conferenceseries.com

Se Jin Lee, J Develop Drugs 2016, 5:4(Suppl)
http://dx.doi.org/10.4172/2329-6631.C1.020

International Conference and Expo on

Generic Drug Market & Contract Manufacturing

November 07-09, 2016 Barcelona, Spain

Se Jin Lee

Korea Conformity Laboratories, Republic of Korea

A comparative study of test method development of Pharmacopoeia reference standards for quality verification

Conditions of medicinal drugs should be equipped with safety and efficiency. Safety and efficiency of materials can be ensured by development of a method through preclinical studies and clinical trials, and a qualitative guarantee of commercial products using the method. Nevertheless, verifying quality of reference standard using the mass balance method had its disadvantages of spending many samples. We think that another suitable method of verifying quality of reference standard need to be developed in light of current science level and status of pharmaceutical industry and the method results in reducing wasteful expenditure for stability test of expensive reference standard made more difficult. In the study, we have given positive consideration to the method of TGA, ICP-OES, and qNMR as alternative testing methods instead of verifying impurity of reference standard by using the mass balance method. Especially, ICP-OES method has been proven to be alternative testing method of inorganic impurities. qNMR method that can detect impurity has been proven to be alternative testing method of periodic stability test of reference standard so that this method could reduce sharply the amount of samples for examining the quality of reference standard. Thus, the study analyzed by applying the eight substitutable Test Method [Inductively Coupled Plasma Spectroscopy (ICP-OES) and qNMR assay] with respect to the number of test methods consumption at the time of quality verification samples with respect to the items through the test method was justified; it is an alternative plan to determine whether the test developed as a method for the Thermal Mass Measurement (TGA).

Biography

Se Jin Lee has completed his Master's in Chemical Engineering from University of Seoul. He has published more than 1 paper on drug delivery in reputed journal. He is currently working in Korea Conformity Laboratories in Korea.

sejin@kcl.re.kr