

医薬品の研究開発における安全性薬理試験の現状と課題

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(受付:平成24年2月28日, 受理:平成24年12月14日)

Current Status and Issues Regarding Safety Pharmacology Studies in Drug Discovery and Development

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Summary

Safety pharmacology studies are conducted according to several guidelines, such as ICH S7A, ICH S7B, ICH S6, ICH S9 and ICH M3 (R2), whose recommendations include a variety of test items. Given the diversity of pharmaceutical products being developed, selection of appropriate test items may differ depending on the characteristics of products, the planned clinical applications, and the company's experience. A survey was conducted to determine which test items had been evaluated on a sample of 129 pharmaceutical products. The results were analyzed using a classification based on the characteristics of products, such as small-molecular compounds, biotechnology-based medicines, vaccines, combination drugs and anti-cancer drugs. The results indicated that safety pharmacology studies have generally been conducted according to the ICH S7A guideline for small-molecular products, except for anti-cancer drugs. On the other hand, some safety pharmacology studies were omitted for some antibody-targeted drugs, combination drugs and vaccines. Safety pharmacology studies were incorporated into toxicology studies for some biotechnology-based medicines. Our survey results indicate that comprehensive evaluation of both safety pharmacology and toxicology study results is important in order to predict potential safety concerns for humans on the basis of animal studies.

Key words

Safety pharmacology, ICH 7A, ICH 7B, Core battery study, Follow-up study