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A Guidebook to Generic Drug registration in India

Based upon International Standards

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Since drugs are so-called life-saving substances, the quality, safety, and efficacy of these substances pose a unique challenge for the manufacturers as well as regulators. The drug has to undergo several phases of screening by governmental agencies before it is being placed in the market. A country like India's skill mostly lies in developing low priced generic medicines. Our infrastructure and economy do not allow us to invest like the western countries. The quality of medicines produced in India is no way inferior to any of the medicines available globally. However irony of the situation is such that India produces the best quality medicine for the world, not for itself. This is primarily because of the reason that it does not have a standard for itself. All the countries in the world starting from highly regulated markets to less regulated market have a certain form of guidelines for registration of the drugs in their own territories. This current work proposes some guidelines those can be adapted by Indian Regulatory authorities so as to enhance the quality of pharmaceutical products in India to meet international standards.

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