

Transdermal Delivery of Drugs in Cats Using a Compounded Lecithin Organic Gel Matrix

Auburn University /Winn Foundation/American Association of Feline Practitioners

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Web Site:

http://www.vetmed.auburn.edu/index.pl/transdermal_gel_study_-_clinical_pharmacology

VETERINARIAN CHECK LIST

- 1) Download the following from the website (or call the lab for a faxed copy):
 - a) Client Information Brochure
 - b) Client Informed Consent (CIC; 2 copies, one for client and one for sample submission)
 - c) Submission form (only if you do NOT want to submit the form electronically)

- 2) Discuss study with client and obtain signed Client Informed Consent
 - a) Suggestion: focus on therapeutic drug monitoring aspects of study
 - b) Have client sign CIC prior to participation (client keeps one copy)
 - i) Enter on the CIC the cat's name, the drug and check the appropriate route of drug delivery
 - ii) Give one copy to client
 - iii) Hold second copy to submit with samples
 - iv) The Informed Consent needs to be signed only 1 time per client
 - c) Discuss drug administration
 - i) Assure amount and method of administration is clear
 - ii) Discuss clinical signs indicative of response or failure
 - d) Set up appointment for 7 day collection (earlier days acceptable as well)

- 3) Sample Collection (days 7 and 30 [or just before drug is discontinued, whichever is earliest])
 - a) Assess patient response to therapy at time of sample collection
 - i) include assessment on the Submission Form
 - b) Collect at least 3 ml blood sample 2 and 12 hr after drug was administered
 - i) Plasma or serum okay
 - (1) Do NOT use serum separator tubes (gel binds the drug)
 - ii) Spin sample down and transfer plasma or serum to separate tube for freezing & shipping
 - (1) Label tube with name and date
 - (2) Freeze until ready to ship
 - c) An alternative sequence of collection is:
 - i) Have the client bring the cat in before a dose
 - (1) Collected the 12 hr trough just before the dose
 - (2) Dose the cat
 - (3) Collect a 2 hr peak 2 hr after the dose
 - ii) Make sure the Submission Form indicates the timing of each collection and dose

- 4) Collect a small (0.25 to 0.5 ml) aliquot of the compounded preparation (a sample of the finished dosing form from control animals is not necessary but will be accepted if provided).
 - i) The sample **must** be kept airtight once collected.
 - (1) **Microcentrifuge tubes for collection of drug sample can be obtained at no charge by calling the Clinical Pharmacology Laboratory**
 - (2) Small red top tubes also will suffice.
 - (a) Place the aliquot in the glass, not in the top.
 - (b) Secure the cap tightly
 - ii) Label with name and date (should match blood samples)

- iii) Freeze with the blood samples
- 5) Set up an appointment with the client for the next sample collection if indicated
 - a) Note that samples can be collected earlier, between and after the 7 and 30 day sampling time delineated above. Follow the same procedure.
- 6) Electronically submit sample information at website
 - a) Record unique identifier on informed consent
 - b) Record unique identifier on all three samples
 - c) Each sampling day requires a new Submission Form (but not a new CIC)
- 7) An alternative submission process:
 - a) Download the submission form from the website
 - i) A unique identifier will not be provided unless you call the laboratory and ask for one
 - (1) The unique identifier is not necessary unless you want to submit samples in confidence (ie, you and your client are not identifiable by study investigators)
 - ii) Include the submission form with the sample. Each sampling day requires a new submission form.
- 8) Send samples
 - a) Send the following:
 - i) Two blood samples per sampling day
 - ii) One compounded drug sample per sampling day (day 7 and day 30)
 - iii) The Client Informed Consent (one per patient, regardless of sample numbers)
 - iv) IF NOT SUBMITTING ELECTRONICALLY, the downloaded and completed submission form should be included
 - b) Method of shipment: **MUST BE THROUGH DHL IF THE STUDY IS TO PAY**
 - i) Make sure sample is protected from crushing damage
 - ii) Samples can be submitted via overnight service
 - (1) The study can afford to pay for overnight shipping only if 4 samples or more are simultaneously sent. This might be 4 samples on the same patient, or two samples from two different patients. (Note that any shipping that is not charged to our study will be greatly appreciated and will provide some “wobble-room” for other samples
 - (i) Shipping must be through DHL (previously Airborne)
 - (ii) Include on the airbill:
 - 1. Account number: 135704650
 - 2. The weight of the package must be less than 3 lbs
 - 3. You **MUST** indicated the weight (1 lb is recommended)
 - 4. Do **NOT** select (10:30) morning delivery. Noon or 3 pm express deliver should be selected.
 - (iii) Call DHL for pickup (800-CALLDHL)
 - (2) **Prefilled out airbills can be obtained by calling the Clinical Pharmacology Laboratory and requesting as such. However DHL will bring a blank airbill when they come to pickup.**
 - iii) Alternatively, if you use our laboratory for Therapeutic Drug Monitoring, send the samples with those samples.
- 9) Upon receipt of results from our laboratory, discuss results with client.
 - i) You are welcome to discuss results with the study investigator as well.