

Form H₂O₂-W: Worksheet for Designing Individual Field Trials Under 35% PEROX-AID[®] INAD 11-669

INSTRUCTIONS

- Investigator must fill out Form H₂O₂-W for each trial conducted under this INAD **before** actual use of hydrogen peroxide (35% PEROX-AID[®]). The Investigator is responsible for accurate completion of Form H₂O₂-W.
- Investigator should keep the original on file, and fax a copy to the Study Monitor for review.
- After review, the Study Monitor will fax a copy to the AADAP Office for assignment of the Study Number.
- 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.
- Note:** Both Investigator and Study Monitor should sign and date Form H₂O₂-W.

SITE INFORMATION

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

FISH CULTURE AND DRUG TREATMENT INFORMATION

Pathogen type	Ectoparasite		
Study Objective A or B (circle one)	Objective A Freshwater fish species	Objective B Marine fish species	
Fish species to be treated	Ectoparasite to be treated		
Average fish weight (gm)	Average fish length (in)		
Number of fish per rearing unit (i.e., tank, raceway, or pond)	Number of rearing units to be treated		
Total number of fish to be treated	Number of control rearing units/number of control fish	/	
Intended hydrogen peroxide (35% PEROX-AID [®]) dosage (mg/L)	Planned duration of treatment (minutes)		
Planned number of treatments	Treatment on consecutive or alternate		
Estimated amount of 35% PEROX-AID needed for treatment (L)			
Anticipated date treatment will be initiated			

STUDY DESIGN: Describe in detail the purpose of the clinical field 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):

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

USE AND DISPOSITION OF HYDROGEN PEROXIDE (35% PEROX-AID®) (Environmental Safety Considerations):

Investigator should initial here to indicate awareness that hydrogen peroxide (35% PEROX-AID®) usage and disposition must be in compliance with requirements described in the Study Protocol.

WORKER SAFETY CONSIDERATIONS:

Investigator should initial here to indicate that all personnel handling hydrogen peroxide (35% PEROX-AID®) have read the Material Safety Data Sheet for hydrogen peroxide (35% PEROX-AID®) and have been provided personal protective equipment, in good working condition, as described in the Study Protocol.

Date Prepared: _____

Investigator: _____

Date Reviewed: _____

Study Monitor: _____

FORM H₂O₂-1. Report on Receipt of Drug - Guide for Reporting Investigational New Animal Drug Shipments for Poikilothermic Food Animals

INSTRUCTIONS

1. Investigator must fill out Form H₂O₂-1 **immediately** upon receipt of hydrogen peroxide (35% PEROX-AID®).
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 H₂O₂-1.

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. The following information is submitted in triplicate:

Name of Drug	Hydrogen peroxide (35% PEROX-AID®)	INAD Number	11-669
Proposed Use of Drug	Treatment of ectoparasites that occur in a variety of freshwater and marine finfish		
Date of CVM Authorization Letter	December 19, 2007		
Date of Drug Receipt		Amount of Drug Received	
Drug Lot Number		Trial Number	
Name of Investigator			
Address of Investigator			
Location of Trial			
Pivotal Study	Yes	Non-pivotal Study	----
Approximate Number of Treated Animals		Approximate Number of Control Animals	
Number of Animals Used Previously¹			
Study Protocol Number	11-669		
Approximate dates of trial (start/end)			
Species, Size, and Type of Animals			
Maximum daily dose and duration	200 mg/L for 30 minutes; 100 mg/L for 60 minutes		
Methods(s) of Administration	Immersion (static or flow-through treatment)		
Withdrawal Period	0-day; all species		

¹ To be filled out by the AADAP Office

Date Prepared: _____

Investigator: _____

Date Reviewed: _____

Study Monitor: _____

Date Reviewed: _____

Sponsor: _____

Form H₂O₂-3: Results Report Form for Use of 35% PEROX-AID[®] Under INAD 11-669

INSTRUCTIONS

1. Investigator must fill out Form H₂O₂-3 no later than 10 days after completion of the trial. Study Number must be recorded on all pages of Form H₂O₂-3. Attach lab reports and other information.
2. If 35% PEROX-AID[®] 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 3 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 H₂O₂-3.

SITE INFORMATION

Facility	
Reporting Individual	

FISH CULTURE AND DRUG TREATMENT INFORMATION

35% PEROX-AID [®] lot number		Total amount of drug used (L)	
Study Objective A or B (circle one)		Objective A Freshwater fish species	Objective B Marine fish species
Fish species treated		Ectoparasite treated	
Average fish weight (gm)		Average fish length (in)	
Number of fish per rearing unit (i.e., tank, raceway, or pond)		Number of treated rearing units	
Total number of fish treated		Number of control rearing units/number of control fish	/
35% PEROX-AID [®] dosage used (mg/L)		Treatment duration (minutes)	
Number of treatments		Treatment on alternate or consecutive days	
Treatment date(s)			

WATER QUALITY PARAMETERS

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

Daily Mortality Record

INSTRUCTIONS

1. Investigator must 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. If treatment is on 3 consecutive days, fill in only days 1-3 of the "treatment period" and proceed directly to day 1 of the "post-treatment period". If treatment is on 3 alternate days, fill in days 1-5 of the "treatment period" and proceed to day 1 of the "post-treatment period". If less than 3 treatments are used, proceed directly to day 1 of the "post-treatment period" after the final treatment. 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									
	Treated or Control									
	Number of Fish									
	Day	Date	Water Temp (F°)	Mortality	Mortality	Mortality	Mortality	Mortality	Mortality	Daily Observer Initials
Pre-treatment Period	1									
	2									
	3									
	4									
	5									
Treatment Period	1									
	2									
	3									
	4									
	5									
Post-treatment Period	1									
	2									
	3									
	4									
	5									
	6									
	7									
	8									
	9									
	10									

Daily Mortality Record (Supplemental Post-treatment Period Data)

INSTRUCTIONS

1. Investigator should fill out the Daily Mortality Record (Supplemental Post-treatment Period Data) **only** if data is collected for more than 10 days post-treatment.
2. Use additional copies of this form if more than 6 rearing units are involved in the trial.

FACILITY										
	Rearing Unit ID									
	Treated or Control									
	Number of Fish									
	Day	Date	Water Temp (F ^o)	Mortality	Mortality	Mortality	Mortality	Mortality	Mortality	Daily Observer Initials
Post-treatment	11									
	12									
	13									
	14									
	15									
	16									
	17									
	18									
	19									
	20									
	21									
	22									
	23									
	24									
	25									
	26									
	27									
	28									

RESULTS: Describe in detail treatment results. Was treatment successful? If treatment did not appear to be successful, explain why not? Describe general fish behavior, including feeding behavior. 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.

OBSERVED WITHDRAWAL PERIOD OF TREATED FISH

Investigator should initial here to indicated awareness that fish disposition must be in compliance with FDA-mandated withdrawal times as described in Study Protocol Section XV

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

DISPOSITION OF HYDROGEN PEROXIDE (35% PEROX-AID[®])

Use and disposition of all hydrogen peroxide (35% PEROX-AID[®]) followed Study Protocol guidelines and has been clearly identified on Form H₂O₂-2 (Investigator should initial)

NEGATIVE REPORT: Hydrogen peroxide (35% PEROX-AID[®]) 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: _____