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| |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | 附件4： | | |  | |  |  |  | |  |  |  |  | | **药品批发企业物流服务能力评级评定指标评定标准** | | | | | | | | | | | | | | **评级指标** | | | | | | **评定结果** | | | | | | **备注** | | **大项** | **对应《分级标准》序号** | **评定指标** | | **检查内容**  **与方式** | **评定标准** | **评定分值** | | **适用等级** | | | **评定总分** | | **A** | **AA** | **AAA** | | | **药品质量管理能力** | 3.1 | 运输包装完好率≥95% | | 查看相关记录 | 运输包装完好率：每低于0.1%，减1分。 | **10** | | √ |  |  |  |  | | 3.1 | 运输包装完好率≥99% | | 查看相关记录 | 运输包装完好率：每低于1%，减1分。 | **10** | |  | √ | √ |  |  | | 3.2 | 运输过程信息可追溯率≥70%，其中冷藏药品、特殊管理药品信息可追溯率达到100% | | 查看相关记录 | 运输过程信息可追溯率：每低于1%，减1分。 | **10** | | √ |  |  |  |  | | 查看相关记录 | 特殊管理药品信息可追溯率：每低于1%，减1分。 | | 3.2 | 运输过程信息可追溯率≥80%，其中冷藏药品、特殊管理药品信息可追溯率达到100%。 | | 查看相关记录 | 运输过程信息可追溯率：每低于1%，减1分。 | **10** | |  | √ |  |  |  | | 查看相关记录 | 特殊管理药品信息可追溯率：每低于1%，减1分。 | | 3.2 | 运输过程信息可追溯率≥90%，其中冷藏药品、特殊管理药品信息可追溯率达到100%。 | | 查看相关记录 | 运输过程信息可追溯率：每低于1%，减1分。 | **10** | |  |  | √ |  |  | | 查看相关记录 | 特殊管理药品信息可追溯率：每低于1%，减1分。 | | 3.3 | 冷藏和专用设备达标率≥90% | | 查看相关记录 | 冷藏和专用设备达标率：每低于0.1%，减1分。 | **10** | | √ | √ | √ |  |  | | 3.4 | 冷藏药品运输温度控制合格率达100% | | 查看相关记录 | 冷藏药品运输温度控制合格率：每低于0.1%，减1分。 | **10** | | √ | √ | √ |  |  | | **药品安全风险控制能力** | 4.1 | 具有药品储存、运输中温度控制以及冷库断电、冷链超时限运输等应急预案。 | | 查看文件 和演练记录 | 建立冷链应急机制、处理程序、人员与演练记录。一项不落实，减2分。 | **10** | | √ | √ | √ |  |  | | 4.2 | 风险预案具有可操作性，企业相关管理人员和作业人员熟悉风险预案操作 | | 查看文件 和现场查问 | 健全风险管理组织、负责人、各部门职责、风险处理操作程序。一项不落实，减2分。 | **10** | | √ | √ | √ |  |  | | 4.3 | 每年应缴纳财产保险、运输保险、人身保险 | | 财务系统 和保险合同审核 | 年度财产保险、运输保险、人身保险合同。一项不落实，减2分。 | **10** | | √ | √ | √ |  |  | | **静态物流要素能力** | 5.2 | 5.2.1 4辆以上运营车辆，如租用车辆必须租用有资质的配送企业车辆 | | 查看设备台账 | 1、每少1辆，减1分。 | **10** | | √ | **—** | **—** |  |  | | 查看审计报告和租赁协议 | 2、租用货运车的企业应对被租方企业实施质量审计，符合要求后方可租用。无，本项不得分 | √ | **—** | **—** |  |  | | 5.2.2 配送生物制品、疫苗必须具有1辆以上冷藏车 | | 查看设备台账和现场审核 | 1、至少有1辆冷藏车。无，本项不得分 | **10** | | √ | **—** | **—** |  |  | | 2、冷藏车具有GPS跟踪系统。无，本项不得分 | √ | **—** | **—** |  |  | | 5.2 | 5.2.1 15辆以上运营车辆，如租用车辆必须租用有资质的配送企业车辆 | | 查看设备台账 | 1、每少1辆，减1分。 | **10** | | **—** | √ | **—** |  |  | | 查看审计报告和租赁协议 | 2、租用货运车的企业应对被租方企业实施质量审计，符合要求后方可租用。无，本项不得分 | **—** | √ | **—** |  |  | | 5.2.2 配送生物制品、疫苗必须具有3辆以上冷藏车 | | 查看设备台账 和现场审核 | 1、至少有3辆冷藏车。无，本项不得分；少1辆，减3分。 | **10** | | **—** | √ | **—** |  |  | | 2、冷藏车具有GPS跟踪系统。每少1个，减3分。 | **—** | √ | **—** |  |  | | 5.2 | 5.2.1 30辆以上运营车辆，如租用车辆必须租用有资质的配送企业车辆 | | 查看设备台账 | 1、每少1辆，减1分。 | **10** | | — | — | √ |  |  | | 查看审计报告和租赁协议 | 2、租用货运车的企业应对被租方企业实施质量审计，符合要求后方可租用。无，本项不得分 | — | — | √ |  |  | | 5.2.2 配送生物制品、疫苗必须具有4辆以上冷藏车 | | 查看设备台账和现场审核 | 1、至少有4辆冷藏车。无，本项不得分；少1辆，减3分 | **10** | | — | — | √ |  |  | | 2、冷藏车具有GPS跟踪系统，每少1个，减3分。 | — | — | √ |  |  | |  | 5.4 | 5.4.1 具有仓储信息管理系统（WMS） | | 查看系统 和现场审核 | 仓储信息管理系统（WMS）：具有对仓库作业结果进行记录、核对和管理，并且具有对仓库作业过程指导和规范等功能。无,本项不得分 | **10** | | √ | — | — |  |  | | 5.4.2 药品仓储自动温湿度监测系统 | | 温湿度自动监测系统：具有24小时实时监测药品库房温度；具有对温度异常自动报警、温度数据自动记录、备份等功能。无,本项不得分 | **10** | | √ | — | — |  |  | | 5.4.3 电子订单系统 | | 电子订单系统：具有通过计算机通信网络连接的方式将订单资料传送至公司、供应商、批发商和客户等功能。无,本项不得分 | **10** | | √ | — | — |  |  | | 5.4.4 数码拣选系统（DPS） | | 数码拣选系统（DPS）：具有通过货架和电子显示装置（电子标签）指示拣货的功能。无,本项不得分 | **10** | | √ | — | — |  |  | | 5.4 | 5.4.1 具有现代化仓储信息管理系统（WMS） | | 查看系统 和现场审核 | 仓储信息管理系统（WMS）：具有对仓库作业结果进行记录、核对和管理，并且具有对仓库作业过程指导和规范等功能。无,本项不得分 | **10** | | — | √ | — |  |  | | 5.4.2 药品仓储自动温湿度监测系统 | | 温湿度自动监测系统：具有24小时实时监测药品库房温度；具有对温度异常自动报警、温度数据自动记录、备份等功能。无,本项不得分 | **10** | | — | √ | — |  |  | | 5.4.3 电子订单系统 | | 电子订单系统：具有通过计算机通信网络连接的方式将订单资料传送至公司、供应商、批发商和客户等功能。无,本项不得分 | **10** | | — | √ | — |  |  | | 5.4.4 数码拣选系统（DPS） | | 数码拣选系统（DPS）：具有通过货架和电子显示装置（电子标签）指示拣货的功能。无,本项不得分 | **10** | | — | √ | — |  |  | | 5.4.5 运输信息管理系统(TMS) | | 运输信息管理系统(TMS)：具有运用现代物流管理方法和计算机技术处理各种运输事务功能的信息系统。无,本项不得分 | **10** | | — | √ | — |  |  | | 5.4.6 仓库控制系统（WCS） | | 仓库控制系统（WCS）：具有与WMS进行信息交互，实时监控、参数设置、手动调试的功能。无,本项不得分 | **10** | | — | √ | — |  |  | | 5.4.7 客户关系管理系统（CRM） | | 1、客户关系管理系统（CRM）：具有运用信息科学技术，实现市场营销、销售、服务等活动自动化等功能。无,本项不得分 | **10** | | — | √ | — |  |  | | 2、与重点客户能够网络对接，客户能够及时获得数据查询结果。无,本项不得分 | — | √ | — |  |  | | 5.4 | 5.4.1 具有现代化仓储信息管理系统（WMS） | | 查看系统 和现场审核 | 仓储信息管理系统（WMS）：具有对仓库作业结果进行记录、核对和管理，并且具有对仓库作业过程指导和规范等功能。无,本项不得分 | **10** | | — | — | √ |  |  | | 5.4.2 药品仓储自动温湿度监测系统 | | 温湿度自动监测系统：具有24小时实时监测药品库房温度；具有对温度异常自动报警、温度数据自动记录、备份等功能。无,本项不得分 | **10** | | — | — | √ |  |  | | 5.4.3 电子订单系统 | | 电子订单系统：具有通过计算机通信网络连接的方式将订单资料传送至公司、供应商、批发商和客户等功能。无,本项不得分 | **10** | | — | — | √ |  |  | | 5.4.4 数码拣选系统（DPS） | | 数码拣选系统（DPS）：具有通过货架和电子显示装置（电子标签）指示拣货的功能。无,本项不得分 | **10** | | — | — | √ |  |  | | 5.4.5 运输信息管理系统(TMS) | | 运输信息管理系统(TMS)：具有运用现代物流管理方法和计算机技术处理各种运输事务功能的信息系统。无,本项不得分 | **10** | | — | — | √ |  | | 5.4.6 仓库控制系统（WCS） | | 仓库控制系统（WCS）：具有与WMS进行信息交互，实时监控、参数设置、手动调试的功能。无,本项不得分 | **10** | | — | — | √ |  |  | | 5.4.7客户关系管理系统（CRM） | | 1、客户关系管理系统（CRM）：具有运用信息科学技术，实现市场营销、销售、服务等活动自动化等功能。无,本项不得分 | **10** | | — | — | √ |  |  | | 2、与全部客户能够网络对接，实现网络化管理，客户能够及时获得数据查询结果。无,本项不得分 | **10** | | — | — | √ |  |  | | 5.4.8 无线射频系统（RFID） | | 无线射频系统（RFID）：具有利用无线电波进行双向通信的自动识别系统。无,本项不得分 | **10** | | — | — | √ |  |  | | 5.4.9 货主管理系统（TPL） | | 货主管理系统（TPL）：集业务管理、作业管理、系统管理及电子商务等功能于一体，贯穿整个企业商务活动及业务流程的信息系统。无,本项不得分 | **10** | | — | — | √ |  |  | | 5.5 | 5.5.1 疫苗配送全程温控监测 | | 查看系统 和现场审核 | 具有温度检测测、跟踪的管理制度、系统、设备和记录。无,本项不得分 | **10** | | √ | √ | √ |  |  | | 5.5.2 货物跟踪信息系统 | | 具有基于无线通信(GPS/GSM)技术的货物定位和跟踪系统，及其使用记录。无,本项不得分 | √ | √ | √ |  |  | | 5.6 | 具有网上查询或人工查询的货物追踪系统，信息系统覆盖率覆盖经营区域 | | 查看系统 和现场审核 | 1、具有利用物流条形码和网络技术，为授权客户登陆查询货物每个阶段的递送状态信息的网络查询平台（包括货物品种、数量、货物在途情况、交货期间、发货地和到达地、货物的货主、送货责任车辆和人员等查询信息）。无,本项不得分 | **10** | | √ | √ | √ |  |  | | 2、与客户系统对接，能够实时查询/具有数据交换平台/提供电子数据交换。无,本项不得分 | √ | √ | √ |  |  | | 5.7 | 提高物流中心拣选速度，具有储位优化设计方案 | | 查看文件 和现场审核 | 具有储位优化方案，包括储位优化、实施方法、信息技术支持、效果评测和记录等。无,本项不得分 | **10** | | \_\_ | √ | √ |  |  | | 5.8 | 运用条码技术，实现药品出入库的过程跟踪 | | 查看系统 和现场审核 | 1、具有数据自动采集、处理能力或自动分拣能力。无,本项减50%分 | **10** | | \_\_ | √ | √ |  |  | | 查看系统 和现场审核 | 2、具有RF作业的配套系统、操作工具、管理和操作文件。无,本项减50%分 |  |  | | **静态物流要素能力** | 5.9 | 大专及以上学历且从业3年以上的物流管理人员占物流管理人员总数的55%以上，具有物流师以上专业资格认证的物流管理人员占物流管理人员总数的15%以上 | | 查看相关人事档案 | 1、管理层人员：大专及以上学历并有3年以上管理人员占管理人员总数的55%以上。每低于1%，减1分。按照商务部《药品流通行业“十二五”人才培训方案 》参加各项培训并获得相应证书的，每人次获得一份证书加0.1分，最高加5分。 | **10** | | √ | — | — |  |  | | 2、物流师以上人员占管理人员总数的15%以上。每低于1%，减1分。 | √ | — | — |  |  | | 5.9 | 本科及以上学历且从业3年以上的物流管理人员占物流管理人员总数的40%以上，具有物流师以上专业资格认证的物流管理人员占物流管理人员总数的35%以上 | | 查看相关人事档案 | 1、管理层人员：本科及以上学历并有3年以上管理人员占管理人员总数的40%以上。每低于1%，减1分。按照商务部《药品流通行业“十二五”人才培训方案 》参加各项培训并获得相应证书的，每人次获得一份证书加0.1分，最高加5分。 | **10** | | — | √ | — |  |  | | 2、物流师以上人员占管理人员总数的35%以上。每低于1%，减1分 | — | √ | — |  |  | | 5.9 | 本科及以上学历且从业3年以上的物流管理人员占物流管理人员总数的60%以上，具有物流师以上专业资格认证的物流管理人员占物流管理人员总数的50%以上 | | 查看相关人事档案 | 1、管理层人员：本科及以上学历并有3年以上管理人员占管理人员总数的60%以上。每低于1%，减1分。按照商务部《药品流通行业“十二五”人才培训方案 》参加各项培训并获得相应证书的，每人次获得一份证书加0.1分，最高加5分。 | **10** | | — | — | √ |  |  | | 2、物流师以上人员占管理人员总数的50%以上。每低于1%，减1分。 | — | — | √ |  |  | | 5.10 | 质量管理人员：具有与经营品种相对应的药学专业技术人员，占物流人员总数比例达5%或以上 | | 查看相关人事档案 | 应在职在岗，资质应符合法律法规的要求。低于本指标，不得分 | **10** | | √ | √ | √ |  |  | | 5.11 | 专业技术人员：具有物流、信息、设备管理专业技术人员 | | 查看相关人事档案 | 专业技术人员数量应与经营规模相适应。缺一项，减1分。 | **10** | | √ | √ | √ |  |  | | 5.12 | 物流员工素质：50%以上具有中等专业以上学历 | | 查看相关人事档案 | 中等专业以上学历（含高中）；每低于1%，减1分。 | **10** | | √ | — | — |  |  | | 5.12 | 物流员工素质：70%以上具有中等专业以上学历 | | 查看相关人事档案 | 中等专业以上学历（含高中）；每低于1%，减1分。 | **10** | | — | √ | — |  |  | | 5.12 | 物流员工素质：80%以上具有中等专业以上学历 | | 查看相关人事档案 | 中等专业以上学历（含高中）；每低于1%，减1分。 | **10** | | — | — | √ |  |  | | **物流服务基础能力** | 6.1 | 具有负责药品物流质量、运营、财务、客户服务、安全、设备管理等部门或人员，职能健全 | | 查看文件 | 建立符合药品法律法规的健全的质量、经营、财务、客服、统计、安全、技术等机构和相应的管理制度。少一项或一项不全，减1分。 | **10** | | √ | √ | √ |  |  | | 查看相关人事档案 | 药学技术人员、物流管理人员数量。每少1%，减1分。 | √ | √ | √ |  |  | | 查看文件和记录 | 有健全的运作、考核、持续改进和培训制度。少一项，减2分。 | √ | √ | √ |  |  | | 查看文件 和现场审核 | 各项制度得到落实，记录、档案完整。一项未落实，减1分。 | √ | √ | √ |  |  | | 6.2 | 通过ISO质量管理体系认证，具有健全的质量管理制度 | | 查看证明文件 | 具有合法资质的质量认证机构出具的通过ISO:9001 2008质量管理体系认证的证明文件。无,本项不得分 | **10** | | — | √ | √ |  |  | | 6.3 | 具有物流各个作业环节的作业流程、机械设备使用操作手册 | | 查看文件 和现场审核 | 1、建立完整的作业管理流程、作业指导书。少一项，减1分。 | **10** | | √ | √ | √ |  |  | | 查看文件 和现场审核 | 2、对药品的入库验收、贮存、出库复核、退货、不合格药品、运输、交接等作业指导书必须按照药品法律法规规定，相关文件、单据和记录完整齐全。一项未落实，减1分。 | √ | √ | √ |  |  | | 现场审核 | 3、库容库貌整洁；各种标志规范、清晰、易辨；作业规范；物品堆码整齐。一项未落实，减1分。 | √ | √ | √ |  |  | | 查看文件、记录 | 4、应有培训计划和总结，并保证有效实施，培训内容至少应包含质量制度以及相关法律法规。一项未落实，减1分。 | √ | √ | √ |  |  | | 查看文件、记录 | 5、培训应有考核或评估，建立个人培训档案。一项未落实，减1分。 | √ | √ | √ |  |  | | 6.3 | 储存配送生物制品、疫苗的企业，应有冷链验证体系、包材标准、温度监控及冷链物流作业流程 | | 查看文件 | 1、建立冷链管理组织、具有完整的冷链管理制度、作业指导书。一项未落实，减1分。 | **20** | | √ | √ | √ |  |  | | 查看文件、记录 | 2、应建立验证管理流程，制定年度验证计划，每项验证应有专人负责，有验证文件和记录。一项未落实，减1分。 | √ | √ | √ |  |  | | 查看文件、记录 | 3、冷链设施设备、作业流程（包括但不限于冷链产品的出入库、贮存、保温箱及其使用方法、发运、运输线路等）启用或实施前均应经过验证，符合要求后方可使用，并有相应的作业指导书。一项未落实，减1分。 | √ | √ | √ |  |  | | 查看验证文件 | 4、冷库、冷藏车、保温箱的验证：应经过空载和满载的温度分布验证，符合要求后方可使用。一项未落实，减1分。 | √ | √ | √ |  |  | | 查看验证文件 | 5、冷库的温度验证应在每年的极端天气条件下（夏季、冬季）分别实施。一项未落实，减3分。 | √ | √ | √ |  |  | | 查看台帐 和相关证明文件 | 6、应建立计量器具（包括但不限于温湿度测量仪、温度记录仪）周期校准台账，定期进行校准或检定，有校准或检定证书，并贴有合格标识。一项未落实，减3分。 | √ | √ | √ |  |  | | 查看审计文件和记录 | 7、建立对冷链服务供应商的审核机制，具有年度审计计划、履行情况报告和记录。一项未落实，减1分。 | √ | √ | √ |  |  | | 查看相关文件和现场审核 | 8、生物制品、疫苗等冷藏药品的验收、贮存、出库、运输全过程应有温度监测和记录，并有疫苗专职人员，具备三年以上的实践经验。一项未落实，减1分。 | √ | √ | √ |  |  | | 查看相关文件和记录 | 9、具有针对温度发生异常的偏差处理、变更管理制度和履行记录。一项未落实，减1分。 | √ | √ | √ |  |  | | 查看记录 | 10、具有定期对贮存、运输温度趋势分析和记录。一项未落实，减1分。 | √ | √ | √ |  |  | | 查看文件和记录 | 11、具有运输过程应急预案，并进行演习和记录。无，本项不得分 | √ | √ | √ |  |  | |  | 6.4 | 客户满意度≧91%或客户有效投诉率≦0.4% | | 查看相关记录 | 客户满意度:每低于0.01%，减1分；或客户有效投诉率：每高于0.01%，减1分。 | **10** | | √ | — | — |  |  | | 6.4 | 客户满意度≧93%或客户有效投诉率≦0.08% | | 查看相关记录 | 客户满意度:每低于0.01%，减1分；或客户有效投诉率：每高于0.01%，减1分。 | **10** | | — | √ | — |  |  | | 6.4 | 客户满意度≧95%或客户有效投诉率≦0.01% | | 查看相关记录 | 1、客户满意度:每低于0.01%，减1分；或客户有效投诉率：每高于0.01%，减1分。 | **10** | | — | — | √ |  |  | | 6.5 | 帐货相符率≧99.4% | | 系统记录审核 | 帐货相符率：每低于0.01%，减1分。 | **10** | | √ | — | — |  |  | | 6.5 | 帐货相符率≧99.93% | | 系统记录审核 | 帐货相符率：每低于0.01%，减1分。 | **10** | | — | √ | — |  |  | | 6.5 | 帐货相符率≧99.99% | | 系统记录审核 | 帐货相符率：每低于0.01%，减1分。 | **10** | | — | — | √ |  |  | | 6.6 | 货物准时送达率≧99.4% | | 查看相关记录 | 货物准时送达率：每低于0.01%，减2分。 | **10** | | √ | — | — |  |  | | 6.6 | 货物准时送达率≧99.93% | | 查看相关记录 | 货物准时送达率≧：每低于0.01%，减1分。 | **10** | | — | √ | — |  |  | | 6.6 | 货物准时送达率≧99.99% | | 查看相关记录 | 货物准时送达率：每低于0.01%，减1分。 | **10** | | — | — | √ |  |  | | 6.7 | 出库差错率≦0.4% | | 查看相关记录 | 出库差错率：每超过0.1%，减1分。 | **10** | | √ | — | — |  |  | | 6.7 | 出库差错率≦0.08% | | 查看相关记录 | 出库差错率：每超过0.1%，减1分。 | **10** | | — | √ | — |  |  | | 6.7 | 出库差错率≦0.01% | | 查看相关记录 | 出库差错率：每超过0.01%，减1分。 | **10** | | — | — | √ |  |  | | **物流规划和创新能力** | 7.1 | 企业物流新业务比重不低于10% | | 系统记录审核 | 每低于0.1%，减1分。 | **10** | | — | √ | — |  |  | | 7.1 | 企业物流新业务比重不低于20% | | 系统记录审核 | 每低于0.1%，减1分。 | **10** | | — | — | √ |  |  | |  |  |  | |  |  |  | |  |  |  |  |  | | **注：** | | | | |  |  | |  |  |  |  |  | | 1、表中“大项”系按照《药品批发企业物流服务能力评估指标》附录A《分级标准》中的大项排列；  2、客户投诉率是指在年度周期内客户对不满意业务的投诉总量与企业业务总量的比率；  3、客户满意度是指在年度周期内企业对顾客满意情况的调查统计；  4、租用货运车辆是指企业通过契约合同等方式可进行调配、利用的货运专用车辆；  5、租用仓储面积是指企业通过契约合同等方式可进行调配、利用的仓储总面积。 | | | | | | | | | | | |  | |  |  |