GSDP readiness checklist: 20 points

For one site: factory store, godown, C&F or shop. Based on CDSCO's draft GDP guidelines (CDSCO/GDP.PP Ver. 00).

Draft G.S.R. 984(E)

Site: _____ Licence type: _____ Date: _____ Checked by: _____

#	Control	Yes (2)	Partly (1)	No (0)
	QUALITY SYSTEM AND PEOPLE			
1	**Quality system** Is there a written GDP/GSDP policy or quality manual with a named responsible person?	☐	☐	☐
2	**People** Do store, dispatch and delivery staff have job descriptions and recorded GDP training?	☐	☐	☐
3	**Procedures** Are there written SOPs for receipt, storage, dispatch, returns, recall and complaints?	☐	☐	☐
	PREMISES AND STORAGE			
4	**Temperature mapping** Has the storage area been temperature-mapped under representative (summer and winter) conditions?	☐	☐	☐
5	**Temperature monitoring** Are calibrated temperature (and, where needed, humidity) monitors placed at the mapped worst-case spots, with readings recorded?	☐	☐	☐
6	**Cold chain** If you handle 2 to 8 °C products: does cold storage have an alarm, backup power and an excursion procedure? (Answer Yes if not applicable.)	☐	☐	☐
7	**Segregation** Are there separate, labelled areas for quarantine, rejected, returned, recalled and expired stock?	☐	☐	☐
8	**Pest control** Is there a written pest-control programme with service records?	☐	☐	☐
9	**FEFO** Is FEFO enforced at issue, with a regular near-expiry check?	☐	☐	☐
	TRANSPORT			
10	**Vehicles** Are vehicles or shippers suitable for the label storage condition, with qualified shippers for cold chain?	☐	☐	☐
11	**Data loggers** Are transport data loggers used for sensitive products and calibrated at least once a year?	☐	☐	☐
12	**Contract parties** Are there written agreements with transporters, C&F agents and 3PLs that define GDP responsibilities?	☐	☐	☐
	SUPPLY-CHAIN INTEGRITY			
13	**Licensed sources** Do you buy only from licensed sources and sell only to licensed parties, with their licences on file?	☐	☐	☐
14	**Spurious and NSQ** Is there a procedure to segregate suspected spurious or NSQ products and report them to the regulator?	☐	☐	☐

#	Control	Yes (2)	Partly (1)	No (0)
15	**Traceability** Can every dispatch be traced by batch to the customer within hours?	☐	☐	☐
	RETURNS, RECALLS AND COMPLAINTS			
16	**Returns** Are returned goods quarantined on receipt and resold only after a documented assessment?	☐	☐	☐
17	**Recall** Is there a written recall procedure that has been tested with a mock recall in the last 12 months?	☐	☐	☐
18	**Complaints** Is there a complaint register with investigation and CAPA records?	☐	☐	☐
	DOCUMENTATION AND SELF-INSPECTION			
19	**Record retention** Are records kept for at least one year after product expiry (temperature records for shelf life plus one year)?	☐	☐	☐
20	**Self-inspection** Is there an annual self-inspection of storage and distribution, with CAPA follow-up?	☐	☐	☐

34 to 40: low gap. Focus on evidence an inspector can see: records, mapping reports, agreements.

24 to 33: moderate gap. Controls exist but are incomplete or undocumented. Fix the No items first.

Below 24: significant gap. Start with temperature mapping, segregation, licensed-source checks and written SOPs.

Total score: _____ / 40. Draft rule G.S.R. 984(E), dated 4 Nov 2026, is not yet in force; the DTAB-adopted guideline text may differ from the CDSCO draft used here. This checklist is indicative and is not an inspection. Online version with instant gap report: laafon.com/gsdp-guidelines-india. Reviewed by Darshan Singh, a 23+ year QA/QC/regulatory practitioner. Laafon Galaxy Pharmaceuticals · contact@laafon.com · WhatsApp +91 98124 46733