

CDSCO REGISTRATION

Manufacturing Drug License

Document Checklist for CDSCO Registration

For manufacturing drugs/pharmaceutical products, issued by the State/Central Licensing Authority.

Documents Required

- PAN card of the business/company
- Business registration/incorporation proof
- Site plan and building layout of the manufacturing unit
- Ownership/lease proof of the manufacturing premises
- List of machinery and equipment installed
- Qualified technical staff details (Production/Quality Control/Quality Assurance - degree and registration)
- Master formula and manufacturing process details of each product
- Water testing report and quality control lab details
- Good Manufacturing Practice (GMP)/Schedule M compliance details
- List of products proposed to be manufactured

Note: The above list indicates commonly required documents. Additional documents may be requested by the Central Drugs Standard Control Organisation (CDSCO) or State Drug Licensing Authority depending on the specific case. Expert Registration confirms the exact requirement after a brief consultation.