



Pharmaceutical Manufacturing in Sri Lanka: Production and Formulation Challenges

M.A.S.U. Manimendra¹, H.W.A.S. Subasinghe^{1}, M. Jayasinghe¹*

¹ Department of Pharmacy, Faculty of Allied Health Sciences, University of Ruhuna, Sri Lanka

**Corresponding author: sewwandisubasinghe@ahs.ruh.ac.lk*

Sri Lanka's pharmaceutical industry has been recognized as a key sector that can support national economic growth. However, 85% of the country's pharmaceutical needs are met through imports. Improving self-sufficiency requires a clear understanding of the challenges experienced within the industry. This study identifies the key factors that limit the production capacity of Sri Lankan pharmaceutical manufacturers, with a specific focus on production and formulation activities. Production and formulation managers from local pharmaceutical companies listed on the National Medicines Regulatory Authority website (as of January 2023) were invited to participate. Data were collected using a semi-structured, open-ended questionnaire, allowing participants to describe their experiences. Five participants representing five companies contributed to the study. Due to the limited number of participants, data saturation was not reached. The responses were analyzed using inductive thematic analysis. The first major theme identified was difficulties in meeting Good Manufacturing Practice (GMP) requirements, due to complex regulations, limited financial and technical resources, and the heavy burden of documentation. A second major theme focused on human resource constraints, encompassing challenges in recruiting skilled personnel, providing adequate training, and managing workplace attitudes. Product recall management emerged as another major theme, with subthemes such as difficulties in identifying root causes, coordinating with distributors, managing public reactions, and safeguarding company reputation. Ensuring consistent drug quality, particularly when using imported active pharmaceutical ingredients (APIs) and responding to quality failures, were identified as ongoing concerns. Participants also described strategies to improve production capacity, including process optimization, greater automation, better resource planning, workforce development, and stronger government support. The findings suggest that both industry-level initiatives and government-level investments are required to strengthen local pharmaceutical manufacturing and reduce Sri Lanka's reliance on imported medicines. These results offer exploratory insights and should be interpreted considering the limited participant representation.

Keywords: Challenges, Drug quality, Pharmaceutical industry, Production capacity, Self-sufficiency