

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	

Worksheet for Designing Individual Field Trials under INAD 9033

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: _____

**FORM OTIMM-1. Report on Receipt of Drug - Guide for Reporting Investigational New
Animal Drug Shipments for Poikilothermic Food Animals**

INSTRUCTIONS

1. Investigator must fill out Form OTIMM-1 **immediately** upon receipt of oxytetracycline.
2. Investigator should keep the original on file, and send one copy to the Study Monitor for review.
3. Within 10 days of receipt, the Study Monitor should send a copy to the AADAP Office.
4. **Note:** Both Investigator and Study Monitor should sign and date Form OTIMM-1.

The sponsor, U.S. Fish and Wildlife Service, submits a notice of claimed investigational exemption for the shipment or delivery of a new animal drug under the provisions of Section 512 of the Federal Food, Drug, and Cosmetics Act.

Name of Drug	Terramycin-343	INAD Number	9033
Proposed Use of Drug	Treatment of certain bacterial diseases that occur in a variety of fish species		
Date of CVM Authorization Letter	October 1, 2007		
Date of Drug Receipt		Amount of Drug Received	
Drug Lot Number		Study Worksheet Number	
Name of Investigator			
Address of Investigator			
Location of Trial			
Pivotal Study (yes/no)		Non-pivotal Study (yes/no)	
Approximate Number of Treated Animals		Approximate Number of Control Animals	
Number of Animals Used Previously¹			
Study Protocol Number	9033		
Approximate dates of trial (start/end)			
Species, Size, and Type of Animals			
Maximum daily dose and duration	20 mg/L for 1 hour		
Methods(s) of Administration	Immersion (static bath treatment 1 - 4 days)		
Withdrawal Period	21 days for 1 day treatment; 60 days for 2 - 4 day treatment		

¹ To be filled out by the NIO

Date Prepared: _____

Investigator: _____

Date Reviewed: _____

Study Monitor: _____

Date Reviewed: _____

Sponsor: _____

Form OTIMM-3: Results Report Form for use of Terramycin 343® under INAD 9033

INSTRUCTIONS

- Investigator must fill out Form OTIMM-3 no later than 10 days after completion of the 30-day post-treatment observation period. Study Number must be recorded on all pages of Form OTIMM-3. Attach lab reports and other information.
- If Terramycin 343® was not used under the assigned Study Number, fill out only the Site Information portion on this page, and skip to the end of page 4 and fill out only the "Negative Report" section.
- Investigator should keep the original on file, and send a copy to the Study Monitor. Within 10 days of receipt, the Study Monitor should send a copy to the AADAP Office for inclusion in the permanent file.
- Note:** Both Investigator and Study Monitor should sign and date Form OTIMM-3.

SITE INFORMATION

Facility	
Reporting Individual	

TREATMENT INFORMATION AND SCHEDULE

Drug lot number		Total amount drug used (gm)	
Fish species treated		OTIMM dosage used (mg/L)	20
Duration of drug treatment (hours)	1	Number of treatments	
Disease treated		Disease diagnosed by	
Average fish weight (gm)		Average fish length (in)	
Number of fish per unit (e.g. 10,000 fish/raceway)			
Number of treated units		Total number of treated fish	
Number of control units		Total number of control fish	
Treatment date(s)			

WATER QUALITY PARAMETERS

Ave pre-treatment temp (°F)		Dissolved Oxygen (mg/L)	
Ave treatment temp (°F)		pH	
Ave post-treatment temp (°F)		Hardness - CaCO ₃ (mg/L)	

Daily Mortality Record

INSTRUCTIONS

1. Investigator should fill out the Daily Mortality Record as completely as possible.
2. Prior to initiation of the trial, fill out Rearing Unit ID, whether a rearing unit is Treated or Control, and the number of fish in each rearing unit.
3. Water temperature and individual tank mortality should be recorded on a daily basis.
4. Please mark all treatment days with an asterisk.
5. Use additional copies of this form if more than 6 rearing units are involved in the trial.

FACILITY										
	Rearing Unit ID									
	<u>T</u> reated or <u>C</u> ontrol									
	Number of Fish									
	Day	Date	Water Temp (F°)	Mortality						
Pre-treatment period	1									
	2									
	3									
	4									
	5									
Treatment period	1									
	2									
	3									
	4									
Post-treatment period	1									
	2									
	3									
	4									
	5									
	6									
	7									
	8									
	9									
	10									

RESULTS: Describe in detail treatment results. Was treatment successful? If treatment did not appear to be successful, explain why not? Were there any mitigating environmental conditions that may have impacted treatment results? Were there any deviations from the Study Protocol?

Pathology Report: Attach pathology report to this form. Report should include: 1) a description of how the pathogen(s) was identified; 2) disease identification records that confirm the presence of the pathogen; and 3) the name and title of the individual performing the diagnosis.

Pathology Report included: pre-treatment post-treatment

Toxicity observations: Report any apparent drug toxicity including a description of unusual fish behavior.

DRUG DISCHARGE RESULTING FROM THIS TREATMENT: Use Addendum 2: Discharge Worksheet for calculations and attach completed Discharge Worksheet to this form. Enter the value from Addendum 2 step 3 in this space.

OBSERVED WITHDRAWAL PERIOD: (Investigator should initial the appropriate box below)

Observed withdrawal period: _____ 21 days; Objectives A & B

Observed withdrawal period: _____ 60 days; Objectives C & D

Estimated number of days between last treatment and first availability of fish for human consumption (ensure this time period meets the withdrawal period). _____

NEGATIVE REPORT Oxytetracycline for Immersion was not used at this facility under this Study Number during the reporting period. (Investigator should initial for negative reports as soon as the Study Number is known to be no longer needed or valid.)

Date Prepared: _____ Investigator: _____

Date Reviewed: _____ Study Monitor: _____

