

Form MT-3: Results Report Form for Clinical Field Trials Using MT Medicated Feed Under INAD 11-236

INSTRUCTIONS

- Investigator must fill out Form MT-3 no later than 10 days after completion of treatment. Study Number must be recorded on all pages of Form MT-3. Attach lab reports and other information.
- If MT 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 2 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 MT-3.

SITE INFORMATION

Facility	Tilapia Farm A
Reporting Individual	John Doe

FISH CULTURE AND DRUG TREATMENT INFORMATION

MT medicated feed batch number	R-82A-143-2008	MT medicated feed manufacture date	5/22/08
Treatment dosage	9 mg/kg bw/day	Treatment duration	28 days
Fish species treated	California Mossambica	Total number of fish treated	359,411
Number of rearing units treated	18	Number of fish per treated rearing unit	34,000 - 86,000
ID of all treated rearing units (e.g. Tank 5, Pond 6B)		1 - 18	
Number of control units	0	Number of fish per control unit	0
Fish age (days post-hatch)	2	Average fish length (mm)	5
Treatment date (initiated)	8/1/08	Treatment date (completed)	9/23/08
Sample collection ¹ (yes/no)	no	Sample collection date	
Number of fish remaining at the completion of the treatment period (i.e. number of fish treated minus treatment period mortality)			199,906

¹ Sample of 60 fish collected for determination of sex ratio and sent to AADAP Office for histological evaluation

WATER QUALITY PARAMETERS

Mean Treatment Temperature (°F)	78.8	Mean Dissolved Oxygen (mg/L)	6.5
Mean pH	8.2	Mean Hardness - CaCO ₃ (mg/L)	200

RESULTS: Describe in brief detail treatment results. Did treatment go as planned? Did all fish readily consume MT medicated feed? Was any unusual fish behavior or unexpected mortality associated with the treatment?? 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?

Treatment went as planned. All medicated feed was consumed and there was no deviations from the study protocol. Note: there was a period of cold weather during the treatment which caused some mortality.

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

No toxicity/adverse effects were observed.

OBSERVED WITHDRAWAL PERIOD OF TREATED FISH:

Observed withdrawal period for BATCH CULTURE: jd **120 days** (Investigator should initial)

Observed withdrawal period for PARTIAL HARVEST/RESTOCK CULTURE: _____ **350 g fish weight** (Investigator should initial)

Estimated number of days between last treatment and first availability of fish for human consumption (ensure this time period meets the withdrawal period). 240 days

DISPOSITION OF MT MEDICATED FEED

jd

 Use and disposition of all MT medicated feed followed Study Protocol guidelines and has been clearly identified on Form MT-2 (Investigator should initial)

_____ **NEGATIVE REPORT** MT 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: 9/5/08 **Investigator:** John Doe

Date Reviewed: 9/5/08 **Study Monitor:** Joe Brown