

Form OTC-3b: Results Report Form for use of Terramycin® 200 for Fish under INAD 9332- All therapeutic use excluding salmonids with coldwater disease and *Oncorhynchus mykiss* with columnaris treated at 3.75g/100 lb fish/day

INSTRUCTIONS

1. Investigator must fill out Form OTC-3b 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 OTC-3b. Attach lab reports and other information.
2. If Oxytetracycline 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 OTC-3b.

SITE INFORMATION

Facility	
Reporting Individual	

TREATMENT INFORMATION AND SCHEDULE

OTC-Feed lot number		Total amount OTC-Feed used (lbs)	
Fish species treated		Daily percent body-weight fed	
Planned % TM pre-mix (e.g. 2, 4, 6%) in feed		OTC dosage (gm/100lb fish/day)	
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	
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, 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 treatment period mortality only for days which fish were treated. For example, if fish were treated for ten days enter mortality for treatment days 1 - 10 and then proceed directly to post-treatment day 1 and leave days 11 - 14 of the treatment period blank.
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	Mortality	Mortality	Mortality	Mortality	Mortality	Daily Observer Initials
Pre-treatment	1									
	2									
	3									
	4									
	5									
Treatment	1									
	2									
	3									
	4									
	5									
	6									
	7									
	8									
	9									
	10									
	11									
	12									

FACILITY										
	Rearing Unit ID									
	Treated or Control									
	Number of Fish									
	Day	Date	Water Temp (F°)	Mortality	Mortality	Mortality	Mortality	Mortality	Mortality	Daily Observer Initials
	13									
	14									
Post-treatment	1									
	2									
	3									
	4									
	5									
	6									
	7									
	8									
	9									
	10									
	11									
	12									
	13									
	14									
	15									
	16									
	17									
18										
19										
20										

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:

Observed withdrawal period: _____ 21 days _____ 35 days _____ 40 days _____ 70 days

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 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:** _____