附表五：医疗机构制剂研制情况申报表

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| 制剂名称 | | | | | | 制剂类别 | | | | 剂型 | | | | | | | 规格 | | | |
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| 申请人 | | | |  | | | | | | | | | | | | | | | | |
| 联系人 | | | |  | | 联系电话 | | | |  | | | | | | | | | | |
| 药学药理毒理研究 | 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) | | | | | (如GLP、GMP等) | | |  | | | | |  | |
| 质量标准研究 | | |  | |  | | | | |  | | |  | | | | |  | |
| 样品试制 | | |  | |  | | | | |  | | |  | | | | |  | |
| 稳定性研究 | | |  | |  | | | | |  | | |  | | | | |  | |
| 药理毒理研究 | | |  | |  | | | | |  | | |  | | | | |  | |
| 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 | 批号 | | 试制日期 | | 用途 | | | 主药投量 | | | | 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 | | | | | |
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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） | | | | | | | |  | | | | | |
| 临床研究 | 实验项目 | | | 试验机构名称 | | | 起止时间 | | | | | | 样品量 | | | | | 主要研究者 | | | |
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| 我们保证：本报告表中填写内容和所附资料均属实。如查有不实之处，本机构负法律责任，并承担由此造成的一切后果。  申请人：  法人代表（签字）：  日期： 年 月 日 （公章）  注：其他需要说明的情况可另附页。 | | | | | | | | | | | | | | | | | | | | | |