投稿 ▶原著

日局医薬品各条合成グルカゴンの定量法等に関する研究*3

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Study of Assay of Synthetic Glucagon Monograph of the Japanese Pharmacopoeia*3

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Summary

In Japan, two types of glucagon products, one containing recombinant glucagon and the other containing synthetic glucagon, have been approved and marketed. On June 7th, 2021, the Glucagon (Genetical Recombination) monograph was newly listed in the eighteenth edition of the Japanese Pharmacopeia (JP). In addition, Synthetic Glucagon has been listed as a new candidate monograph of JP. For the approval of synthetic glucagon, in vivo bioassay has been adopted as an assay method, although high-performance liquid chromatography (HPLC) has been designated for the assay and purity test in the JP Glucagon (Genetical Recombination) monograph. The HPLC method has also been adopted in the Glucagon, Human monograph in the European Pharmacopeia, and the Glucagon monograph in the United States Pharmacopeia. Therefore, an HPLC method for synthetic glucagon is required as an alternative to bioassay from the viewpoints of animal welfare and harmonization of analytical methods between the Synthetic Glucagon and Glucagon (Genetical Recombination) monographs in JP. In this study, we demonstrate that the HPLC assay method described in the Glucagon (Genetical Recombination) monograph is applicable to synthetic glucagon.

Key words

Synthetic glucagon, Glucagon (Genetical recombination), Glucagon assay, Purity test, Liquid chromatography