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指定成分であるコレウス・フォルスコリーを含む健康食品の 定性及び定量分析

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Qualitative and quantitative analyses of *Coleus forskohlii*, "an ingredient calling for special attention" in a health food

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Abstract

In 2020, the government of Japan has designated *Coleus forskohlii* as "an ingredient calling for special attention". To ensure the efficacy and safety of health food products containing *C. forskohlii*, it is essential to identify and quantify the active compounds present in that plant. In this study, we established a specific TLC identification method and a quantitative HPLC assay, and evaluated the quality and quantity of 14 health food products. For TLC identification and for a cleaner analysis method, we modified the USP method in which toluene is used as the TLC eluent. Forskolin and its isomer, isoforskolin, were clearly separated with *n*-hexane/ethyl acetate (1:1) and detected with 4-methoxybenzaldehyde/sulfuric acid/ethanol (1:1:18) spray on TLC plates. For HPLC quantification of forskolin in *C. forskohlii*-containing products, we developed a simpler and more sensitive method based on the USP monograph. Good linearity with a coefficient of determination (r² > 0.998) was achieved over a concentration range 2–4000 μg/mL. The limit of detection and the limit of quantification were estimated to be 0.42 and 1.28 μg/mL, respectively. The precision of the method was confirmed by 92.01% forskolin recovery. Surprisingly, the forskolin content in health food products varied greatly and ranged up to 300 fold (0.35–120.10 mg/day). Thus, it was considered that the differences in the forskolin content in the sample products were caused by the differences in their merchandise design. These developed methods would be useful for the qualitative and quantitative evaluations of health food products containing *C. forskohlii*.

Keywords: 指定成分、コレウス・フォルスコリー、健康食品、定性分析、定量分析 ingredient calling for special attention, *Coleus forskohlii*, health food product, qualitative analyses, quantitative analyses

I 緒言

シソ科コレウス・フォルスコリー (Coleus forskohlii Briq.) はインド原産の熱帯植物で、その根はインドの伝統医学アーユルヴェーダにおいて、古くから高血圧、胃腸障害、呼吸器疾患、神経疾患などの治療に利用されてきた^{1,2)}。近年では、世界各国で体重減少を謳うダイエタリーサプリメント等「いわゆる健康食品」の素材として用いられ、様々な商品が流通している一方で、インターネットを介した調査において、回答者

の13%が体調不良経験を持ち、そのうち78%が下痢症状を訴える等の有害事象の発生も報告されている³⁻⁵⁾。コレウス・フォルスコリーの主成分であるフォルスコリンは、アデニル酸シクラーゼの活性化により cAMP の細胞内濃度を高めるため^{6,7)}、脂質代謝に作用して体重減少が期待されると同時に、消化管内への液体貯留によりコレラ様の下痢を誘発すると考えられている⁸⁾。さらに、フォルスコリンは急性毒性が高く劇薬基準相当の活性を有すること⁹⁻¹¹⁾、コレウス・フォルスコリーは海外において「ヒトの健康への懸念を生じる可能