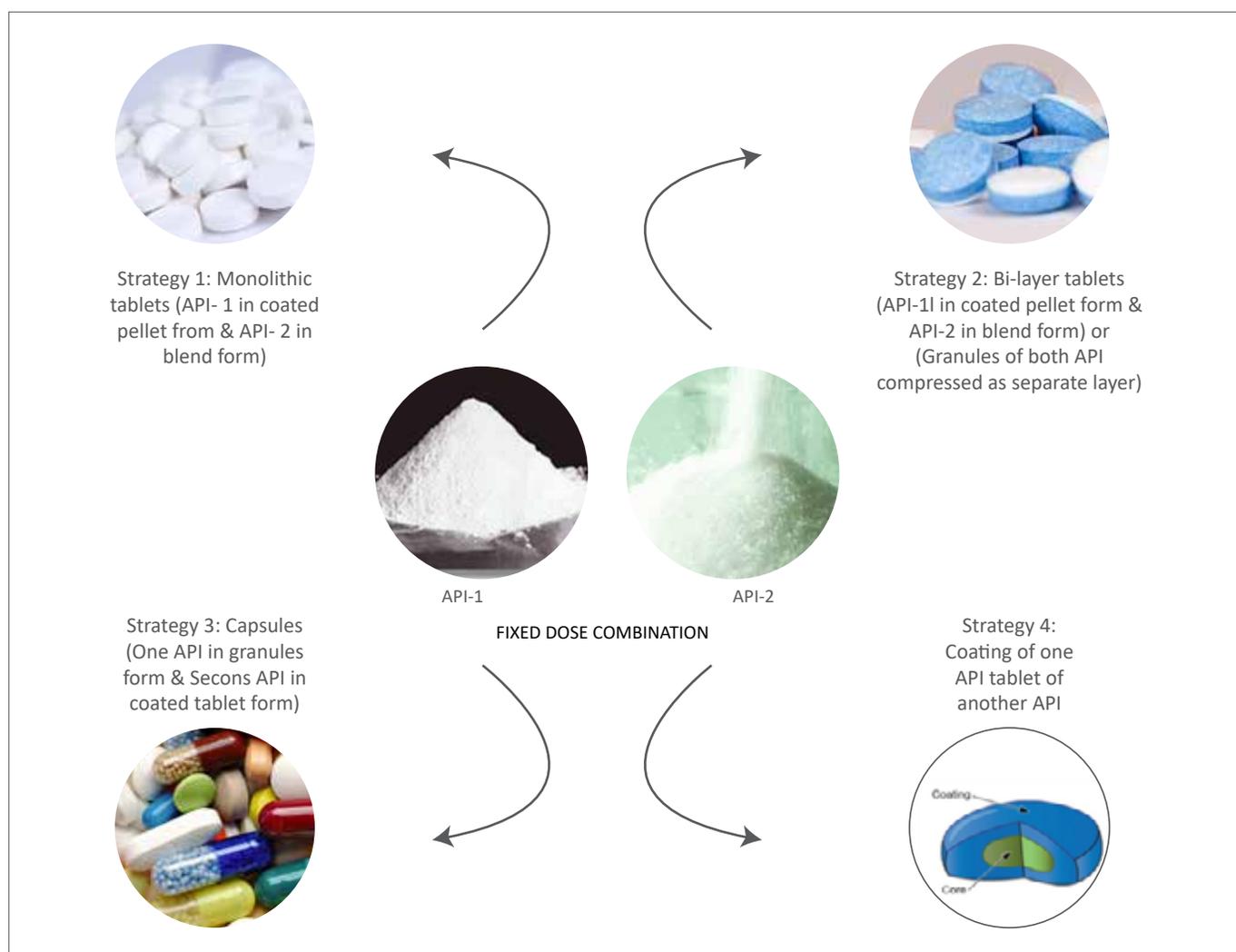
The biggest challenge in developing this formulation was combining mutually incompatible actives. Additionally, both the known molecules had stability issues along with varied conditions (one active stable in acidic conditions and other active stable in alkaline conditions). The formulation was to be derived in a way to minimize interaction between both the APIs, yet in one single product.

## WHAT WE DID

In order to achieve stability between both the actives, extensive API- API compatibility studies were done. Formulation with extensive studies on parameters to minimize the interactions and nullify the frictional effect was carried out. The developed formulation was robust with acceptable 3M accelerated stability data and matched the dissolution profile with corresponding reference drug. With an aim to develop a compatible formulation and to mitigate risks, two different strategies were designed for Pilot BE studies.

## VALUE DELIVERED TO CUSTOMER

Stable formulation with similar dissolution to innovator to ensure bioequivalence. Risk mitigation studies for further purpose taken in consideration. New Branded product was made ready for marketing in emerging countries!





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