附件2

医疗机构应用传统工艺配制

中药制剂备案表

编号：

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| **声明** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **我们保证：**  ①本次备案遵守《中华人民共和国药品管理法》《中华人民共和国中医药法》《中华人民共和国药品管理法实施条例》和《医疗机构制剂注册管理办法（试行）》等法律、法规和规章的规定；  ②备案内容及所有备案资料均真实、来源合法、未侵犯他人的权益；  ③一并提交的电子文件与打印文件内容完全一致。  如有不实之处，我们承担由此导致的一切法律后果。 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **备案事项** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 备案类型 | □首次 □变更 □年度报告 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 备案事由 | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **制剂基本信息** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 制剂名称 | | 通用名称 | | |  | | | 剂型 | | | |  | | | | | 规格 | | | | |  | | | 有效期 | | | | | |  | |
| 汉语拼音 | | |  | | |
| 处方  （含辅料） | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 处方在本医疗机构是否具有5年以上（含5年）使用历史 | | | | | | | | | | | | | | | □是 | | | | | | | | | | | □否 | | | | | | |
| 处方中药味是否存在以下情形 | | 含法定标准中标识有“剧毒”“大毒”及现代毒理学证明有明确毒性的药味 | | | | | | | | | □是 | | | | | □否 | | | | 备注 | | | | | | | | | | | | |
| 含有十八反、十九畏配伍禁忌 | | | | | | | | | □是 | | | | | □否 | | | |
| 配制工艺  （含辅料） | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 功能主治 | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 用法用量 | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 辅料信息 | | 名称 | | | |  | | | | | 生产企业 | | | | | | |  | | | | | | | | | | | | | | |
| 执行标准 | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 包装材料信息 | | 名称 | | | |  | | | | | 生产企业 | | | | | | |  | | | | | | | | | | | | | | |
| 执行标准 | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **备案机构信息** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 名称 | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 《医疗机构执业许可证》 | | | 登记号 | | |  | | | 有效期限 | | | | 年 月 日 至 年 月 日 | | | | | | | | | | | | | | | | | | | |
| 《医疗机构制剂许可证》 | | | □有 | | | 有无此  配制范围 | | | □有 | | | | 编号 | | | | | |  | | | | 有效  期限 | | | | | | 年 月 日至 年 月 日 | | | |
| □无 | | | |  | | | | | | | | | | | | | | | | | | | |
| □无 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **制剂配制信息** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 是否委托配制 | | | □否 | 制剂配制地址 | | | | | |  | | | | | | | | | | | | | | | | | | | | | | |
| □是 | 制剂配制单位名称 | | | | | |  | | | | | | | | | | | | | | | | | | | | | | |
| 《医疗机构制剂许可证》 | | | | | | □是 | | | | 编号 | | | | | | |  | | | 有效期限 | | | | 年 月 日至  年 月 日 | | | | |
| 《药品生产许可证》 | | | | | | □是 | | | |
| 制剂配制地址 | | | | | |  | | | | | | | | | | | | | | | | | | | | | | |
| 联系人 | | | | | |  | | | | | | 电话 | | | | |  | | | | | | | | | | | |
| 制剂配制单位法人代表 | | | | | | （签字） | | | | | | （公章）  　 年 月 日 | | | | | | | | | | | | | | | | |
| **备案变更信息（变更备案时填写）** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 序号 | | | 历次备案号 | | | | 变更时间 | | | 变更内容 | | | | | | | | | 变更原因概述 | | | | | | | | | | | | | |
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| **年度报告信息（年度报告时填写）** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 报告年度 | | | | | | | | | 年 月 日 至 年 月 日 | | | | | | | | | | | | | | | | | | | | | | | |
| 配制的总批次数： | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 内控制剂标准全检不合格的批次数： | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 使用数量： | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 变更情形汇总 | | | 变更内容 | | | | | | | 变更时间 | | | | | | | | | | 对应的备案号 | | | | | | | | | | | | |
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| **不良反应监测情况** | | | 不良事件/反应报告 | | | | □有 | | | 报告例数： | | | | | | | | | | | | | | | | | | | | | | |
| □无 | | | | | | | | | | | | | | | | | | | | | | | | | |
| 风险控制主要措施 | | | | □有 | | 主要措施： | | | | | | | | | | | | | | | | | | | | | | | |
| □无 | | | | | | | | | | | | | | | | | | | | | | | | | |
| **备案资料** | | | | | | | | | | | | | | | | | 有 | | | | | 无 | | | 无需 | | | | | 备注 | | |
| □《医疗机构应用传统工艺配制中药制剂备案表》原件 | | | | | | | | | | | | | | | | |  | | | | |  | | |  | | | | |  | | |
| □制剂名称及命名依据 | | | | | | | | | | | | | | | | |  | | | | |  | | |  | | | | |  | | |
| □立题依据和目的、同品种及其他剂型中药制剂的市场供应情况 | | | | | | | | | | | | | | | | |  | | | | |  | | |  | | | | |  | | |
| □证明性文件 | | | | | | | | | | | | | | | | |  | | | | |  | | |  | | | | |  | | |
| □标签及说明书设计样稿 | | | | | | | | | | | | | | | | |  | | | | |  | | |  | | | | |  | | |
| □处方组成、来源、理论依据以及使用背景情况 | | | | | | | | | | | | | | | | |  | | | | |  | | |  | | | | |  | | |
| □详细的配制工艺及工艺研究资料 | | | | | | | | | | | | | | | | |  | | | | |  | | |  | | | | |  | | |
| □质量研究的试验资料及文献资料 | | | | | | | | | | | | | | | | |  | | | | |  | | |  | | | | |  | | |
| □制剂的内控标准及起草说明 | | | | | | | | | | | | | | | | |  | | | | |  | | |  | | | | |  | | |
| □制剂的稳定性试验资料 | | | | | | | | | | | | | | | | |  | | | | |  | | |  | | | | |  | | |
| □连续3批样品的自检报告书 | | | | | | | | | | | | | | | | |  | | | | |  | | |  | | | | |  | | |
| □原、辅料的来源及质量标准，包括药材的基原及鉴定依据、前处理、炮制工艺、有无毒性等 | | | | | | | | | | | | | | | | |  | | | | |  | | |  | | | | |  | | |
| □直接接触制剂的包装材料和容器的选择依据及质量标准 | | | | | | | | | | | | | | | | |  | | | | |  | | |  | | | | |  | | |
| □主要药效学试验资料及文献资料 | | | | | | | | | | | | | | | | |  | | | | |  | | |  | | | | |  | | |
| □单次给药毒性试验资料及文献资料 | | | | | | | | | | | | | | | | |  | | | | |  | | |  | | | | |  | | |
| □重复给药毒性试验资料及文献资料 | | | | | | | | | | | | | | | | |  | | | | |  | | |  | | | | |  | | |
| □变更研究资料 | | | | | | | | | | | | | | | | |  | | | | |  | | |  | | | | |  | | |
| □变更情形年度汇总 | | | | | | | | | | | | | | | | |  | | | | |  | | |  | | | | |  | | |
| □质量情况年度分析 | | | | | | | | | | | | | | | | |  | | | | |  | | |  | | | | |  | | |
| □使用、疗效情况年度分析 | | | | | | | | | | | | | | | | |  | | | | |  | | |  | | | | |  | | |
| □不良反应监测年度汇总 | | | | | | | | | | | | | | | | |  | | | | |  | | |  | | | | |  | | |
| □其他资料：  　具体资料名称： | | | | | | | | | | | | | | | | |  | | | | |  | | |  | | | | |  | | |
| 备案负责人 | | |  | | | | 职位 | | |  | | | | | | | 电话 | | | | |  | | | | | | | | | | |
| 联系人 | | |  | | | | 职位 | | |  | | | | | | | 电话 | | | | |  | | | | | 传真 | | | | |  |
| 法定代表人 | | | （签名） | | | | （加盖公章处）  　 年 月 | | | | | | | | | | | | | | | | | | | | | | | | | |

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| 抄送：省中医药管理局。 |
| 甘肃省药品监督管理局综合和规划财务处 2025年6月6日印发 |