

CAFOLI LIFecare

Wholesale Drug License (20B & 21B) Complete Guide

This guide provides a complete overview for pharma distributors and PCD franchise partners in India to obtain a Wholesale Drug License (Forms 20B & 21B). It includes application steps, required documents, infrastructure checklist, and inspection readiness requirements.

1. Application Process (ODLS Portal)

- Obtain Class 3 Digital Signature (DSC)
- Register on State Drug Authority Portal
- Upload documents (PAN, GST, Premises, QP, Layout)
- Apply for Form 20B & 21B
- Pay Government Fees
- Schedule Inspection

2. Required Documents Checklist

Category	Document Required	For
Identity	PAN Card, Aadhaar, Photos	20B & 21B
Business	GST, Firm Registration	20B & 21B
Premises	Rent Agreement, Electricity Bill, Layout	20B & 21B
Qualified Person	Pharmacist Degree / Experience	Mandatory
Storage	Refrigerator, Thermometer, Logs	21B Mandatory

3. Inspection Readiness

- Minimum 15 sq.m premises
- Storage racks installed
- Medical refrigerator working
- Temperature log maintained
- Separate quarantine area
- Qualified person present during inspection

4. Post-License Compliance

- Maintain purchase & sale records
 - Batch tracking system
 - Expiry & damage register
 - Retain records for minimum 5 years
 - Pay retention fee every 5 years
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Prepared by Cafoli Lifecare – PCD Pharma Franchise & Third Party Manufacturing Partner