投稿 ▶原著

日本薬局方グルカゴン（遺伝子組換え）各条確認試験で使用する試薬の規格に関する検討

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（受付：令和4年7月25日，受理：令和4年10月21日）

Study on Reagent Specifications in Glucagon (Genetical Recombination) Monograph of the Japanese Pharmacopoeia

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Summary

In Japan, two types of glucagon products, which contain recombinant glucagon or synthetic glucagon as an active ingredient, have been approved and marketed. On June 7th, 2021, the Glucagon (Genetical Recombination) monograph was newly listed in the eighteenth edition of the Japanese Pharmacopoeia (JP). In the monograph, peptide mapping with α-chymotrypsin was set as the identification test; however, the specification of the α-chymotrypsin reagent is unclear because there is no information about the substrate used in the activity assay, the definition of the enzyme unit or the purity. Therefore, selecting an α-chymotrypsin reagent can be an issue when performing the identification test. In this study, we measured the chymotrypsin activity and residual trypsin activity of several α-chymotrypsins, including the United States Pharmacopeia and the European Pharmacopoeia chymotrypsin reference standards and commercially available α-chymotrypsin reagents, and conducted an identification test according to the JP glucagon monograph; these α-chymotrypsins were used to evaluate the effect of differences in the activity of the chymotrypsin and residual trypsin on the test results. As a result, it was found that the current specification for chymotryptic activity of the JP α-chymotrypsin reagent may be higher than necessary to obtain the intended peptide map, and slight tryptic activity is required to generate the reference peptide peaks. Based on these findings, we discuss the appropriate specification of the JP α-chymotrypsin reagent.

Key words

Glucagon (Genetical Recombination), Synthetic Glucagon, α-chymotrypsin, chymotrypsin activity, trypsin activity, Japanese Pharmacopoeia