

Effectiveness of AQUI-S[®] to Sedate Freshwater Finfish



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Efficacy Studies

- AQUI-S® only available under INAD 10-541
- FDA/CVM required a mountain of data to demonstrate efficacy



- AADAP has completed
 - 11 Pivotal Field Efficacy Studies on a variety of cold-, cool-, and warmwater fish species

Pivotal Efficacy Studies



All pivotal studies conducted to satisfy FDA guidelines under an approved research study protocol and in accordance to Good Clinical Practices (GD #85)



Experimental Design



 **Blinding**

 **Completely randomized design**

 **Dose-verification of AQUI-S[®] concentrations**

 **For each species of fish:**

15 individual fish per concentration

Two life-stages tested 2 different water temperatures

 **Data collected:**

Time to handleable

Time to recover from the handleable stage

Behavior during and after sedation

Temperature, dissolved oxygen, and pH



Finfish Species

Salmonids (coldwater): **3 different species**

Pivotal - Rainbow trout, Chinook salmon, & Kokanee salmon

Coolwater: **4 different species**

Pivotal - Walleye, Largemouth bass, Smallmouth bass, & Pallid sturgeon

Warmwater: **4 different species**

Pivotal - Channel catfish, Tilapia, Hybrid striped bass, & June suckers



Why So Many Studies ?

 **New Product**

 **Limited Data**

 **Comfort Factor**



Efficacy Section Complete

All efficacy studies for AQUI-S® to support an all freshwater finfish claim have been completed.



Coldwater Fish (Salmonids)

Times to Handleable and Recovery
Temperature range – 8 to 15°C



| Target Dose (mg/L) | Approximate median time to Handleable | Approximate median time to Recover |
|-------------------------------|--|---|
| 20 | 10 minutes (range, 2.5 – 30 min) | 4.0 minutes (range, 1 – 9 min) |
| 40 | 3.0 minutes (range, 1 – 6 min) | 4.0 minutes (range, 2 – 7 min) |
| 60 | 2.0 minutes (range, 1 – 3 min) | 4.0 minutes (range, 1.5 – 7 min) |

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| 60 | 2.0 minutes (range, 1 – 3 min) | 4.0 minutes (range, 1.5 – 7 min) |

Coolwater Fish

Times to Handleable and Recovery
Temperature range – 12 to 22°C



| Target Dose (mg/L) | Approximate median time to Handleable | Approximate median time to Recover |
|-------------------------------|--|---|
| 20 | 6.1 minutes (range, 4.0 – 16.5 min) | 3.9 minutes (range, 2.0 – 6.0 min) |
| 40 | 2.8 minutes (range, 1.6 – 5.7 min) | 4.8 minutes (range, 2.7 – 7.6 min) |
| 60 | 2.3 minutes (range, 1.0 – 3.2 min) | 5.3 minutes (range, 2.6 – 8.5 min) |

Warmwater Fish

Times to Handleable and Recovery
Temperature range – 20 to 32°C



| Target Dose (mg/L) | Approximate median time to Handleable | Approximate median time to Recover |
|-------------------------------|--|---|
| 40 | 4.1 minutes (range, 2.1 – 6.7 min) | 2.2 minutes (range, 1.0 – 10.4 min) |
| 60 | 2.4 minutes (range, 1.5 – 3.5 min) | 2.8 minutes (range, 0.9 – 9.4 min) |

SUMMARY

- Fish recover faster in warmer temperatures than in colder temperatures
- Times are slower than MS-222
- 40 mg/L AQUI-S[®] to be highest concentration on label for salmonids
- 60 mg/L AQUI-S[®] to be highest concentration on label for cool- and warmwater fish



Ideal Anesthetic ?

1. Induction time of <15 min (preferably <3 min)
2. Short recovery time (≤ 5 min)
3. Nontoxic to fish and has a large safety factor
4. Inexpensive
5. No persistent effects on fish physiology and behavior
6. Engenders no cumulative effects or problems from repeated exposures
7. Easy to handle and not harmful to humans during normal use
8. Rapidly excreted or metabolized, leaving no residues and requiring no withdrawal time



(Summerfelt and Smith 1990)

SUMMARY

- All safety and efficacy testing completed for the following claim:
“To sedate all freshwater finfish to the handleable stage of anesthesia for handling and management purposes”
- Progress is being made to gain FDA-approval of AQUI-S®
- Initial label claim will most likely be for all freshwater-reared salmonids
- Initial approval still a few years out



Questions ?



Aquatic Animal Drug Approval Partnership (AADAP) Program
www.fws.gov/fisheries/aadap