

# NO DISCHARGE OF PHARMACEUTICALLY ACTIVE INGREDIENTS MFR & LAB CERTIFICATION

Industrial Wastewater Control Program  
(858) 654-4100

Applicability: These instructions apply to any industry whose Industrial User Discharge Permit Attachment B, Self Monitoring and Reporting Requirements, includes "Certify no pharmaceutically active ingredients discharged - Manufacturing". To report compliance with this requirement, the following statement must be submitted, signed as required in the permit under STANDARD CONDITIONS, **Signatory Requirements**.

## Disposal

The discharge to sewer of wastes containing pharmaceutically active ingredients from laboratory experimentation or bench-scale, pilot scale, and/or full-scale manufacturing is prohibited. This includes, but is not limited to unused pharmaceuticals, expired pharmaceuticals, rejected batches or lots, pharmaceuticals received in take-back programs, etc. It does not include trace residuals in the wastewater generated during cleaning and sanitizing operations if the discharge is otherwise in compliance with permit requirements. Pharmaceutically active ingredients include any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect. For more information on the proper disposal of pharmaceutical waste please contact the County of San Diego Department of Environmental Health.

---

**Pharmaceutically Active Ingredient Manufacturing and Lab Certification:** The following statement must be signed by an authorized representative of the industry and submitted with each self monitoring report:

“Based on my inquiry of the person(s) directly responsible for managing compliance with the permit requirements, I certify that to the best of my knowledge and belief, no discharge to sewer of wastes containing pharmaceutically active ingredients from laboratory experimentation, bench-scale, pilot scale, and/or full-scale manufacturing, occurred during the monitoring period covered by this report. I am aware of the potential for significant penalties for submission of false information, including the possibility of fines and imprisonment for knowing violations. I will retain copies of all manifests and/or waste hauler receipts on-site for no less than 3 years and make them available to IWCP personnel upon request.”

PMT-  
Permit Number

ISF-  
ISMF Number

Print Name

Title

Signature  
(Attach to Industry Self-Monitoring Form)

Date