

Table 8 Self-Inspections Standards

- 8.1 Principle: Self-inspections should be conducted in order to monitor implementation and compliance with GDP regulations principles and to propose necessary corrective measures.
- 8.2 Self-Inspections:
- 8.2.1 A self-inspection programme should be implemented covering all aspects of the regulations and compliance with the regulations, guidelines and procedures within a defined time frame. Self-inspections may be divided into several individual self- inspections of limited scope.
- 8.2.2 Self-inspections should be conducted in an impartial and detailed way by designated competent wholesale dealer personnel. Audits by independent external experts may not be used as a substitute for self-inspection.
- 8.2.3 All self-inspections should be recorded. Reports should contain all the observations made during the inspection. A copy of the report should be provided to the management and other relevant persons. In the event that irregularities and deficiencies are observed, their cause should be determined and the corrective and preventive actions should be documented and followed up.