GOOD MANUFACTURING PRACTICES GMP

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DRUG AND COSMETIC ACT 1940,1945

SCHEDULE – T

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Objectives-
Quality maintenance, free from adulteration
Standardization
Raw material
in process-SOP- Standard operating procedure
Final product

Factory Premises-
Location surrounding-
Building- Separate sections , spacious, safety ,proper drainage system , proper ventilation,clean

Water supply
Disposal of waste
Cleaning
Stores-
1.Raw material-FIFO system
Yellow-Under test
Green- Approved
Red- Rejected

2. Packaging material
3.Finished good store
4. Working space
5. Health ,clothing, Hygiene of workers

Records-
Batch manufacturing records-
Distribution records
Record of market complaints

Quality control-
Testing of raw material, in process, final products

Part- II

1.List of machines and equipments, area

2.List of equipment for quality control section