写

事　務　連　絡
令和６年７月 17 日

各都道府県衛生主管部（局）薬務主管課　御中

厚生労働省医薬局医薬品審査管理課

第十八改正日本薬局方第一追補（英文版）正誤表の送付について（その１）

第十八改正日本薬局方第一追補（令和４年厚生労働省告示第 355 号）の英文版につきまして、一部に誤植等がありましたので別紙のとおり正誤表を送付いたします。

Supplement I to JP18 table of errata

July 17, 2024

General Tests / 2.00 Chromatography

Page	Line	Correction	Error
2812	right ↓ 23-36	• Column dimensions (particle size, length): The particle size and/or length of the column may be modified provided that the ratio of the column length (L) to the particle size (d_p) remains constant or in the range between −25% to +50% of the prescribed L/d_p ratio. Adjustment from totally porous to superficially porous particles: For the application of particle-size adjustment from totally porous to superficially porous particles, other combinations of L and d_p can be used provided that the plate number (N) is within −25% to +50%, relative to the prescribed column. These changes are acceptable provided system suitability criteria are fulfilled, and selectivity and elution order of the specified impurities to be controlled are demonstrated to be equivalent.	• Column dimensions (particle size, length): The particle size and/or length of the column may be modified provided that the ratio of the column length (L) to the particle size (d_p) remains constant or in the range between −25% to +50% of the prescribed L/d_p ratio. • Adjustment from totally porous to superficially porous particles: For the application of particle-size adjustment from totally porous to superficially porous particles, other combinations of L and d_p can be used provided that the plate number (N) is within −25% to +50%, relative to the prescribed column. These changes are acceptable provided system suitability criteria are fulfilled, and selectivity and elution order of the specified impurities to be controlled are demonstrated to be equivalent.