

Form CALC-W: Worksheet for Designing Individual Field Under SE-MARK® INAD 10-987

INSTRUCTIONS

1. Investigator must fill out Form CALC-W for each trial conducted under this INAD **before** actual use of SE-MARK® for marking. The Investigator is responsible that Form CALC-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 CALC-W.

SITE INFORMATION

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

FISH CULTURE AND DRUG TREATMENT INFORMATION

Fish species to be treated		Number of fish to be treated	
Average fish weight (gm)		Average fish length (in)	
Volume of treatment tank/ container (gal)		Number of fish per treatment tank/container	
Planned duration of drug treatment (e.g. min or hr)		Intended drug dosage (mg/L)	
Salt pre-treatment (yes or no)		% salt solution and duration of treatment (min)	
Anticipated date treatment will be initiated			
Estimated total weight of fish treated (lbs)		Estimated total amount of drug needed for proposed treatment (ml)	
Drug manufacturer	Western Chemical	Drug lot number	

STUDY DESIGN: Describe in detail the purpose of the clinical 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.

DISPOSITION OF MARKING SOLUTION (Environmental Safety Considerations):

Marking solution will be stored on-site in a secure, leak-proof container that clearly identifies container contents (Investigator should initial).

Marking solution will be disposed of by shipment to Emerald Services, Inc., 1825 Alexander Avenue, Tacoma, WA 98451 according to procedures detailed in general Waste-stream Profile #216200B (Investigator should initial).

WORKER SAFETY CONSIDERATIONS:

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

Date Prepared: _____ **Investigator:** _____

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