附件3：

仿制药质量和疗效一致性评价

生产现场检查申请表

编号：

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| 药品名称 |  | 受理号 | |  |
| 剂 型 |  | 规 格 | |  |
| 批准文号 |  | | | |
| 申 请 人 |  | 联 系 人 |  | |
| 联系电话 |  | 手 机 |  | |

**1药学研制现场部分：**

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| 药 学 研 究 | | 研究项目 | | 研究机构名称 | | | 研究地点 | | | 体系认证 | | | | | 起止日期 | | | 研究负责人 | |
| 处方/工艺  研究 | |  | | | (具体楼座、实验室) | | |  | | | | |  | | |  | |
| 样品试制 | |  | | |  | | |  | | | | |  | | |  | |
| 质量研究 | |  | | |  | | |  | | | | |  | | |  | |
| 体外评价 | |  | | |  | | |  | | | | |  | | |  | |
| 稳定性研究 | |  | | |  | | |  | | | | |  | | |  | |
| 研究主要仪器设备 | | | 型 号 | | | | 研究主要仪器设备 | | | | | | | | 型 号 | | |
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|  | | |  | | | | (样品试制设备填下页) | | | | | | | |  | | |
| 对照品/标准品/参比制剂 | | 来 源 | | | 批 号 | | | | | 数 量 | | 剩 余 量 | | | | | |
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| 原料药/辅料/内包材 | | 来 源 | | | 批 号 | | | | | 数 量 | | 注册情况 | | | | | |
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| 样 品 试 制 | 批 号 | | 试制日期 | | | 用 途 | | 主药投料量 | | | | | 试 制 量 | 使 用 量 | | | | | 剩 余 量 |
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| 主要设备 | | | | | 试制地点 | | | | | 主要设备 | | | | | 试制地点 | | | |
|  | | | | | (具体楼座、实验室) | | | | |  | | | | |  | | | |
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|  | 试制原始记录共 页 | | | | | | | | | | 负责人（签名） | | | | |  | | | |
| 主要检验仪器 | | | | | 检验地点 | | | | | 主要检验仪器 | | | | | 检验地点 | | | |
|  | | | | | (具体楼座、实验室) | | | | |  | | | | |  | | | |
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| 检验原始记录共 页 | | | | | | | | | | 负责人（签名） | | | | |  | | | |

**2生产现场部分：**

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| 生产单位 | |  | | | | | | 生产地址 | | | |  | | | | |
| 该剂型生产线 1条 2条及以上 | | | | | | | | | | | | | | | | |
| 样品生产车间或生产线名称 | | | | |  | | | | | | | | | | | |
| 上市生产批量 | | | | |  | | 生产线取得药品GMP证书  编号及证书有效期 | | | | | | |  | | |
| 认证范围 | | | | |  | | 认证时间/上次接受现场  检查时间 | | | | | | |  | | |
| 生物等效性研究  产品批次 | 批 号 | | 批 量 | | 生产日期 | | 生产线（是否与该品种商业化生产同一条生产线） | | | | | | | 生物等效性研究类型 | | |
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| 工艺验证批次 | 批 号 | | 批 量 | | 生产日期 | | 生 产 线 | | | | | | | 验证审核人 | | |
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| 近3年生产情况/一致性评价研究以来生产批次情况 | 批 号 | | 批 量 | | 生产日期 | | 生 产 线 | | | | | | | 生产审核人 | | |
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| 品种生产所用设施设备情况 | 设备名称 | | | | | 型 号 | | | 购买时间 | | | | | | 安放位置 | |
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| 拟安排生产情况 | 主要生产工序名称 | | | | | 计划开始时间 | | | 计划完成时间 | | | | | | 主要操作人 | |
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| 原辅料情况 | 名 称 | | | 规 格 | | 标 准 | | | 生产单位 | | | | 批准文号/  核准的编码 | | | 用途 |
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| 包装材料情况 | 名 称 | | | 规 格 | | 标 准 | | | 生产单位 | | | | | | 批准文号/  核准的编码 | |
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| 该生产线生产的其他品种情况 | 药品名称 | | | 规 格 | | 批准文号 | | | | 批 量 | | | 生产频率  （批/年、批/季度、批/月） | | | |
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| 生产人员登记表 | 姓 名 | | | | | 部 门 | | | | | 所在岗位 | | | | | |
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| 附件 |  | | | | | | | | | | | | | | | |

**3 可接受现场检查时间**

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| 可接受现场检查时间填写时应写明本月（上半月）、本月（下半月）、下月（上半月）、下月（下半月）、如有其他时间，请写明原因。可接受检查时间可选择填写多项。 | |
| 可接受现场检查时间 |  |

**4声明**

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| 声明 | 接受现场检查的药品批量生产的处方及工艺与注册核准的/本次申报的批量、处方、工艺、原辅料标准和来源、设施设备等一致。申请人对申报资料和数据的真实性负责。本报告表中填写内容和所附资料均属实。如查有不实之处，本单位负法律责任，并承担由此造成的一切后果。  申报单位负责人签名：  (申请人公章)  年 月 日 |