

**Form OTCS-W: Worksheet for Designing Individual Field Trials under INAD 8069
(Terramycin®200 for Fish for treatment of bacterial diseases of marine penaeid shrimp)**

INSTRUCTIONS

1. Investigator must fill out Form OTCS-W for each trial conducted under this INAD **before** actual use of Terramycin®200 for Fish (T200) medicated feed. The Investigator is responsible that Form OTCS-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 OTCS-W.

SITE INFORMATION

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

SHRIMP CULTURE AND DRUG TREATMENT INFORMATION

Shrimp species to be treated		Disease to be treated	
Average shrimp weight (gm)		Average fish length (in)	
Approximate number of shrimp per unit (e.g. 10,000 shrimp/raceway)			
Number of treated units		Approximate number of treated shrimp	
Number of untreated control units		Approximate number of control shrimp	
Estimated total weight of shrimp to be treated (lbs)		Approximate % body weight to be fed	
Planned % T200 pre-mix (e.g. 2, 4, 6%) in feed (see feed company order sheet)		Intended oxytetracycline (OTC) dosage (gm/kg feed)	
Planned duration of drug treatment (days)		Estimated total amount of medicated feed needed for proposed treatment (lbs)	
Anticipated date treatment will be initiated			
Medicated feed manufacturer		Medicated feed lot number	

STUDY DESIGN: Describe in detail the purpose of the clinical trial. For example you might compare OTC dosage, number of fish per unit, or disease to be treated. 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 SHRIMP (Human Food Safety Considerations):

Investigator should initial here to indicate awareness that shrimp disposition must be in compliance with FDA-mandated 2-day withdrawal period 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® 200 for Fish and have been provided protective equipment, in good working condition, as described in the MSDS.

Date Prepared: _____ **Investigator:** _____

Date Reviewed: _____ **Study Monitor:** _____

FORM OTCS-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 OTG1 **immediately** upon receipt of Terramycin® 200 for Fish premix or medicated feed.
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 OTCS-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® 200 for Fish	INAD Number	8069
Proposed Use of Drug	Treatment of certain bacterial diseases that occur in marine penaeid shrimp		
Date of CVM Authorization Letter	August 15, 2003		
Date of Drug Receipt		Amount of Drug Received	
Drug Lot Number		Trial Number	
Name of Investigator			
Address of Investigator			
Location of Trial			
Pivotal Study	no	Non-pivotal Study	yes
Approximate Number of Treated Animals		Approximate Number of Control Animals	
Number of Animals Used Previously¹			
Study Protocol Date	September 2010		
Approximate dates of trial (start/end)			
Species, Size, and Type of Animals			
Daily dose and duration	4.5 g oxytetracycline per kg feed, fed to satiation for 14 days		
Methods(s) of Administration	Medicated-feed		
Withdrawal Period	2 days		

¹ To be filled out by the AADAP Office

Date Prepared: _____ **Investigator:** _____

Date Reviewed: _____ **Study Monitor:** _____

Date Reviewed: _____ **Sponsor:** _____

Form OTCS-3: Results Report Form for use of Terramycin® 200 for Fish under INAD 8069 (marine penaeid shrimp)

INSTRUCTIONS

1. Investigator must fill out Form OTCS-3 no later than 10 days after completion of the 20-day post-treatment observation period. Study Number must be recorded on all pages of Form OTCS-3. Attach lab reports and other information.
2. If Terramycin® 200 for Fish (T200) medicated feed 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.
3. 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.
4. **Note:** Both Investigator and Study Monitor should sign and date Form OTCS-3.

SITE INFORMATION

Facility	
Reporting Individual	

TREATMENT INFORMATION AND SCHEDULE

Lot number of T200 medicated feed or premix		Total amount T200 medicated feed used (lbs)	
Shrimp species treated		Daily percent body-weight fed	
Planned % T200 pre-mix (e.g. 2, 4, 6%) in feed		Oxytetracycline (OTC) dosage (g/kg feed)	4.5
Purpose of T200 treatment	Control certain bacterial diseases of penaeid shrimp	Disease diagnosed by	
Average shrimp weight (g)		Number of shrimp per unit (e.g., 10,000 shrimp per raceway)	
Number of treated units		Total number of treated shrimp	
Number of control units		Total number of control shrimp	
Date treatment started		Date treatment ended	

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, indicate 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. Enter daily mortality data for the treatment regimen, i.e., the pretreatment, treatment and posttreatment periods.
5. Use additional copies of this form if more than 6 rearing units are involved in the trial.

FACILITY										
X	Rearing Unit ID									
	Treated or Control									
	Number of Fish									
	Day	Date	Water Temp (F°)	Mortality						
Pre-treatment	1									
	2									
	3									
	4									
	5									
Treatment	1									
	2									
	3									
	4									
	5									
	6									
	7									
	8									
	9									
	10									
	11									
	12									
	13									
	14									

Post-treatment	1																		
	2																		
	3																		
	4																		
	5																		
	6																		
	7																		
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RESULTS: Describe in detail treatment results. Was treatment successful? If treatment did not appear to be successful, explain why not? Was mortality considered “normal” during the treatment and posttreatment periods? If unanticipated mortality was observed, explain possible cause(s). 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 shrimp 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:

Was the 2 day withdrawal period observed? yes no

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 T200 medicated feed 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:** _____

ADDENDUM 2 - Discharge Worksheet – Oxytetracycline/Shrimp

Instructions: Use this Worksheet to calculate estimates of 1) the *maximum* amount of oxytetracycline (OTC) to be fed each day during treatment of the shrimp at your facility, and 2) the resulting maximum estimated daily concentration of oxytetracycline in your total hatchery wastewater discharge.

Handy conversion factors: 1 part per million (ppm) = 0.0283 grams per ft³
 1 part per million (ppm) = 0.0038 grams/gallon

Calculations:

Step 1 - Calculate the total volume of treated and untreated water:

1a	Number of rearing units in this study (treated & control)	
1b	Total water volume passing through all treated units during 24 hours (gallons or ft ³ of <u>treated</u> flow)	
1c	Total water volume passing through all untreated (control) units during 24 hours (gallons or ft ³ of <u>untreated</u> flow)	
1d	Grand total hatchery discharge (<u>treated</u> + <u>untreated</u>) during 24 hours (gallons or ft ³ of flow)	

Step 2 Calculate the daily amount of OTC fed each day (24 hours) in this trial:

OTC fed (g) = medicated feed fed per day (kg) x concentration of OTC in medicated feed (g/kg)

= _____ kg x _____^{4.5} g OTC per kg of feed

OTC fed (g) = _____ g of OTC

Step 3 Calculate OTC level resulting in hatchery discharge during treatment period:

Maximum estimated daily OTC discharge (ppm) = daily OTC fed (from Step 2) ÷ daily hatchery discharge (from Step 1) ÷ Conversion factor for either grams per gallon or grams per ft³ to ppm

= _____ ÷ _____ ÷ _____

Maximum estimated daily OTC discharge = _____ ppm