

**DIGITALIZATION OF TABLET HARDNESS TESTING FOR ENHANCE
EFFICIENCY AND PROCESS SIMPLIFICATION IN THE
PHARMACEUTICAL INDUSTRY**

By

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MASTER'S DEGREE

in

MASTER OF MECHANICAL ENGINEERING

FACULTY OF ENGINEERING AND INFORMATION TECHNOLOGY



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STATEMENT BY THE AUTHOR

I hereby declare that this submission is my own work and to the best of my knowledge, it contains no material previously published or written by another person, or material which to a substantial extent has been accepted for the award of any other degree or diploma at any educational institution, except where due acknowledgement is made in the thesis.



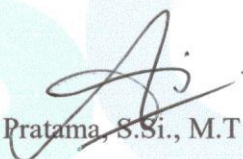
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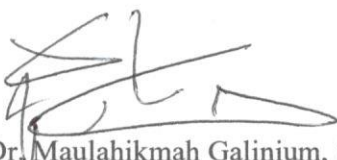


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ABSTRACT

DIGITALIZATION OF TABLET HARDNESS TESTING FOR ENHANCED EFFICIENCY AND PROCESS SIMPLIFICATION IN THE PHARMACEUTICAL INDUSTRY

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This study investigated the digitalization of tablet hardness testing at KALBE, which align with the Indonesian Government Making Indonesia 4.0 initiative. In the traditional system, hardness testing creates production bottlenecks that are simulated by Tecnomatix Plant Simulation, requiring 42.24 hours or 37% of the total cycle time of 4.72 days. The company aimed to reduce its cycle time to 4 days. To achieve the target, the MicroNIR OnSite-W digital tester was integrated with MATLAB analytics under the DMAIC methodology. ANOVA was used to test tablet consistency of tablet samples across three batches and tablet positions, while decision support was provided by the Analytical Hierarchy Process (AHP). The results showed a dramatic improvement, with testing time reduced from 42.24 hours to 0.24 hours (>99% reduction), while ANOVA confirmed consistent performance across operators and testing modes to establish SOP. The AHP analysis showed a strong preference for the digital method, and ROI calculations indicated a payback period of approximately 1.2 years, despite a negative initial ROI (−14.63%) due to the high capital investment.

.Keywords: Pharmaceutical Industry, Tablet Hardness, Digitalization, MicroNIR, MATLAB, Quality Control, Making Indonesia 4.0, ROI



DEDICATION

I dedicate this thesis to my family, Swiss German University (SGU), and the pharmaceutical industry. Their constant support and encouragement have been invaluable throughout my academic journey. This work is also a reflection of my commitment to contributing to the advancement of digital transformation in the pharmaceutical field.



ACKNOWLEDGEMENTS

First, I would like to express my deepest gratitude to Allah SWT for all His countless blessings and guidance throughout my academic journey. I would also like to express my deepest gratitude to my beloved family, who have given me support, prayers, and love that have become the fire of encouragement. Their unwavering faith and motivation provided the foundation of my confidence and the successful completion of this thesis.

I am sincerely thankful to Dr. Eng. Aditya T. Pratama, S.Si., M.T, my Advisor, Dr. Maulahikmah Galinium, S.Kom., M.Sc, my Co-Advisor, and Dr. Yunita Umniyati, S.Si., M.Sc, my Assessor, for their invaluable guidance, constructive feedback, and continuous encouragement that significantly improved the quality of this thesis. I also extend my appreciation to the lecturers and staff of the Swiss German University (SGU) Master of Mechanical Engineering program for their support throughout my academic journey. Special thanks to all SGU colleagues from Class 19, especially Arif Wibowo and Agung Juhardi, for their friendship and support throughout this study journey.

Lastly, my deepest gratitude also goes to M. Rahmatullah Zakaria, R&D Manager at PT KALBE Farma, for his generous support and permission to conduct this research in his department, and to everyone who contributed directly or indirectly. Your presence and encouragement have made this thesis possible.

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