



Drug Distributor Compliance Keys

This list reflects the most commonly observed inspection violations and does not represent a comprehensive listing. Licensees should review all applicable laws to ensure compliance. (This list is random and not in any specific order)

FACILITIES

- Insufficient outside lighting. [20 CSR 2220-5.030(3)(C)12.]
- Lack of equipment to measure temperature in drug storage refrigerators/freezers. [20 CSR 2220-5.030(3)(B)]
- Lack of equipment to measure temperature/humidity in other drug storage areas. [20 CSR 2220-5.030(B)]
- No alarm system on facility. [20 CSR 2220-5.030(3)(C)13.]
- No separate area for distressed/outdated products. [20 CSR 2220-5.030(3)(C)7.]
- No separate area for flammable products. [20 CSR 2220-5.030(3)(C)8.]
- Veterinary products not stored separately from human products. [20 CSR 2220-5.030(3)(C)9.]
- Drug products not kept off floor or on pallets. [20 CSR 2220-5.030(3)(C)4.]
- No daily temperature recordings for refrigerators/freezers used for drug storage. [20 CSR 2220-5.030(3)(B)]
- No daily temperature/humidity recordings for other drug storage areas. [20 CSR 2220-5.030(3)(B)]
- Insufficient security (i.e.- drop ceilings, doors/locks insufficient to prevent access). [20 CSR 2220-5.030(3)(C)]

RECORDS

- No current written list of personnel authorized to be in facility. [20 CSR 2220-5.030(3)(H)]
- Non-existent or incomplete policies and procedures. [20 CSR 2220-5.030(3)(M)]
- No written job description of Manager-in-Charge or other supervisors of distribution and control. [20 CSR 2220-5.030(2)(C)]

MISCELLANEOUS

- Purchasing from unlicensed vendors. Rule 20 CSR 2220-5.020 generally provides legend drugs and drug-related devices may only be received from Missouri-licensed distributors or pharmacies.
- Distributing to customers not appropriately licensed to receive legend drugs.

