



mersi

PT. MERSIFARMA TM
MANUFACTURING DIVISION
SUKABUMI-INDONESIA

SITE MASTER FILE

2026 EDITION

PT. MERSIFARMA TIRMAKU
MERCUSANA
(PT. MERSIFARMA TM)

Halaman : Page 2 of 37
No. Dokumen :
MTM.SMF.26.00
Tanggal Berlaku
Menggantikan No. :
MTM.SMF.25.00

ATTACHMENT

- 1.1 Business Registration Number of PT. Mersifarma TM
- 1.2 Product list with registration number
- 1.3 GMP certificate : Non-betalactam Tablet and Coated Tablet
- 1.4 GMP certificate : Non-betalactam Oral Liquid
- 1.5 GMP certificate : Non-betalactam Small Volume Parenteral
- 1.6 GMP certificate : Non-betalactam Large Volume Parenteral
- 1.7 GMP certificate : Betalactam Tablets and Coated Tablet and Derivatives
- 1.8 GMP certificate : Betalactam Oral Powder and Derivatives
- 1.9 GMP certificate : Non-betalactam Hard Capsule
- 1.10 GMP certificate : Non-sterile Inhalation and Nasal Liquid
- 1.11 GMP certificate : Non-betalactam Semi Solid
- 1.12 Approval UKL / UPL (Waste Management) from Environmental Agency
- 1.13 License for Waste Water Treatment Plant
- 1.14 License for Temporary Hazardous Waste Storage
- 2.1 List of contract giver and receiver, including address and phone number that can be contacted
- 3.1 Company Organizational Structure
- 3.2 Plant Organizational Structure
- 3.3 Quality Assurance Organizational Structure
- 3.4 Traditional Medicine Organizational Structure
- 3.5 List of qualified key manufacturing personnel with qualification and service years
- 3.6 Pharmacist Practice License of Quality Assurance
- 3.7 Pharmacist Practice License of Quality Control
- 3.8 Pharmacist Practice License of Production
- 3.9 Pharmacist Practice License of Traditional Medicine Industry
- 4.1 Plant lay-out
- 4.2 Unit 1 - Non Sterile production building include Cleanliness zone concept
- 4.3 Unit 1 - Sterile production building include Cleanliness zone concept
- 4.4 Unit 2 production building include Cleanliness zone concept
- 4.5 Unit 3 production building include Cleanliness zone concept
- 4.6 Unit 4 production building include Cleanliness zone concept
- 4.7 Unit 5 production building include Cleanliness zone concept
- 4.8 Unit 6A production building include Cleanliness zone concept
- 4.9 Unit 6B production building include Cleanliness zone concept
- 4.10 Unit 7 production building include Cleanliness zone concept
- 4.11 Unit 8 production building include Cleanliness zone concept
- 4.12 Unit 8C traditional medicine production building include Cleanliness zone concept
- 4.13 Chemical laboratory
- 4.14 Microbiology laboratory include Cleanliness zone concept
- 4.15 Central Warehouse
- 4.16 Cleanliness zone concept of Sampling Room
- 4.17 General scheme of Air Handling Unit at production building and microbiology laboratory
- 4.18 HVAC scheme of Unit 1 Non-Sterile Production Building
- 4.19 HVAC scheme of Unit 1 Sterile Production Building
- 4.20 HVAC scheme of Unit 2 Production Building
- 4.21 HVAC scheme of Unit 3 Production Building
- 4.22 HVAC scheme of Unit 4 Production Building
- 4.23 HVAC scheme of Unit 4, 2nd Floor Production Building
- 4.24 HVAC scheme of Unit 5 Production Building