

Form AQSE-W: Worksheet for Designing Individual Field Trials under AQUI-S® 20E INAD 11-741

INSTRUCTIONS

1. Investigator must fill out Form AQSE-W for each trial conducted under this INAD **before** actual use of AQUI-S® 20E. The Investigator is responsible that Form AQSE-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 AQSE-W.

SITE INFORMATION

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

FISH CULTURE AND DRUG TREATMENT INFORMATION

Fish species			
Number of treated fish			
Average fish weight (gm)		Average fish length (in)	
Estimated total weight of fish treated (lbs)			
Intended level of anesthesia (Handleable - H ; Anesthetized - AN ; Euthanized - E)			
Intended dosage (mg/L eugenol)		Planned duration of treatment (minutes)	
Estimated total amount of AQUI-S® 20E needed for proposed treatment (ml)			
Anticipated date treatment will be initiated			
AQUI-S® 20E manufacturer	AQUI-S New Zealand, Ltd.	AQUI-S® 20E lot number	

STUDY DESIGN: Describe in detail the purpose of the clinical trial, the number of experimental animals, treatment dosage, anticipated treatment duration, and primary response variable(s) (e.g. time to anesthesia, level of anesthesia, time to recovery, etc.). 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

Note: Euthanized fish must not be sent to slaughter or be otherwise available for food.

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.

WORKER SAFETY CONSIDERATIONS:

Investigator should initial here to indicate that all personnel handling the drug have read the Material Safety Data Sheet for AQUI-S® 20E and have been provided protective equipment, in good working condition, as described in the MSDS.

Date Prepared: _____ Investigator: _____

Date Reviewed: _____ Study Monitor: _____

FORM AQSE-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 AQSE-1 **immediately** upon receipt of AQUI-S®20E.
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 AQSE-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	AQUI-S® 20E	INAD Number	11-741
Proposed Use of Drug	Sedation/anesthesia in a variety of fish species		
Date of CVM Authorization Letter	June 28, 2012		
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 Previously ¹			
Study Protocol Number	11-741		
Approximate dates of trial (start/end)			
Species, Size, and Type of Animals			
Maximum daily dose and duration	100 mg/L eugenol for 15 minutes		
Methods(s) of Administration	Immersion		
Withdrawal Period	Hatchery use = 72 hours; Field-based use = no withdrawal (immediate release) <u>Note:</u> Euthanized fish must not be sent to slaughter or be otherwise available for food		

¹ To be filled out by the AADAP Office

Date Prepared: _____ Investigator: _____

Date Reviewed: _____ Study Monitor: _____

Date Reviewed: _____ Sponsor: _____

Form AQSE-3: Results Report Form for AQUI-S® 20E Use under INAD 11-741

INSTRUCTIONS

1. Investigator must fill out Form AQSE-3 no later than 10 days after completion of the trial. Study Number must be recorded on all pages of Form AQSE-3. Attach lab reports and other information.
2. If AQUI-S® 20E 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 AQSE-3.

SITE INFORMATION

Facility	
Reporting Individual	

FISH CULTURE AND DRUG TREATMENT INFORMATION

AQUI-S® 20E lot number		Total amount of AQUI-S® 20E used in treatments (ml)	
Fish species treated		Dosage used (mg/L eugenol)	
Average fish weight (gm)		Average fish length (in)	
Total number of treated fish		Approximate fish age (fingerling/juvenile/adult)	
Treatment bath vol. (gal)		Number of fish/bath	
Treatment duration (minutes)		Treatment date(s)	

WATER QUALITY PARAMETERS

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

Anesthesia Record - Version 1

INSTRUCTIONS

1. Investigator should fill out the Anesthesia Record as completely as possible.
2. Enter the number of fish in the treatment tank at one time. Dependent upon the size of the tank, fish size, etc., this number could vary from 1 to 20 or possibly even higher.
3. Level of anesthesia desired may vary. Use "H" for handleable, "AN" for anesthetized, and "E" for euthanized as described in the Study Protocol. If other measurements or parameters are used to determine level of desired anesthesia, describe anesthesia level in detail on a separate sheet of paper and attach to Form AQSE-3.
4. Use additional copies of this form if more than 20 individual treatments are involved in the trial.

Date	Treatment Number	Species	Fish per Treatment	Level of Anesthesia (H; AN; or E)	Aqui-S® 20E Dose (mg/L)	Time to Anesthesia (min)	Time to Recovery (min)	Observer Initials
	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 (e.g., fish were sedated and recovered within desired time periods; there were no mortalities; treatment-associated stress appeared minimal/normal; etc.)? 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? Attach any supplemental reports.

TOXICITY OBSERVATIONS: Report any apparent drug toxicity including a description of unusual fish behavior.

DRUG DISCHARGE RESULTING FROM THIS TREATMENT: If AQUI-S® 20E was discharged to ground, simply write "Ground Discharge" below. If AQUI-S® 20E was discharged to facility effluent, calculate approximate eugenol concentration (mg/L) in effluent.

OBSERVED WITHDRAWAL PERIOD OF TREATED FISH:

Observed withdrawal period: _____ 72 hours

_____ No withdrawal (immediate release; field use only)

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

Note: Euthanized fish must not be sent to slaughter or be otherwise available for food.

_____ **NEGATIVE REPORT** AQUI-S® 20E 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:** _____