AGINKO Research

Toxicity Testing

AGINKO propopses a serie of tests for general toxicology assessment. These can be either acute or chronic toxicology studies. We also conduct studies with very specific adapted designs (adapted to the tested product and specific national regulatory requirements if needed).

The routes of administration can be diverse:

- Oral: gavage, capsules, dietary admixtures, drinking water
- Parenteral:
  - Intravenous : bolus, slow injection, continuous infusion, cycles (vascular acces port)
  - Others : subcutaneous, intradermal, intramuscular, intraperitoneal
- Dermal: open, semi-occluded and occluded dressing, patches and other devices, with or without rinsing, with or without collar. Each study is adapted to the specificity of the product
- Ocular: including intra-vitreous
- Intra-nasal
- Inhalation: in non-rodents
- Intra-vaginal
- other routes: we have experience in a number of very specific routes of administrations in different species. Please contact us for any specific request.

Code	Test	Type of Study	Method	Turnover (Week)
AGR1	Acute Toxicity (p.o, i.v., i.m., s.c.,i.p., dermal), rodents	Full study	OECD 420, 423, 425, 402, EU B.1.tris, , EU B.1bis, EU B.3, OPTTS 870-1200	8 - 10
		Limit Test		8
AGR2	Acute injection toxicity/pathogenicity, rodents	Full study	OPTTS 885.3200	8 - 10
AGR4	Acute oral toxicity/ pathogenicity, rodents	Full study	OPTTS 885.3300	8 - 12
AGR5	Maximum tolerated dose, rodents	Full study (3 - 5 dose levels), clinical and clinical-laboratory observation, gross pathology	CHMP/SWP/3 02413/08	8 - 12

AGR6	Extended single dose toxicity study, rodents	Full study, clinical and clinical-laboratory observation, gross and histopathology	CPMP/ICH/286/95, M3 (R2)	8 - 12
AGR7	Maximum tolerated dose, non-rodents (rabbits, ferrets, dogs, non-human primates)	Full study (3 - 5 escalated dose levels), clinical and clinical-laboratory observation, gross pathology	CHMP/SWP/302413/08	8 - 12
AGR8	Dose range finding study (p.o, i.v., i.m., s.c.,i.p., dermal), rodents	2 weeks of administration, 7d/wk exposure, clinical and clinical-laboratory examination, gross pathology, optional histopathology of selected organs	CPMP/SWP/1041/99, OPTTS 870-3050,	8 - 12
AGR9	Dose range finding study (p.o, i.v., i.m., s.c.,i.p.), non-rodents, (rabbits, ferrets, dogs, non-human primates)	2 weeks of administration, 7d/wk exposure, clinical and clinical-laboratory examination, gross pathology, optional histopathology of selected organs	CPMP/SWP/1041/99, OPTTS 870-3050,	8 - 12
AGR10	14-21 days repeated dose toxicity study (p.o, i.v., i.m., s.c.,i.p., dermal), rodents	2 - 3 weeks of administration, 7d/wk exposure, clinical and clinical-laboratory examination, gross pathology, full set of histopathology	CPMP/SWP/1041/99, OECD 407, EU B.7, OPTTS 870-3050,	10 - 16
AGR11	14-21 days repeated dose toxicity study (p.o, i.v., i.m., s.c.,i.p.), non-rodents, (rabbits, ferrets, dogs, non-human primates)	2 - 3 weeks of administration, 7d/wk exposure, clinical and clinical-laboratory examination, gross pathology, full set of histopathology	CPMP/SWP/1041/99, OECD 407, EU B.7, OPTTS 870-3050,	10 - 16
AGR12	28-day repeated dose toxicity study (p.o, i.v., i.m., s.c.,i.p., dermal), rodents, primates)	7d/wk exposure, clinical and clinical-laboratory examination, functional observation battery, gross pathology, full set of histopathology	OECD 407, 410, EU B.7. OPTTS 870-3050	18 - 22
AGR14	28-day repeated dose toxicity study (p.o, i.v., i.m., s.c.,i.p., dermal), non-rodents	7d/wk exposure, clinical and clinical-laboratory examination, functional observation battery, gross pathology, full set of histopathology	OECD 407, EU B.7. OPTTS 870-3050	18 - 22
AGR16	6-month repeated dose toxicity study, rodents	7d/wk exposure, clinical and clinical-laboratory examination, gross pathology, full set of histopathology	OECD 452, CPMP/SWP/1041/99	40 - 42
AGR17	6-month repeated dose toxicity study, non-rodents (rabbits, ferrets, dogs, non-human primates)	7d/wk exposure, clinical and clinical-laboratory examination, gross pathology, full set of histopathology	OECD 452, CPMP/SWP/1041/99	40 - 42

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