

〔一般論文〕

## バルプロ酸ナトリウム非発酵性糖シロップ剤の研究 ～付加価値としての非齲蝕性甘味料の提案～

A Study of Sodium Valproate Syrup Sweetened with Non-fermentable Sugar  
— Proposal of Non-cariogenic Sweetener as Added Value —

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Summary : Generic drugs require differentiation strategy and it is reasonable that the differentiation gives some benefit to users. Syrup is a formulation that keeps and encourages children's compliance. However, it is indicated that sugar-containing medicines could cause dental caries. It is the key problem that all antiepileptic syrup drugs contain sugar in Japan. Antiepileptic drugs are often used from the cradle, so affected children have an increased risk of developing dental caries. The aim of this study is to make sodium valproate syrup sweetened with erythritol, a non-cariogenic substance, and to assess its flavoring ability and physical and long-term stability. Assessment of flavoring ability was carried out in healthy adult volunteers. We assessed the flavoring ability of the test syrup in terms of five elements, flavor, acidity, smell, aftertaste and total assessment on a four-grade scale. Physical stability was measured by HPLC. Thermodynamical stability was assessed by measuring the amount of remaining sodium valproate after autoclaved sterilization. Long-term stability was assessed by measuring the amount of remaining sodium valproate over 90 days. As a result, it is demonstrated that the test syrup has enough flavoring ability for sodium valproate. Its thermodynamical stability and long-term stability were also favorable. Our results suggest that it is possible to clinically apply sodium valproate syrup sweetened with erythritol, a non-cariogenic substance. In late years, it is said that erythritol is useful for oral care. Clinical application of erythritol makes it possible to maintain the compliance and the intraoral health of children.

Key words : oral health, syrup, caries, sweetener

要旨：後発医薬品には差別化戦略が求められている。シロップ剤は、小児のコンプライアンスの維持及び増進には有用な剤形である。近年、発酵性糖を使用したシロップ剤の齲蝕原性が問題となっている。幼少期から長期投与されることが多い抗てんかん薬においては、全ての品目に発酵性糖が使用されている。そこで本研究では、甘味料に非齲蝕原性であるエリスリトールを使用したバルプロ酸ナトリウムシロップ剤の調製を試みた。またその試験液の味の改善効果と安定性を評価した。官能試験は健常成人ボランティアを対象に実施し、試験液を味、刺激性、におい、後味及び総合の5項目について4段階で評

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