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

General Tests / 2.00 Chromatography

July 17, 2024

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