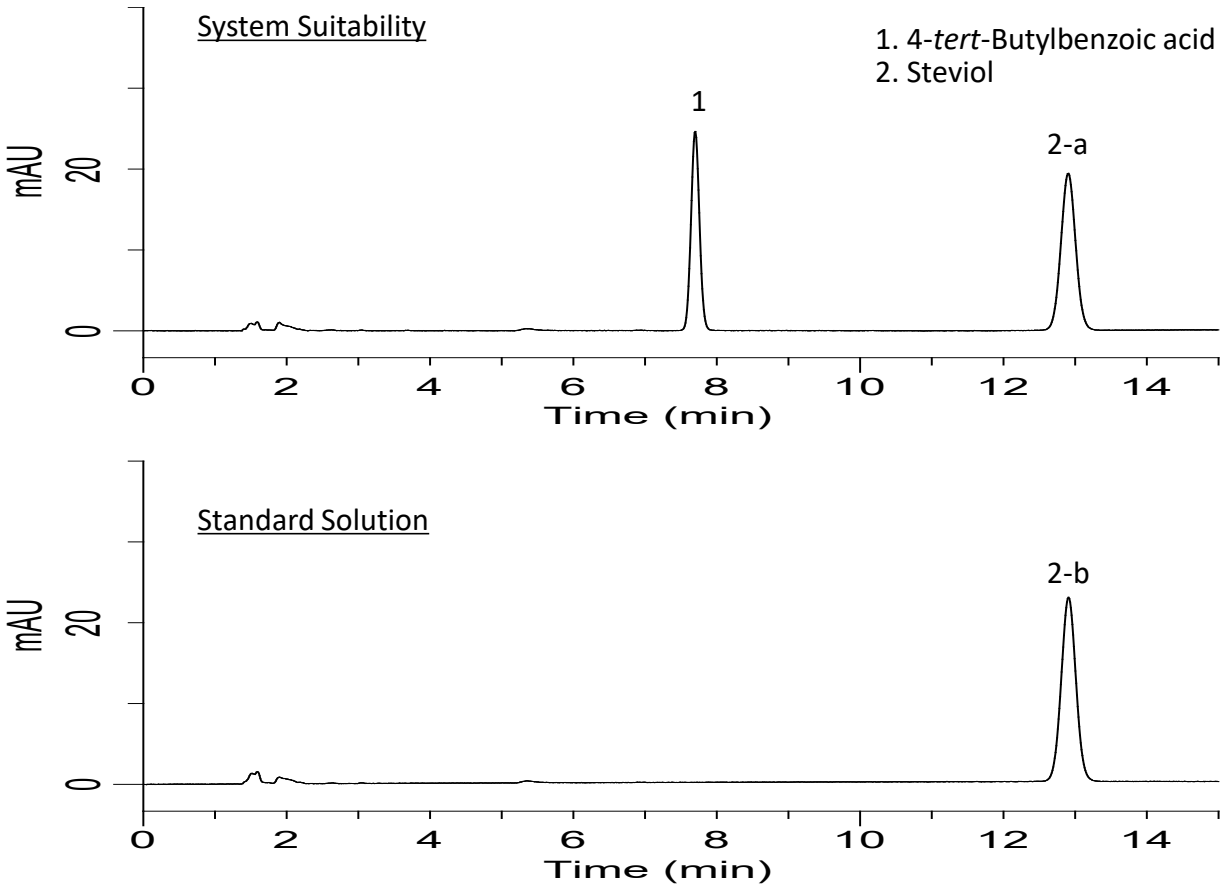
Analysis of Steviol Glycoside -- Japanese Pharmaceutical Excipients

The Ministry of Health, Labour and Welfare issued a notification on March 29, 2018, for revise the Standards for Japanese Pharmaceutical Excipients 2018 (Notification No. 0329-1 of the Crude Drug Administration). In this Pharmaceutical Excipients Specification 2018, the specifications for the five newly reviewed products were listed, partially revised for the 25 already listed products, and the four ingredients of the eight products were combined, resulting in 489 listed products. This paper presents the results of HPLC analyses of "purified Stevia extract" among the five newly listed products.

(M. Mano)

Purified Stevia Extract Purity Test (4) Steviol



HPLC Conditions

System	: GL7700 HPLC system
Column	: Inertsil ODS-HL (5 µm, 250 x 4.6 mm I.D.)
Eluent	: A) CH_3CN B) 0.1 % H_3PO_4 in H_2O A/B = 55/45, v/v
Col. Temp.	: 40 ℃
Detector	: UV 213 nm
Injection Vol.	: 20 µL
Flow Rate	: 1.25 mL/min

【System Suitability Test】

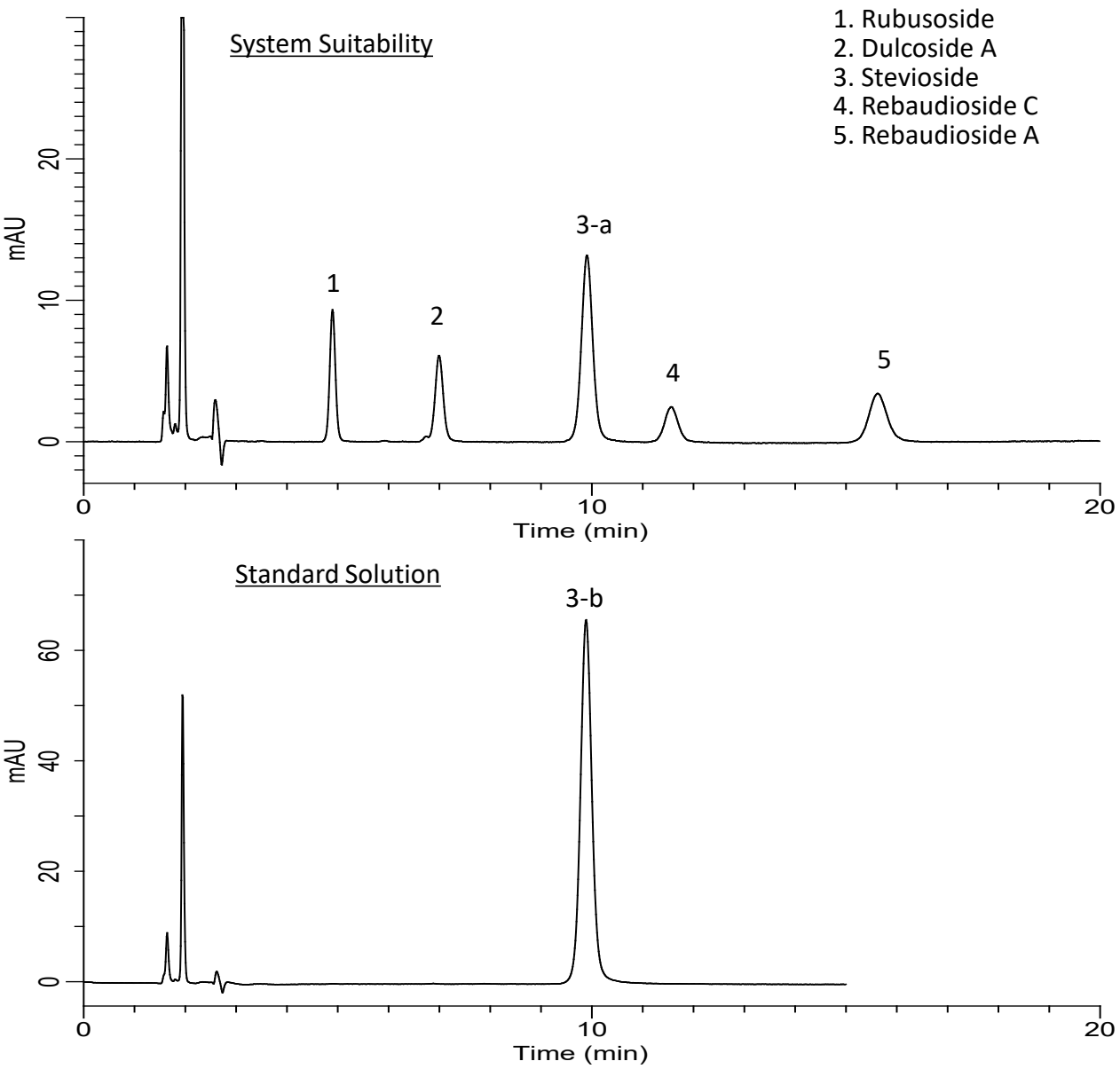
◆System Stability

(1, 2-a) : 17.5 (≧6)

◆System Reproducibility

Steviol Peak Area (2-b)
RSD (%) (*n*=6) : 0.10 (≦1.5)

Purified Stevia Extract Assay



HPLC Conditions

System	: GL7700 HPLC system
Column	: Inertsil NH2 (5 µm, 250 x 4.6 mm I.D.)
Eluent	: A) CH_3CN B) H_2O A/B = 80/20, v/v
Col. Temp.	: 35 ℃
Detector	: UV 213 nm
Injection Vol.	: 20 µL
Flow Rate	: 1.40 mL/min

【System Suitability Test】

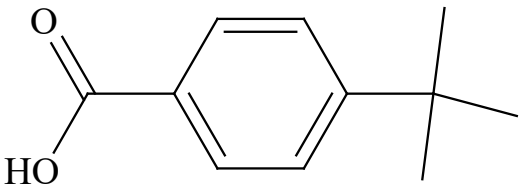
◆System Stability

Separation (3-a, 4) : 3.73 (≧1.5)

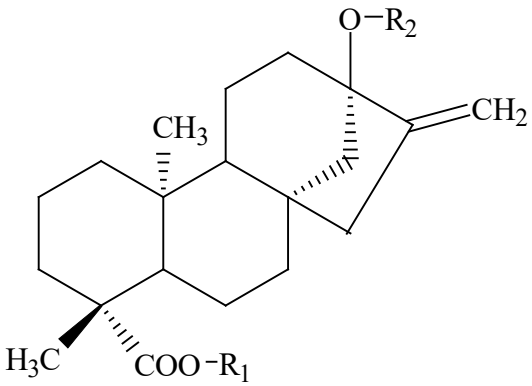
◆System Reproducibility

Steviol Peak Area (3-b)
RSD (%) (*n*=6) : 0.08 (≦1.5)

Chemical Structure



4-*tert*-Butylbenzoic acid



Structures are created using Chemistry 4-D Draw which is provided by ChemInnovation Software, Inc.

Compounds	R_1	R_2
Steviol	H	H
Rubusoside	β-Glucose	β-Glucose
Dulcoside A	β-Glucose	β-Glucose - α-Rhamnose (2→1)
Stevioside	β-Glucose - β-Glucose (2→1)	β-Glucose - β-Glucose (2→1)
Rebaudioside C	β-Glucose	β-Glucose - α-Rhamnose (2→1) | β-Glucose (3→1)
Rebaudioside A	β-Glucose	β-Glucose - β-Glucose (2→1) | β-Glucose (3→1)

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