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Regulatory requirements for generic drugs (ANDS) in Canada

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Every country's ultimate goal is to protect their people's health by providing medicines in a qualitative, safe & cost effective manner. Particularly, Canada is showing much more attention on their people because of the diseases relevant to their different climatic conditions. Because of low cost, most of the countries are providing generics. It is necessary to apply ANDS (Abbreviated New Drug Submission) to get marketing approval for generics in Canada by considering the guidance, regulations of its regulatory federal authority Health Canada (TPD) along with ICH guidelines. Everyone should follow CTD to compile generics in Canada. This study is aimed to explain about development, compilation, review & approval of dossiers for generic drugs in Canada and as well as brief information regarding exclusivities. Regulatory executives need to collect all relevant information, documents from manufacturing industries which were authorized by QA department of organization.

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