

## G-20 CHROMATOGRAPHY

The harmonised general chapter *Chromatography* was signed-off by the Pharmacopoeial Discussion Group (PDG), which brings together the European Pharmacopoeia (Ph. Eur.), Japanese Pharmacopoeia (JP) and the United States Pharmacopoeia (USP), on 28 September 2021. The coordinating pharmacopoeia for this text was the Ph. Eur.

During a joint PDG-industry meeting in 2009, the PDG was encouraged to add harmonisation of the three regional chapters on chromatography to the PDG work programme. Although the chapters in question differed in content and format, it was considered feasible to develop a chapter describing *core requirements* applicable for TLC, HPLC and GC.

After discussion, it was agreed not to include more general (textbook type) descriptions of individual techniques as each of the PDG pharmacopoeias has its own approach, decided at regional level.

These harmonised requirements promote the development of individual monographs with a consistent approach and enhance understanding of basic requirements by users in all three regions.

Owing to the complexity of the topic, the differences in the individual approaches mentioned above and the large impact on existing monographs or general chapters, considerable time and effort were invested in finding the best possible compromise.

During harmonisation of the text, particular attention was paid to:

1. Terminology, definitions and interpretation of chromatograms;
2. System suitability: this section provides requirements intended to guarantee that the performance of the chromatographic system is appropriate. They apply to multiple monographs and are to be read in conjunction with the requirements described therein;
3. Adjustment of chromatographic conditions;
4. Quantitation procedures.

The corresponding regional texts are scheduled for publication in July 2022 (Ph. Eur.), December 2022 (JP) and December 2022 (USP).

Contact:  
Division of Pharmacopoeia and Standards for Drugs,  
Office of Review Management, PMDA  
TEL: +81-(0)3-3506-9431 FAX: +81-(0)3-3506-9445