

Form OTIMM-W: Worksheet for Designing Individual Field Trials under Terramycin 343® INAD 9033

INSTRUCTIONS

1. Investigator must fill out Form OTIMM-W for each trial conducted under this INAD **before** actual use of Oxytetracycline for Immersion. The Investigator is responsible that Form OTIMM-W is completed accurately.
2. Investigator should keep the original on file, and fax a copy to the Study Monitor for review.
3. After review, the Study Monitor will fax a copy to the AADAP Office for assignment of the Study Number.
4. The AADAP Office will review the worksheet, and then fax the assigned trial Study Number to both the Investigator and Study Monitor, at which time the trial may be initiated.
5. **Note:** Both Investigator and Study Monitor should sign and date Form OTIMM-W.

SITE INFORMATION

Facility			
Address			
Investigator			
Reporting Individual (if not Investigator)			
Phone		Fax	

FISH CULTURE AND DRUG TREATMENT INFORMATION

Fish species to be treated		Disease to be treated	
Average fish weight (gm)		Average fish length (in)	
No. of fish per unit (e.g. 10,000 fish/raceway)			
Number of treated units		Number of treated fish	
Number of untreated control units		Number of control fish	
Anticipated date treatment will be initiated		Anticipated number of treatment	
Intended drug target dosage (mg/L)	20	Estimated total weight of fish treated (lbs)	
Estimated total amount of drug needed for proposed treatment (gm)		Planned duration of drug treatment (hours)	1
Drug manufacturer		Drug lot number	

STUDY DESIGN: Describe in detail the purpose of the clinical trial. Study design must be carefully focused and lend itself to rigorous evaluation. If more space is required to describe study details, title additional page(s) "Study Design" and attach them to this Worksheet.

Study designed by _____

DISPOSITION OF TREATED FISH (Human Food Safety Considerations):

_____ Estimated time (days, months) from last treatment day to first possible harvest for human consumption

Check applicable box(es):

- Study Objective A - Withdrawal period of 21 days for variety of salmonid fish.
- Study Objective B - Withdrawal period of 21 days for non-salmonid fish.
- Study Objective C - Withdrawal period of 60 days for variety of salmonid fish.
- Study Objective D - Withdrawal period of 60 days for non-salmonid fish.

- Investigator should initial here to indicate awareness that fish disposition must be in compliance with FDA-mandated withdrawal times as described in Section VI of the Study Protocol.

WORKER SAFETY CONSIDERATIONS:

- Investigator should initial here to indicate that all personnel handling drug have read Material Safety Data Sheet for Terramycin 343[®] and have been provided protective equipment, in good working condition, as described in the MSDS.

Date Prepared: _____

Investigator: _____

Date Reviewed: _____

Study Monitor: _____