



VIII. Symposium of Young Researchers on Pharmaceutical Technology, Biotechnology and Regulatory Science

28–30 January, 2026 – Szeged, Hungary

FP-03

DOI: [10.14232/syrptbrs.2026.61](https://doi.org/10.14232/syrptbrs.2026.61)

Pharmacopoeial mass uniformity testing of alpha-lipoic acid dietary supplements

Milana Vuković¹, Mladena Lalić-Popovića^{1,2}, Nemanja Todorović¹, Jelena Čanji Panić¹, Dunja Vesković^{3,4}, Ivana Smiljanić⁵, Jelena Jovičić-Bata¹

¹Department of Pharmacy, Faculty of Medicine, University of Novi Sad, Novi Sad, Serbia

²Centre for Medical and Pharmaceutical Investigations and Quality Control (CEMPhIC), Faculty of Medicine Novi Sad, University of Novi Sad, Novi Sad, Serbia

³Department of Dermatovenereology, Faculty of Medicine, University of Novi Sad, Novi Sad, Serbia

⁴Clinic for Dermatology, Clinical Center of Vojvodina, Novi Sad, Serbia

⁵Clinic for Plastic and Reconstructive Surgery, Clinical Center of Vojvodina, Novi Sad, Serbia



Uniformity of mass is a fundamental quality attribute that reflects the manufacturing consistency of solid oral dosage forms. In this study, mass variation testing was performed on a total of 17 commercial alpha-lipoic acid (ALA) dietary supplements (DS), including 14 capsule formulations and three tablet formulations. The testing was conducted in accordance with the requirements of the chapter 2.9.40. of the European Pharmacopoeia, 10th edition.

Among the tested products, one tablet formulation and three capsule formulations failed to comply with the pharmacopoeial acceptance criteria for mass uniformity. The compliant products were predominantly characterized by relatively simple formulations, typically containing ALA as the main active ingredient, combined with conventional excipients such as microcrystalline cellulose, magnesium stearate, silicon dioxide, and hydroxypropyl methylcellulose- or gelatin-based capsule shells. In some cases, a limited number of additional active substances, including B-group vitamins, zinc oxide, glutathione, or vitamin D, were present without adversely affecting mass uniformity. In contrast, the non-compliant formulations generally exhibited increased compositional complexity, incorporating multiple active ingredients such as vitamins, minerals, flavonoids, and trace elements, together with a broader range of excipients, including inorganic fillers and modified starches. The non-compliant tablet formulation contained ALA, gelatin, calcium carbonate, and modified starch.

Overall, the findings indicate that formulation composition and excipient selection may influence mass uniformity outcomes in ALA dietary supplements. Mass non-uniformity may compromise dose consistency between individual units, highlighting uniformity of mass as a simple yet meaningful test for assessing manufacturing consistency of ALA dietary supplements.