QUALITY POLICY - MAPRIMED S.A.

Maprimed S.A. is a chemical-pharmaceutical company that is exclusively dedicated to the production of synthetic Active Pharmaceutical Ingredients (APIs) in accordance with current Good Manufacturing Practices (cGMP) to ensure that their products have reproducible quality and comply with pre-established specifications.

This commitment entails the following:

- Compliance with cGMP regulations issued by the Argentine control agency ANMAT/INAME, as well as other international organizations such as (in alphabetical order): FDA, ICH, PIC/S, TGA, WHO or specific customer requirements.
- Regarding as pre-established specifications we consider those in the Pharmacopoeia (in alphabetical order): Argentina, BP, EP, USP, etc. and also those indicated by the ICH in connection with purity and residual solvents or those agreed with customers.
- Being updated and ensure to have all necessary materials for complying with regulations and procedures and to have the equipment, facilities and other means to ensure a working environment in accordance with cGMP and continuous improvement.
- Having a Quality Assurance unit that works independently from Production unit.
- Ensuring a good organization where all units dealing with management, manufacturing and product control are fully participant and responsible for product quality.
- Perform and document the activities of the units according to standard operating procedures and instructions as described in the respective manuals: General Use, Research & Development, Pilot Plant, Plant, Quality Control, Occupational Safety and Health and Environmental (SySOMA).
- Keeping updated training plans to ensure continuous improvement.
- Quality Assurance unit releases products after a satisfactory evaluation of its manufacture and analysis.
- Customers and Regulatory Agencies are notified about any changes in manufacturing processes and specifications that may affect product quality.

MAPRIMED

Eng. Ariel Plaza
General Manager

APIs: Active Pharmaceutical Ingredients.
cGMP: Current Good Manufacturing Practices.
ANMAT: Argentina Organization for Drugs, Food and Medical Technology.
INAME: National Drug Institute (Argentina).
FDA: Food and Drug Administration.
ICH: International Conference on Harmonisation.
PIC/S: Pharmaceutical Inspection Co-Operation Scheme.
TGA: Therapeutic Goods Administration.
WHO: World Health Organization.
BP: British Pharmacopoeia.
EP: European Pharmacopoeia.
USP: United States Pharmacopeia.
SySOMA: Occupational Safety and Health and Environmental

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