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Study on the component analysis and establishes reference standards for the pharmacopoeial raw materials

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Conditions to be equipped this drug is to ensure safety and efficacy. Safety and efficacy with respect to the materials developed as a means for securing to secure the development of a method through the preclinical studies and clinical trials, and then a method of securing to ensure the quality of the commercial product.The former is a secure time already developed the inherent property of the material, the latter manages to establish whether a suitable gauge by means of commercially available products for quality assurance standards to maintain the quality of a certain level.

In this regard, there are three raw material components(pregabalin, p-aminophenol, L-cystein) for use as a reference standard with respect to the raw materials and the method for evaluation of the impurity components of the raw meal to determine the material through optical analysis. In addition, a review of whether to perform Mass Balance method (volatile impurities, inorganic impurities, purity analysis reflects the organic impurity content measurements) the amount of the check for the results of the Republic of Korea Pharmacopeia, USP and EP standards of quality cross after three or more organizations the reliability is verified by performing a high-quality verification methods (statistical analysis) to verify the quality.

Therefore, in this study were confirmed by the quality assurance with respect to the ingredients and contents in the raw materials of the three, is ensuring the safety and efficacy in pharmaceutical companies plan to be used with confidence. Import through which the standard is expected to be able to replace.

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Notes: