

Cross Contamination in Control Animals

... a GLP Issue?

But a problem keeping busy
receiving authorities and GLP people

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COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS
(CPMP)

DRAFT

GUIDELINE ON THE EVALUATION OF CONTROL SAMPLES FOR
TOXICOKINETIC PARAMETERS IN TOXICOLOGY STUDIES:
CHECKING FOR CONTAMINATION WITH THE TEST SUBSTANCE

DISCUSSION IN THE SAFETY WORKING PARTY

October 2002–
February 2004

TRANSMISSION TO CPMP

March 2004

Cross Contamination in Control Animals **Consequences for Studies with Repeated Dosing**

Handling of Test Article and Vehicle

- Storage
- Labelling



Preparation of the Formulation

- Solution / Suspension → Gavage
- Topical Formulation
- Feed Admix
- Aerosol for Inhalation



Cross Contamination in Control Animals

Test Article Application

- Gavage
- Diet
- Injection i.v., i.p., s.c., i.m.
- Dermal
- Inhalation



Cross Contamination in Control Animals

Animal Housing

- Single (with/without Restraining)
- In Groups
- Single/separated Rooms
- Air Condition



Cross Contamination in Control Animals

Blood, Excreta, Tissue Sampling

- Sequence
- Syringe Changes
- Metabolic Cages



Cross Contamination in Control Animals

Sample Handling

- Labelling
- Packaging
- Shipping



Cross Contamination in Control Animals

Sample Receipt

- Storage
- Processing (e.g. Dilution, Autosampler)



Cross Contamination in Control Animals

Data Processing

- Manually
- By Computer



Documentation