日本薬局方130周年記念シンポジウム
Japanese Pharmacopoeia 130th Anniversary Symposium

Session 1　日本薬局方の今後に向けた役割と期待
Session 1:　Expectations for the future and the role of Japanese Pharmacopoeia

日本製薬団体連合会
薬局方委員会
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日本薬局方　Japanese Pharmacopoeia

通則、製剤総則、一般試験法と各条で構成

General rules, general provisions concerning preparations, general test procedures, and articles

1886年6月　日本薬局方（第一版）　468品目収載

June 1886:468 items included in Japanese Pharmacopoeia (1st edition)

2016年4月　第十七改正日本薬局方　1,962品目収載

化学薬品　1,638品目（ 製剤約570品目）

生薬等　324品目

April 2016:1962 items included in Japanese Pharmacopoeia (17th edition)

Chemicals: 1638 items (570 preparations)

Crude drugs and others: 324 items

日本薬局方各条の制定過程の変化

Change of the establishment process of the Japanese Pharmacopoeia Articles

初期の薬局方は、学識経験者による局方制定
→医薬品の品質標準の作成

Academic experts formulated the initial pharmacopoeia
→Prepared quality standards for pharmaceutical products

医薬品の承認制度の変遷により企業側が原案提供
→医薬品の基準の統一化

The system for approval of pharmaceutical products changed, leading pharmaceutical companies to provide the company's drafts
→Unified standards for pharmaceutical products

分析法の進歩
Advancement of Analytical Methods

酸塩基滴定法
Acid-base titration
↓leading to:
吸光光度法
Absorption photometry
↓leading to:
クロマトグラフ法
Chromatography
特異性や、類縁物質、分解物との分別精度も高度化
Enhancing the accuracy and precision of differentiation from analogs and degradation products

日本薬局方への期待
Expectations for Japanese Pharmacopoeia

多様化への対応
Correspondence to diversification

統一規格→「別に規定する」
Unified specification → Being specified separately

日本薬局方への期待
Expectations for Japanese Pharmacopoeia

日本薬局方の各条収載方針
Policies for Inclusion of Articles in Japanese Pharmacopoeia

医療上の必要性、汎用性又は使用経験等を指標に、保健医療上重要な医薬品は市販後可及的速やかな収載を目指す→収載にあたっての企業への優遇措置

Aim to include important pharmaceutical products in terms of healthcare as soon as possible after marketing, referring to the necessity, the frequency of use, and the experience of using the products as a guide.

→The incentive “administrative strategy or action” to encourage pharmaceutical companies to list the important pharmaceutical products may be expected.

日本薬局方への期待
Expectations for Japanese Pharmacopoeia

グローバル流通に適応した、薬局方の国際調和
International Harmonization of Pharmacopoeia to adapt to globalized distribution

残留溶媒管理→元素不純物管理
The management of residual solvents is shifted to that of elemental impurities.

日本薬局方への期待
Expectations for Japanese Pharmacopoeia

通則、製剤総則及び一般試験法や参考情報等
General rules, general provisions concerning preparations, general test procedures, reference information, and others

→全ての医薬品における、参照規則として運用
最新の管理手法の速やかな収載が望まれる
→These should operate as a reference for the rules of all pharmaceutical products.
It is desirable to swiftly include the latest management techniques.

ご清聴ありがとうございました

Thank you for your attention.

FPMAJ

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