|  |  |  |  |
| --- | --- | --- | --- |
| **I. 基本信息 STUDY INFORMATION** | | | |
| **专题名称/编号Study Title/Number: {%study-title%}/{%study-num%}** | | | |
| **试验目的Study Purpose：{%study-purpose%}** | | | |
| **拟动物使用时间Animal Used Period:**共Total Period {%day1%} 天Days，  其中：检疫/适应期Quarantine Period {%day2%} 天Days，给药期Administration Period {%day3%} 天Days，  其它Others\_\_{%day4%}\_\_\_\_天Days。 | | | |
| **专题负责人**  **Study director** | {%sd%} | **兽医**  **Veterinarian** | {%sy%} |
| **主要试验人员**  **Personnel** | {%person%} | | |

**II. 拟使用动物信息ANIMAL INFORMATION**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **种/系 (通用名)**  **Species/Strain(common names)** | **等级**  **Level** | **数量**  **Number(s)** | **年龄/体重**  **Age/Weight** | **来源Source** |
| {%species%} | {%level%} | **♀:{%n1%}**  **♂:{%n2%}** | **♀:{%age1%}/{%weight1%}**  **♂:{%age2%}/{%weight2%}** | {%sourse%} |
| **动物种系及数量选择理由Reason for Selection of Animal species and quantity:**  **{%reason1%}**  **{%reason2%}** | | | | |
| **是否是相关管理机构推荐的方法Recommended by Related Regulatory Agencies:**   |  | | --- | | □是Yes 请简述(Describe briefly)：《药物重复给药毒性试验技术指导原则》（原CFDA，2014年05月）。  □否No 理由(Describe Reason)：**参考文献或其他参考信息 (非管理机构推荐的方法需列出)** **Literature Retrieval (Must Complete if non- Recommended by Related Regulatory Agencies Study):** | | | | | |
| **是否有替代方法Alternatives Considered:**  □ 无No  □ 有Yes　请说明不选择替代的理由(Reason for not Considering Alternatives)： | | | | |
| **本试验中动物遭受的痛苦是预先知道的吗Do you anticipate the pain that animals suffered during the study？**  □是Yes  □否No | | | | |
| **是否是重复试验Is it a duplicate experiment:**  □ 非重复No    □ 重复Yes　　请说明重复试验的理由(Describe Reasons)： | | | | |

**III.动物拟接受的处理ANIMAL PROCEDURE**

简单描述该试验中动物试验的操作程序，便于IACUC成员了解动物在试验中所接受的处理及状况

Provide one or two sentences to describe the procedures employed on the animals in this project. This information will help the IACUC members understand any conditions while your animals used.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 受试药物Substance administered to animals：  供试品名称Substance for Testing ：\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  阳性对照品名称Positive reference substance： \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  阴性对照品名称Negative reference substance： \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  其它 Others： \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | 组别  Group | 动物数量（只）  Number of animals | | 给药途径  Route of  Administration | 给药剂量  Dosage of  Administration | 给药频率  Frequency of  Administration | 给药体积  Volume of  Administration | | 雌Female | 雄  Male | |  |  | |  |  |  |  | |  |  | |  |  |  |  | |  |  | |  |  |  |  | |  |  | |  |  |  |  |   注Note：如果静脉给药（Intravenous Injection），请说明给药速率（Rate of Administration）：\_\_\_\_\_\_\_\_\_\_\_\_临床观察(Clinical Observation)：□常规Routine　□特殊要求Special Requirement：  健康检查项目及频率Items and Frequency of Physical Examination：    临床检查项目及频率Items and Frequency of Clinical Examination：  其他检查Other Examination：    动物保定（可能涉及到的保定方式请逐一描述，包括保定方式及选择理由、保定时长）Restraint of Animals（Describe the Way, the Reason and the Duration of Restraint ）：  实验终点的描述及理由Experimental Terminative Indicator：    剩余动物处理Residue Animals Conduct：  □转入备库 (Shift to Backup)  □安乐死Anesthesia，方法Method：  □其它Other，请描述Description of Other Methods： |

**IV. 动物饲养ANIMAL HUSBANDRY**

|  |
| --- |
| **饲养方式：**  □合笼Social housing  □ 单笼 Single housing 单笼饲养理由及动物福利保障措施（Describe the reason and supporting measures of animal well-being）： |
| **特殊环境丰富计划Will Environmental Enrichment be provided?**  □ 不需要No（按照本机构相关SOP，Comply with Institutional SOP）  □ 需要Yes  说明理由及特殊环境丰富计划内容Describe the reason and special Environmental Enrichment plan： |
| **兽医护理**  □ 常规护理Routine nursing（按照本机构相关SOP，Comply with Institutional SOP）  □ 特殊护理Special requirements 请说明特殊护理理由及项目Describe the Reason and Items： |
| **濒死动物或遭受慢性痛苦的动物将被实施安乐死Animals which are moribund or in chronic pain will be euthanized**  □ 是 Yes 确定实施人道终点的时机及方法（Describe the timing and method of humane ending）：  □ 否No 说明理由及处理方法 （Describe the Reason）： |
| **动物饲养管理要求**  □ 常规 （按照本机构相关SOP，Comply with Institutional SOP）  □ 特殊饲养 Special requirements 请说明需特殊饲养理由及方案Describe the Reason and Items： |

**V. 试验药品SUBSTANCES ADMINISTERED TO ANIMALS**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **试验药品是否有害? Are substances administered noxious?**  □是Yes □否No □未知Unknown  **其他需要说明事项 Other conditions that require description：**  **给药是否给动物造成瞬时疼痛之外的更多痛苦或损伤？**  **Will administration cause more pain or distress to animals, besides momentary pain?**  □ 否No  □ 是Yes 损伤或痛苦程度Degrees of lesion：□1级 □2级 □3级 □4级（见附表Appendix）  处理方法Disposition：  **试验过程中是否存在其他有害物质？Are there any noxious substances?**  □ 未知 Unknown □ 否 No □是Yes  **如果是，请填写下表If yes, fill out the following sheet**   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **序号No.** | **有害物质Noxious substances** | **种类**  **Category** | **商品名/化学名**  **Chemical name/Trade name** | **危害性描述**  **Hazard** | **贮存条件**  **Storage Conditions** | **MSDS** | | | **有Yes** | **无No** | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |   **个人防护方法推荐 PPE Recommendations:**  □护目镜Goggles □面罩Face shield □无菌衣Germfree coat □工作服Lab coat □手套 Gloves  □口罩Mask □工作帽Bouffant cap □呼吸面罩Respirator □其他 Others  注：如果试验样品性质未知，则至少应有以下防护（护目镜、工作服、手套、口罩）  Note: Goggles, lab coat, gloves and mask should be provided at least if substances information is unknown. |

**VI. 样本采集SPECIMENS COLLECTED**

|  |
| --- |
| **是否从活体动物采集样本?** **Are any specimens collected from living animals?**  □ 否No  □ 是Yes 理由Describe the reason：  □血样Blood Sample：采集部位Position：\_\_\_\_\_\_\_\_\_\_\_\_\_采集次数Frequency：\_\_\_\_\_\_\_\_\_\_\_\_\_  单次最大采血体积Max Volume at a time：\_\_\_\_\_\_\_\_\_\_\_\_\_  24小时最大采血量Max Volume in 24 hrs：\_\_\_\_\_\_\_\_\_\_\_\_\_  □病理检查Biopsy：    □其它样品Others：  **采样时是否使用麻醉剂？Are anesthetic used when sampling?**  □ 是 Yes 使用麻醉剂名称和剂量Name and Dosage of Anesthetic： \_  □ 否No 理由Describe the reason：  **样品采集是否给动物造成瞬时疼痛之外的更多痛苦或损伤？Will collection cause more pain or distress to animals, besides momentary pain?**  □ 否No  □ 是Yes 程度Levels of lesion：□1级 □2级 □3级 □4级 （见附表Appendix）  处理办法Disposition： |

**VII. 安乐死EUTHANASIA**

|  |
| --- |
| **研究结束时是否对动物实施安乐死?** **Will animals be euthanized at the end of this study?**  □ 是Yes 方法Methods of Euthanasia：  □ 否No 理由Reason：  处理方式Disposition： |

**VIII. 研究人员Personnel**

|  |
| --- |
| **试验人员是否接受对本试验相关操作培训? Is the Technical Staff trained to perform the procedures in this study?**  □ 是 Yes    □ 否 No 说明理由Describe the Reason： |

**IX. 特殊操作SPECIAL PROCEDURES**

|  |
| --- |
| **是否进行任何外科手术操作 ?** **Are any surgical procedures performed?**  □ 否 No    □ 是 Yes 请描述手术部位、操作程序、麻醉方法、术前准备和术后观察、镇痛处理等：  Describe the operative site, procedure, method of anesthesia, preoperative preparation, postoperative observation and analgesia treatment.  **除了手术和安乐死外，是否还需对动物进行其他用途的麻醉？Are any else purpose of anesthesia except surgical and euthanasia procedures？**  □ 否 No    □ 是 Yes 请描述（Describe below)  **是否进行其它未提及的、可能给动物造成瞬时疼痛之外的更多痛苦或损伤的试验操作**  **Are any other procedures, not noted elsewhere, performed, which may cause more pain or distress to animals, besides momentary pain?**  □ 否 No    □ 是 Yes 请描述（Describe below) |

**X.非药用级别药品NON-PHARMACEUTICAL-GRADE DRUGS**

|  |
| --- |
| **本试验中是否使用非药用级别的药品？Is there any non-pharmaceutical-grade drugs?**  □ 否 No    □ 是 Yes 请描述药品名称、对试验动物的危害及采取的应对措施Describe the drug name, potential hazards to animals and correspondent treatments： |

**XI.预期不良影响 EXPECTED ADVERSE EFFECTS**

|  |
| --- |
| **本试验预期的不良反应List expected adverse effects:**  **对本试验过程中发生的临床症状和体征是否需要采取治疗措施？Shall we do some treatment to the animals according to the above symptom?**  □ 不需要No 请说明不采取治疗措施的理由Describe the reason of not treatment：    □ 需要Yes 请说明拟采取的治疗措施Describe the specific treatment： |

**附表Appendix：伤害的类别THE CATEGORIES OF LESION**

|  |  |
| --- | --- |
| **类别**  **Categories** | **症状描述 Description** |
| **1** | **不产生不适或紧张**  **譬如：**动物仅饲养于设施，可能计划用于进行研究和/或实验，但还未进行任何的实验操作。  Little or no discomfort or stress  Examples: Animals being held, bred, or conditioned for use in teaching, experiments, research or surgery, but not yet used for such purposes. Such as animal just holding, it is not undergoing any experimental procedures. |
| **2** | **轻微紧张或短期疼痛**  **譬如**：对动物进行的实验操作不会引起动物的不适和/或疼痛，或者只有轻微紧张或短期疼痛，不需要使用药物来减轻动物的不适。如给啮齿类动物打耳号等。  Minor stress or pain of short duration  Examples: Animals that are subject to procedures that cause no pain or distress, or only momentary or slight pain or distress and do not require the use of pain-relieving drugs. Such as applying identification tags, ear notching, tattoos, ect. |
| **3** | **中到重度不适**  **譬如**：相关操作会给动物造成潜在的痛苦和不安，需要使用合适的药物以减轻动物的不适。如适当麻醉后进行的手术，腹腔镜检查，活组织检查等。  Moderate to severe distress  Examples: Animal subjected to potentially painful or stressful procedures for which they receive appropriate anesthetics, analgesics and/or tranquilizer drugs. Such as surgical procedures, tumor induction or implantation if alleviation of pain/distress. |
| **4** | **接近、处于或超过忍受极限的疼痛**  **譬如：** 相关操作给动物造成潜在的痛苦和不安，但不能使用药物来减轻动物的痛苦。如暴露于药品、化学品或感染性物质的程度可显著危害机体健康并可引起死亡、严重疼痛或极度紧张，LD50试验等。  Severe pain near, at or above the pain tolerance threshold  Examples: Animals subjected to potentially painful or stressful procedures that are not relieved with anesthetics, analgesics and/or tranquilizer drugs. Such as toxicological or microbiological or infectious disease research that requires continuation after clinical symptoms are evident without medical relief or require death as an endpoint, and LD 50 studies. |

**申明Declaration:**

我郑重承诺，本试验动物管理与使用审批表中所提供的信息完全属实，没有IACUC的进一步批准将不做与动物福利相关的任何改动。我保证本研究没有不必要的重复前期的试验。

I affirm that the information provided in this Animal Care and Use Review Form is completely true. The information related to animal welfare in this form will not be changed without advanced approval of the IACUC. I further certify that this study does not unnecessarily duplicate previous experiments.

|  |  |  |  |
| --- | --- | --- | --- |
| **专题名称Study Title：** | | | |
| **专题编号Study Number：** | | | |
| **专题负责人Study Director**  **（签字Signature）** |  | **日期Date** |  |
| **兽医Veterinarian**  **（签字Signature）** |  | **日期Date** |  |

**IACUC 批准签字IACUC Approval Signatures:**

根据中国科技部“关于善待实验动物的指导性意见”（国科发财字〔2006〕398号）、AAALAC International “The Guide for the Care and Use of Laboratory Animals ”(Guide, NRC, 2011)，IACUC于 年 月 日进行了方案审查会议， 人参与，与会者评价了本试验方案中描述的动物管理与使用事项，认为所描述的试验操作程序适当并可以接受，同意进行该项试验。

The undersigned have evaluated the care and use of animals described in this protocol in accordance with the Guidance of Take Care of Laboratory Animal（MOST, China[2006]398）, Ministry of Science and Technology of China. The Guide for the Care and Use of Laboratory Animals (Guide, NRC, 2011), Laboratory Animal-Requirements of Environment and Housing Facilities(GB, China). Date of Inspection Meeting： year month day , \_\_\_\_\_\_\_ participants evaluated the procedures described as appropriate and acceptable.

|  |  |
| --- | --- |
| **IACUC主席签字(chair Signature)** | **日期Date:** |
|  |  |