

To,
The All Concerned

Kindly send your valuable comments on this check list up to 25th September, 2008 at
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CHECKLIST FOR WHO GMP

Sl. No.	GMP CLAUSE	AREAS/ACTIVITIES TO BE AUDITED	OBSERVATIONS		
			Docum ent Review	Evidence	Grade
1		General Names & address of the Manufacturing unit. Manufacture Lic. No. Validity of Manufacture Lic. Tele. No. Fax. No. E-Mail. Web site.			
	1.	QUALITY ASSURANCE IN THE MANUFACTURE OF HERBAL MEDICINES			
		Is there any appropriate quality assurance system for manufacturing of herbal medicine?			
	2.	GOOD MANUFACTURING PRACTICE FOR HERBAL MEDICINE			
		Do production operation follow defined procedures to obtain products of requisite quality?			

		3.	SANITATION AND HYGIENE			
		3.1 Maintenance and cleaning	Whether proper sanitation and hygiene are being maintained in the manufacturing			
		3.1.1 General	Are establishment and equipment kept in an appropriate state of working?			
			Are cleaning chemicals handled and used carefully and in accordance with manufacturers instructions?			
			Are cleaning chemicals stored separately from ASU herbal medicine, in clearly identified containers to avoid the risk of (malicious or accidental) contamination of herbal medicine?			
		3.2 Cleaning programmes				
		3.2.1 Specifications	Do cleaning procedures specify: - areas, items of equipment and utensils to be cleaned; - responsibility for particular tasks; - method and frequency of cleaning; - monitoring arrangements.			
			Are cleaning schedule available for floors, walls, ceiling, doors and windows, electrical fitting?			
			Are SOP's available for cleaning & sanitation?			
			Are disinfectants used rotated?			
			Are log books maintained for cleaning and sanitation?			
			Is microbial load monitored in different sections?			
			Are adequate facilities like wash-basin with running water, hand drier & clean towels, etc., available for personal hygiene before entering into production area?			
			Is high level of sanitation and hygiene is being maintained during the manufacturing process?			
			Is the water supply to the manufacturing unit is being monitored for consistency of quality?			
			Is the waste from the manufacturing unit is being disposed of regularly in order to maintain a high level of hygiene in the manufacturing area?			

			Is clearly marked waste-bins are available?			
		4.	QUALIFICATION AND VALIDATION			
			Is quality control facility is available for raw materials, intermediates and finished products?			
			Is competent persons are available for carrying out validation?			
			Is batch-to-batch consistency being maintained ensuring quality, efficacy and safety between the batches?			
			Is SOP specifying critical process steps and factors like extraction time, temperature and solvent purity available?			
			Is annual review of qualification and validation done?			
			Is predefined and approved protocols for validation available?			
			Are validation of analytical methods automated systems and procedures done?			
		5.	COMPLAINTS			
		1.	Is the person dealing with the complaints and deciding on the measures to be taken on herbal medicines is having proper training/ in this regard or having enough experience in the quality control of herbal drugs?			
		2.	Is there a written procedure describing the action to be taken?			
		3.	Is there separate registers being maintained for product quality and adverse reaction?			
		4.	Is the complaints records reviewed regularly and licensing authority being informed regularly?			
		6.	PRODUCT RECALL			
		6.1 Tracing & tracking	Are written procedures available for receipt and control of return products?			
			If reasons for returning the product implicates other batches is an investigation made and report prepared?			
			Is SOP for storage to recalled herbal medicines in secure segregated area?			

			Is a responsible person authorised for this job?			
		6.2 Destroy or reprocess	Are returned or salvaged drug products destroyed unless QC determines their reprocessing?			
			Are records of returned products maintained including their disposition?			
			Are all competent authorities of all counties to which a given product has been distributed have been informed?			
		7.	CONTRACT PRODUCTION AND ANALYSIS			
			1. Is contract given/permitted to audit facilities of the contract acceptor?			
			2. Is the contract giver is following principles of GMP?			
			3. Is the contract giver provide all information regarding manufacture, quality control, premises, personnel and other materials?			
			4. Is the contract acceptor deliver processed product and material which comply specifications and released by authorized person?			
			5. Is contract partner is knowledgeable in herbal medicines including their production & quality control?			
		8.	SELF - INSPECTION			
			1. Is there exists a self-inspection team for inspection of various tools of GMP?			
			2. Is any one of the member of the self - inspection team possess a thorough knowledge of herbal medicines and GMP?			
			3. Whether there is written instructions for self-inspection?			
			4. What is the frequency of self-inspection?			
			5. Is self-inspection with quality and suppliers audit is being carried out?			
		9.	PERSONNEL			
			Name of Incharge (a) Production (b) Quality Assurance			
			Number of Production Supervisors/Asstt. Mfg. Chemist			
			Are sufficient number of analysts with necessary qualification and adequate experience available?			

			Is responsible staff have their specific duties recorded in written?			
			Are production and quality functions independent of each other?			
			Are all sections adequately staffed (Supervisors / Asstt. Mfg. Chemist)			
			Do all personnel receive GMP training? (Check course content of training)			
			Is training documented?			
			What is the periodicity of training?			
			Are training records available?			
		10.	TRAINING			
			Are the personnel have adequate training in the field of ASU herbal medicines?			
		10.1 Awareness and responsibilities	Are personnel aware of their role and responsibility in protecting ASU herbal medicine from contamination or deterioration?			
			Do ASU herbal medicine handlers have the necessary knowledge and skills to enable them to handle ASU herbal medicine hygienically? Are personnel who handle strong cleaning chemicals or other potentially hazardous chemicals instructed in safe handling techniques?			
		10.2 Training programs	Are the following factors taken into account in assessing the level of training required :			
			- the nature of the ASU herbal medicine, in particular its ability to sustain growth of pathogenic or spoilage micro-organisms;			
			- the manner in which the ASU herbal medicine is handled and packed, including the probability of contamination;			
			- the extent and nature of processing or further preparation before final consumption;			
			- the expected length of time before consumption.			
		10.3 Instruction and supervision	Are periodic assessments of the effectiveness of training and instruction programmes carried out to ensure that procedures are being implemented effectively?			
			Are training programmes routinely reviewed and updated?			

		10.4 Refresher training	Is a system in place to ensure that ASU herbal medicine handlers remain aware of all procedures necessary to maintain the safety and suitability of ASU herbal medicine?			
		11.	PERSONAL HYGEINE			
			Establishment : Personal hygiene			
		11.1 Health status				
		11.2 Access prevention	Is recruitment of an employee preceded by medical examinations?			
			What is the periodicity of subsequent medical examinations?			
			Is an employee whose state of health is doubtful immediately removed from work site until he is fully recovered?			
			Illness and injuries			
		11.3 Conditions to be reported	Are following conditions reported to management in order to assess the need for medical examination and or possible exclusion from ASU herbal medicine handling, include : -jaundice -diarrhea -vomiting -fever -sore throat with fever -visibly infected skin lesions (boils, cuts, etc.) -discharges from the ear, eye or nose			
			Personal cleanliness			
		11.4 Protective clothing	Do ASU herbal medicine handlers maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing, head covering and footwear.			
		11.5 Cuts and wounds	Are personnel with minor injury, cuts and wounds permitted to work in processing areas?			

		11.6 Washing hands	Do personnel always wash their hands : -at the start of ASU herbal medicine handling activities; -immediately after using the toilet; -after handling raw ASU herbal medicine or any contaminated material which could result in contamination of other ASU herbal medicine items.			
			Personal behaviour			
		11.7 Smoking, eating, sneezing	Do people engaged in ASU herbal medicine handling activities refrain from behaviour which could result in contamination of ASU herbal medicine, for example: -smoking; -spitting; -chewing or eating; -sneezing or coughing over unprotected ASU herbal medicine.			
		11.8 Jewellery	Are personal effects such as jewellery, watches, pins, etc. brought in ASU herbal medicine handling areas?			
		11.9 Cleanliness and behaviour	Do visitors to ASU herbal medicine manufacturing, processing or handling areas wear protective clothing and adhere to the other personal hygiene provisions in this section?			
		12.	PREMISES			
		12.1 Design and layout	Do the internal design and layout of establishment permit good ASU herbal medicine hygiene practices including protection from cross-contamination?			
		12.2 Design and layout	Do the internal design and layout of establishment permit good ASU herbal medicine hygiene practices including protection from cross-contamination?			
		12.3 Internal structures and fittings	Is the structure of establishment built of durable materials and easy to clean, maintain and where appropriate, disinfect?			
			Are surfaces of walls, partitions and floors made of impervious materials and have smooth surface?			

			Are floors constructed to allow adequate cleaning and drainage?			
			Are ceilings and overhead fixtures constructed and finished to minimize build up of dirt, condensation and shedding of particles?			
			Are windows easy to clean and constructed to minimize build up of dirt?			
			Where necessary, are windows fitted with removable and cleanable insect-proof screens?			
			Are doors smooth, non-absorbent and easy to clean and disinfect?			
			Are working surfaces that come into direct contact with ASU herbal medicine of sound condition, durable and easy to clean, maintain and disinfect?			
		12.4 Temporary/ mobile premises; vending machines	Are temporary/mobile premises located, designed and constructed to avoid contaminating ASU herbal medicine and harbouring pests? Is there proper storage conditions for available for plant extracts, tinctures and other preparation require special condition of humidity & temperature?			
		12.5 General	Is suitable air exhaust mechanism employed to prevent accumulation of fumes & vapours?			
			a) Any open drain blocked sewer or public lavatory nearby? b) Are any products other than drugs manufactured in the same building?			
			Is there adequate space for equipment, material and movement of personnel and materials?			
			Is there any programme to check entry of birds, rodents and insects?			
			Are lighting and ventilation adequate?			
			Are facilities for changing street clothes, footwear, washing and toilets adequately and satisfactorily maintained?			
			Are sewage, trash and other effluent disposal adequate?			
			Is there any programme for general house-keeping?			
			Are records of cleaning & painting of the premises maintained?			
			Key aspects of hygiene control systems			

		12.6 Time and temperature control	Are control systems for temperature and time during heating, cooling and storage in place?			
			Are critical limits defined and registered?			
			Are the equipment tested for accuracy?			
		12.7 Specific process steps	Are any specific process steps like chilling, irradiation, drying, chemical preservation, vacuum packaging considered and controlled?			
		12.8 Microbiological and other specifications	Are physical, chemical and microbiological specification available for ASU herbal medicine and ASU herbal medicine ingredients?			
			Are these based on sound scientific principles?			
			Are monitoring procedures, action limits and analytical methods in place for these?			
		12.9 Microbiological cross-contamination	Are raw materials, semi-finished and finished products stored separately?			
			Is access to processing areas restricted or controlled?			
			Is the access and control procedure defined and documented?			
			Are surfaces, utensils, equipment, fixtures and fittings cleaned and where necessary, disinfected after contact with raw ASU herbal medicine, to prevent contamination?			
		12.10 Physical and chemical contamination	Is a system in place to prevent contamination of ASU herbal medicine products by foreign bodies (e.g. glass, metal, dust, harmful fumes) and hazardous chemicals.			
			Are suitable and effective detection or screening devices used where necessary?			
			Product information and consumer awareness			
		12.11 Batch identification	Is there master production document for each drug product being produced?			
			Are alterations to processes recorded and authenticated by competent authorized persons?			
			Is the addition of components verified by another person?			
			Is an appropriate in process control being performed?			
			Are non sterile products tested for microbial load & whether microbial			

			load is less than limits recommended by WHO?			
			Are adequate efforts are taken to prevent cross contamination during production of different product in the same facility?			
			If drying ovens are used – Whether one product is dried at one time?			
			Are instruments used for temperature, pressure or other recording calibrated periodically and records maintained?			
			Are semi finished products stored properly and are identified?			
			Is stage of manufacture clearly indicated on containers?			
			Is batch production record prepared for each batch of product and maintained?			
			Do the batch production records indicate that each significant step in manufacturing was performed and checked by second individual whenever appropriate?			
			Are master instructions or procedures readily available in production areas?			
			Are these instructions and procedures being followed?			
			Are only materials, containers and appliances necessary for the job in hand stored in the vicinity of the manufacturing areas and are these properly labeled with name of the product, batch no. date etc.?			
			PRINTED LABELING AND PACKAGING MATERIAL CONTROL			
			Packaging			
		12.12 Design and materials	Do packaging design and materials provide adequate protection for products to minimize contamination, prevent damage and accommodate proper labeling?			
		12.13 “ASU HERBAL MEDICINE-grade” materials and gases	Are packaging materials non-toxic? Do they pose a threat to the safety and suitability of ASU herbal medicine under specific conditions, storage and use?			
		12.14 Reusable packaging	Are re-usable packaging easy to clean and disinfect?			

			Do the containers and closures meet required specification?			
		13.	EQUIPMENT			
		13.1 General	Are equipment and containers designed such that they can be adequately cleaned, disinfected and maintained?			
			Are equipment made of non-toxic materials?			
		13.2 Containers for waste and inedible substances	Are containers for waste suitably identified?			
			Are containers for waste closable to prevent malicious or accidental contamination of ASU herbal medicine?			
		General	Is it constructed in such a way that lubricants, coolant, etc. cannot contaminate the drug product?			
			Does the equipment permit cleaning and maintenance?			
			Do all apparatus/equipment bear appropriate labels to identify the product for which the equipment is used, its batch no., date, etc.?			
			Are SOP's available for cleaning maintenance and sanitation of major equipment?			
			Are logbooks maintained for cleaning, maintenance and sanitation of major equipment?			
			Are SOP's readily available to operators?			
		14.	MATERIALS			
			Whether the starting material is being checked for its quality?			
			Is this starting material kept in the storage area is properly labeled?			
			Is there any mechanism for quarantining incoming raw material?			
			Are all materials and product and stock rotation by a first expire, first-out rule?			
			Are status of the contents (e.g. on quarantine, on test, released, rejected, returned, recalled) being maintained			
		14.1 Packing materials	Are the printed packaging material is stored in secured condition and managed only by designated persons?			
			Is out dated and obsolete packaging material is destroyed properly and its disposal recorded?			
			Are intermediate and bulk products kept under appropriate conditions?			

			Are finished products has been quarantined until their final release?			
			Are rejected materials and products clearly marked as such and kept in restricted areas?			
			Are recalled products identified and stored in a secured area?			
			Are products returned from the market destroyed and record of action taken is maintained?			
			Are records for the receipt and preparation of reagents and culture media being kept?			
			Are the reagents prepared in the laboratory being prepared according to written procedures and properly labeled?			
			Is the label on the reagent bottle indicates concentration, standardization factor, shelf life, the date when standardization is due and the storage conditions?			
			Are reference standards maintained for comparison?			
			Are reference standard kept under the responsibility of a designated person in a secured area?			
			Is secondary or working standard being maintained and periodically standardized against an official reference standard and checked periodically for deterioration?			
			Are reference standards properly labeled?			
		15.	DOCUMENTATION			
		15.1	Documentation and records			
		15.2 Retaining records	Are appropriate records of processing, production and distribution kept and retained for a period that exceeds the shelf life of the product?			
		15.3 Effectiveness and credibility				
		Documentation	Are SOP's available for the following:			
			- receipt of raw materials and other components?			
			- quarantine and storage?			
			- quality control system and approval / rejection?			

			- release to production?			
			- weighing and dispensing?			
			- processing and production operations?			
			- packaging and labeling?			
			- quality control?			
			- in-process testing & control?			
			- finished product?			
			- storage of finished products?			
			- distribution?			
			- returned goods?			
			- recalls and complaints?			
			- cleaning and maintenance?			
			- quality control of water?			
			- for reworking of nonconforming batches in existence?(If yes, check records)			
			Have these SOP's been prepared, signed and dated by responsible person?			
			Are there additional documents like log books, notebooks or other similar records available to show execution of various functions?			
			In case of review and changes, are SOP's signed by responsible person and do these show their date of effectiveness?			
			Are there records of receipts of raw materials and do these have following information? (Goods Receipt Note-GRN)			
			- receiving GRN document number?			
			- date of receipt?			
			- supplier?			
			- manufacturer?			
			- manufacturer's batch number?			

			- type and size of containers?			
			- number of containers and conditions?			
			Are specification available for all materials?			
			Are they dated authorized?			
			Are test methods validated?			
			Are periodic review of specification carried out to ensure compliance with new/revised National / International pharmacopoeia			
			Are there records of stock and issue of raw materials and do these have following information:			
			- opening balance?			
			- date of receipt?			
			- quantity received?			
			- name and batch number assigned by the manufacturer?			
			- invoice number, date name and address of supplier?			
			- analysis report no. & date?			
			- date of expiry?			
			- name and batch number of product for manufacture for which issued?			
			- balance?			
			- signature of issuing person?			
			Is there master formulation records for each drug product being produced?			
			Is there a separate master production documents for each dosage form/batch size?			
			Are these master production records signed and dated by competent person?			

			<p>Do they show the following particulars:</p> <ul style="list-style-type: none"> -the name, strength and description of the dosage form? -name and quantity of each active ingredient per dosage unit or per unit of weight or me ASU Herbal medicine of the drug product? -the total weight or me ASU Herbal medicine of any dosage unit? -a complete list of components identified by the name /codes? -an accurate statement of the quantity of each component? -calculated excess of component, if any? -the critical weight, me ASU Herbal medicine or yield at appropriate processing stage? -description of containers, closures and packaging materials? -complete manufacturing instructions? -method of preparing critical equipment including cleaning, assembling, calibration & sterilizing? -sampling and testing procedures, including in-process controls? -specifications and precautions to be taken? 			
			Is a batch production record prepared for every batch produced?			
			Is the reproduction of appropriate master production documents or it has all critical information about the batch?			
			Are batch records retained for at least one year after expiry date?			
			Has it been checked for accuracy, signed and dated by a responsible person?			
			Are the records maintained by QC for all the test carried out?			

		<p>Do these records include :</p> <ul style="list-style-type: none"> -the name of the product -number of the batch being manufactured? -issue slip with Lab ref. No? -Job Cards? -graphs, chart, spectra, etc? -list of major equipment used? -in process testing report? -calculations of yield? -notes on deviations with signed authorization? -signature of individuals who performed the? -material return to store slip? -Lab. Report of final product? -review of results for any raw material issued under "Positive Recall"? -signature of the designated person responsible for the review of records for accuracy and compliance with established standards? 			
		Are other associated records available?			
		Is documentation available readily for examination?			
		<p>Where errors have been made in entering or transcribing data :</p> <ul style="list-style-type: none"> -have errors been crossed out with one line? -have corrections been made above those crossed out? -are corrections dated and initialed? 			
		Are batch production records capable of giving complete history of the batch right from the RM stage to the distribution of FP?			
		CALIBRATION OF INSTRUMENTS			
		Are the balances calibrated routinely?			
		Have the equipment used in the production of ASU medicines been calibrated?			
		Have thermometers/thermocouples been calibrated?			
		Have the pressure gauges been calibrated?			
		Are the instruments routinely calibrated?			
		Is the following information available?			

			-fax, telex, telephone numbers and addresses of national, religion and local regulatory authorities? -fax, telex, telephone numbers and addresses of radio, television and press agencies? - fax, telex, telephone numbers and addresses of distribution, wholesalers, hospitals etc? -fax, telex, telephone numbers and addresses of competent authorities of the countries to which the drug products are exported?			
			Is there a system so that distribution records are readily available to the designated person responsible for product recalls?			
			Is the progress of product recalls recorded and final report issued including reconciliation between the delivered and recovered quantities of the product?			
			Is the effectiveness of product recalls evaluated from time to time?			
			Is there a segregated area for recalled products?			
			Is proper documentation is available for manufacturing and marketing authorizations?			
			Are the documents have unambiguous contents with clear title, nature and purpose?			
			Are the documents being regularly reviewed and kept upto date and are superseded documents being maintained for specified period of time?			
			Are proper labels available and are in use for quarantined, accepted, rejected, clean, reference standards etc.?			
			Are SOP's available for testing procedures?			
			Are pharmacopoeias, reference spectra and other reference spectra and other reference material available in the Q.C. laboratory?			
		16.	GOOD PRACTICES IN PRODUCTION			
			Control of operation			
			Is proper care is taken so that material is protected from rain and			

			microbiological contamination?			
			Is proper care is taken to choose cleaning methods for herbal material?			
			Is proper care is taken to avoid cross contamination?			
			Is periodic first-aid training given to staff?			
			Are electrical connections, wiring etc., checked regularly?			
			Is flame-proof equipment used where flammable solvents or materials are stored or handled during manufacture?			
			Is adequate fire fighting equipment like fire extinguishers, ladders, fire buckets filled with water / sand, etc. available?			
			Are staff trained in fire fighting operations?			
			Is the building safe and provided with emergency exit, escape routes, ladders etc.?			
			Does the firm maintain accident history/record? If yes, comment on its adequacy?			
			Is time limit is specified for each step and adhered to time limit?			
			Is handling of materials and products like receipt and cleaning, quarantine, sampling, storage, labeling, dispensing, processing, packaging and distribution are being done in accordance with written procedures or instruction?			
			Is any deviation from written procedures is being avoided or if occur are they being done in accordance with approved procedures?			
			Is operation of different products being carried out in same room?			
			Is there exists facility for proper air control during the production of dust while powdering herbal materials?			
			Is proper control system is there to prevent cross-contamination?			
			Is there any mechanism for indicating breakdown of instruments/machines and rectification of faults?			
			Are the measuring and control instruments being calibrated at regular time interval?			
			Is special care being taken in handling of labels?			
		General	Transportation			

		Requirements	Is ASU herbal medicine adequately protected during transport to assure safety?			
			<p>Are conveyances and bulk containers designed and constructed so that they :</p> <ul style="list-style-type: none"> -do not contaminate ASU herbal medicines or packaging; -can be effectively cleaned and, where necessary, disinfected; -permit effective separation of different ASU herbal medicines or ASU herbal medicines from non-ASU herbal medicine items where necessary during transport; -provide effective protection from contamination, including dust and fumes; -can effectively maintain the temperature, humidity, atmosphere and other conditions necessary to protect ASU herbal medicine from harmful or undesirable microbial growth and deterioration likely to render it unsuitable for consumption; -allow any necessary temperature, humidity and other conditions to be checked? 			
		Use and maintenance	Are conveyances and containers for transporting ASU herbal medicine kept in an appropriate state of cleanliness, repair and condition?			
			Where the same conveyance or container is used for transporting different ASU herbal medicines or non-ASU herbal medicines, effective cleaning and, where necessary, disinfections is there?			
		17.	GOOD PRACTICES IN QUALITY CONTROL			
			Is there any independent Quality control section?			
			Is person experienced in quality control of herbal medicines heading the QC section?			
			Are Raw materials, intermediate products and finished products being tested regularly?			
			Are the tests being carried out in accordance with the written test procedures?			
			Is the finished before dispatch to market is being tested for its quality and consistency?			

			Is the shelf lives of the finished products and when necessary starting materials and intermediate products being carried out.				
			Do the QC persons have access to production areas for sampling and investigations?				
			Signature of persons Comprising self-inspection team				