

Brief C.V. of **Dr.K.V.Jogi.**

Dr.K.V.Jogi, M.Pharm., Ph.D., has several years' experience in teaching Pharmacology and in regulatory testing at Central Drugs laboratory ,Kolkata. He retired as Chief Pharmacologist and Director of Central Drugs Testing Laboratory, Mumbai. Presently , Dr.Jogi is Advisor to Natco Pharma



Biosimilars – NATCO's Experience

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ABSTRACT

Bio-similars or follow-on biologics are emerging as effective alternatives to the potentially toxic and cyto-toxic small molecules in the treatment of many organic diseases and cancers. Ever increasing market share of the bio-similars holds a great promise for the Indian entrepreneurs. However, the regulatory pathway for approval of the Biosimilars is not so well laid out as that of the small molecules and calls for experimental proof of similarity based on biochemical and molecular effects at the cellular level and highly sophisticated physicochemical techniques for characterization of each individual entity. Since in most cases the physico-chemical properties of the final product are process specific and are highly susceptible to even small changes in the process variables, their identity has come to be equated with the process, necessitating in-depth study of the effect of these variables and evolving tighter controls on the process, to assure similarity and consistency.

It is in this context that Natco's experience with developing three divergent drug substances for national and international markets will be presented.