Documents to be produced for Inspection

	Water System	
01	Whether the unit has validate system for treatment of water drawn from own or any other source to render it potable in accordance with standard specified by BIS and water is stored ensuring freedom from microbiological growth	
02	Whether water tank are cleaned periodically and record maintained there of	
	Disposal of waste: -	
03	Whether the unit has obtained consent for air and water from pollution control board	
04	Whether pest control is done regularly	
05	Whether personal handling Beta lactum antibiotics are tested from penicillin sensitivity before employment	
06	Whether personnels in handling of sex hormones cytotoxic and other portent drugs are periodically examined for adverse effect. They should be moved out by rotation	
07	Whether all personnels have undergone medical examination including eye examination and all free from Tuberculosis, Skin and other communicable or contagious diseases and record are maintained thereof	
08	Whether all personnels are trained to ensure high level of Personnel hygiene	
	Raw material	
09	Whether the records of Raw materials are maintained as per schedule U	
	Whether approved vendor list is provided	
	Documentation Record	
10	Whether the records are made at the time of each operation in such a way that all significant activities concerning to the production are traceable. Records and SOPs to be retained at least one year after the expiry of finish products during which all relevant datas should be readily available.	
	Self Inspection and Quality Audit: -	
11	Whether the firm has constituted a self inspection team supplemented with a quality audit procedure to evaluate that GMP is being followed	
	Quality Control System:-	
12	Whether SOPs are available for sampling, inspecting, testing of Raw Materials Finish products and Packing Materials and also for monitoring environmental conditions.	
13	Whether all instruments are calibrated and testing procedure validated before they are deducted for routine testing	
14	Whether Pharmacopoeias, reference standards, working standards and technical books as required are available	
	Specifications:-	
15	Whether specifications for Raw Materials, Packing Materials, Product containers enclosures, Finish Products, In process and Bulk products, for preparation of containers and closures are Available and is complied with as per rules	

	Master Formula Records:-	
16	Whether the unit has maintained Master Formula Records relating to all manufacturing procedures and batch sizes as per rules	
	Packaging Records:-	
17	Whether Authorised packaging instructions for each products, pack size and type are maintained and complied with as per rules.	
	Batch Processing Records:-	
18	Whether the Batch Processing Records for each products on the basis of currently approved master formula is being maintained as per rules	
	Standard Operating Procedure and Records:-	
19	Whether SOPs and records are being maintained and complied with as per rules. Check whether following SOP's are available	
	a) SOP for receipt of material	
	b) SOP for internal labeling, quarantine, storage, packaging material and other materials	
	c) SOP for each instrument and equipment	
	d) SOP for sampling	
	e) SOP for batch numbering	
	f) SOP for testing	
	g) SOP for equipment assembly and validation	
	h) SOP for Analytical apparatus and calibration	
	i) SOP for maintenance, cleaning and sanitation	
	j) SOP for training and hygiene for the personal	
	k) SOP for retaining reference samples	
	l) SOP for handling, re-processing and recoveries	
	m) SOP for distribution of the product	
	Validation and Process Validation:-	
20	Whether validation studies of processing, testing and cleaning procedures are conducted as per rules	
	Product Recalls:-	
21	Whether the prompt and effective recall system of defective products is being maintained by the unit along with SOPs for recall Operations	
	Complaints and Adverse Reactions:-	
22	Whether the unit has maintained review system for complaints concerning the quality of products along with SOPs	
	Site Master File:-	
23	Whether Site Master File as per rules have been prepared & maintained.	
24	Sales Invoices (Domestic & Export) during last Licensing period.	
25	Copies of New drugs, if any, permitted to manufacture during last Licensing period	