

3PL Inspection Form

40-43-83(F)	Permit Displayed
40-43-89(C)(2)	Refrigerator Temperature (36-46 degrees F)
40-43-89(C)(1)	Suitable size & construction to facilitate cleaning, maintenance, operation
40-43-89(C)(2)	Lighting, ventilation, temperature, sanitation, humidity, space, equipment
40-43-89(C)(3)	Quarantine area
40-43-89(C)(4)	Clean and orderly condition
40-43-89(C)(5)	Free from infestation by insects, rodents, birds, vermin
40-43-89(D)(1)	Secure from unauthorized entry
40-43-89(D)(2)	Alarm system to detect entry after hours
40-43-89(D)(3)	Security system that provides suitable protection against theft and diversion
40-43-89(E)	Drugs stored at appropriate temperatures and appropriate conditions
40-43-89(G)(1)	Drugs outdated, damaged, deteriorated, misbranded, or adulterated quarantined
40-43-89(G)(4)	Recordkeeping requirements must be complied with for all outdated, damaged, deteriorated, misbranded, or adulterated drugs
40-43-89(H)(1)	Establish and maintain inventories and records of all transactions
40-43-89(H)(1)(a)	Records contain source of drug, including name and principal address of the seller and address of location shipped from
40-43-89(H)(1)(b)	Records contain identity and quantity received, distributed, or disposed of drugs
40-43-89(H)(1)(c)	Records contain dates of receipt, distribution or other disposition
40-43-89(H)(2)	Records maintained for two years
40-43-89(H)(3)	Records must be readily available
40-43-89(I)	Written policy and procedure for receipt of drugs
40-43-89(I)	Written policy and procedure for security of drugs
40-43-89(I)	Written policy and procedure for storage of drugs
40-43-89(I)	Written policy and procedure for inventory of drugs
40-43-89(I)	Written policy and procedure for distribution of drugs
40-43-89(I)(1)	Written policy and procedure whereby oldest stock is distributed first
40-43-89(I)(2)	Written policy and procedure for drug recalls
40-43-89(I)(3)	Written policy and procedure for disasters
40-43-89(I)(4)	Written policy and procedure to ensure outdated drugs are segregated
40-43-89(I)(4)	Documentation of disposition of outdated drugs maintained for two years
	List of manufacturers, wholesalers, distributors for whom 3PL provides services
	Reports to FDA
	Identifies, records, and confirms losses or thefts in US