PART A: DETAILS OF APPLICATION

Manufacturer:
Address:

Product Registration Holder (PRH) :

PART B: GMP GUIDE EVALUATION

Malaysian Guide: Guidelines on Good Manufacturing Practice (GMP) for Traditional Medicines and Health Supplements (TMHS), Edisi Pertama, 2008.

Guide being reviewed:

Authority / Certification Body & Country:

PART C: Checklist for Minimum Parameters Required for Guideline Evaluation

Chapter	Para as per guide	Scope	Note	Applicant's Review *(please indicate the reference i.e clause, page etc.)*	NPRA's Review
1. Quality Management	1.2	Appropriate system of Quality Assurance established	The guide should be able to show that quality management is in place. Basic concept of QA, GMP and QC are shown inter related		
	1.3	Basic requrements for GMP fulfilled			
	1.4	Basic requirements of Quality Control fulfilled			
	1.5	Regular periodic Product Quality Review (PQR) conducted and documented			
2. Personnel	2.1	Organisation chart, duties recorded in job descripton, independancy of Production and QC Head	The guide show the requirement of an organizational structure; appropriate qualified person are being employed; training program in place along with required documentation. Health of the working personnel and hygiene requirements are discussed		
	2.6	All personel involved in manufacturing trained in particular operations and GMP			
	2.7	Continuous training with adequate frequency to staff			
	2.8	Records of training maintained, training evaluated			
	2.10	Pre-employment and routine health examinations			
	2.11	All personel to practice and trained in personel hygiene			
	2.14	Direct contact between operators hands and raw material, intermediate and bulk product avoided, use of gloves.			
	2.15	Clean full garments appropriate to tasks to be worn, including hair cover and shoes. In-house laundry encouraged.			
	2.17	Smoking, eating, drinking etc in restricted areas and not permitted in areas that may adversely affect product quality.			
3. Premises & Equipm	3.1	Premises of suitable size, design, constuction and location to facilitate proper operation, cleaning and maintenance			
	3.3	All premises maintained in clean and tidy condition			
	3.5	Premises located to avoid contamination from surrounding environment.			
	3.7	Constructed and maintained to protect against weather, pests etc.			
	3.10	Defined areas for operations:eg. incoming, quarantine, dispensing packaging			

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ent	3.11	Requirements of Interior surfaces-smooth, non-shedding, easy cleaning	Premises and equipment must be located, designed, constructed, adapted and maintained to suit the operations to be carried out. Requirements for cleaning, maintenance and minimizing risk of contamination are highlighted.		
	3.13	Buildings effectively lit and ventilated			
	3.14	Pipework, light fittings, ventilation points and other services in manufacturing installed in a way to avoid uncleanable recesses			
	3.16	Conditions of buildings reviewed regularly and repaired where necessary			
	3.18	Storage areas of adequate space, suitable lighting			
	3.20	Special and segregated areas for flammable and explosive substances, highly toxic substances, rejected and recalled materials			
	3.22	Special attention paid to cleanliness and good maintenance particularly when dust is generated			
	3.23	Storage requirements (temperature,humidity, light protection) provided and monitored			
	3.24	Storage areas laid out to permit effective and orderly segregation and rotation of stock			
	3.30	Laboratories or QC areas separated from production			
	3.31	Premises for manufacturing should be of suitable design and construction to facilitate good sanitation			
	3.33	Changing rooms into production has adequate hand washing facilities			
	3.36	All cleaning utensils used in production area must not cause potential risk of contamination			
	3.37	Proper handling of waste material			
	3.39	Written procedures for sanitation- schedules, methods, equipment and materials used			
	3.41	Manufacturing equipment should be adequate for operations performed			
	3.42	Measuring equipment used are of appropriate range and precision			
	3.43	Weighing and testing equipment are calibrated, checked and recorded regularly			
	3.44	Written procedures available and followed for cleaning and maintenance of equipment			
	3.46	Defective equipment should, if possible be removed from production and quality control areas or at least clearly labelled as defective			
	3.51	Equipments and utensils should be cleaned after use according to established procedures, stored in clean condition and checked prior to each use			
	3.55	Written procedures established and followed for cleaning and sanitising equipment, utensils and containers used in manufacturing			
	3.57	Records of cleaning and sanitising of equipment maintained			
4. Documen	4.1	System of documentation able to record complete history of each batch. It should permit investigation and tracing of defective products			
	4.2	Documents should contain neccesary information, kept up to date and any amendment formally authorised.			

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tation	4.3	Production records and reference samples of starting and finished product retained for one year after expiry	The guide should explain that documentation system must be establish to control, monitor and record all activities which directly or indirectly impact on all aspects of the quality of medicinal products. It should be able to record executed activities.		
	4.5	Documents approved, signed and dated by authorised persons			
	4.8	Documents should not be hand written; may be allowed where entry of data required. Entries should be in clear, legible and indelible.			
	4.9	Any alteration made to document should be signed, dated and permit the reading or original information			
	4.10	Records should be made/ completed at the time of action that all significant activities are traceable.			
	4.12	Documents on Quality Control should be readily available to the Quality Control Department			
	4.14	There should be appropriately authorised and dated specifications for starting materials, packaging materials and finished products			
	4.15	Specifications for materials of natural origin should be available			
	4.17	Specifications for starting and primary or printed packaging materials shoud be available			
	4.18	Specifications for intermediate and bulk products should be available if these are purchased or dispatched			
	4.19	Specifications for finished poducts may include tests for microbial and heavy metal contamination, physical appearance, uniformity of weight etc.			
	4.22	Processing Instructions are available and for each product and batch size			
	4.24	Batch Processing Records should be kept for each batch processed. The record should carry the number of the batch being manufactured			
	4.25	Before any processing begins, there should be recorded checks to ensure the work station is clear of previous products, documents or materials			
	4.26	Important information should be recorded at the time each action is taken, and after completion, the record signed and dated by the person responsible for the processing operations			
	4.27	Batch Packaging Record kept for each batch or part of batch processed			
	4.28	Before any packaging operation begins, there should be recorded checks that the work station is clear of previous products, documents or materials			
	4.29	Important information should be recorded at the time each action is taken, and after completion, the record signed and dated by the person responsible for the packaging operations			
	4.34	There should be a standard operating procedure describing the details of the batch numbering system, with the objective of ensuring that each batch of intermediate, bulk or finished product is identified with a specific batch number			
	4.38	Written release and rejection procedures should be available for materials and products in particular for the release for sale of finished product			

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	4.39	Distribution records of each batch of a product should be maintained in order to facilitate the recall of the batch if necessary			
	4.40	SOP and associated records should be available. Eg. maintanance, cleaning of premises and equipment, environmental monitoring, pest control etc			
5. Production	5.2	All handling of materials and products should be done in accordance with written procedures and where necessary, recorded	Processes used in production should be capable of yielding finished products which conform to their specifications.		
	5.3	All incoming materials should be checked to ensure that the consignment corresponds to the order			
	5.7	All materials and products should be stored under the appropriate conditions established by the manufacturer to permit batch segregation and stock rotation			
	5.8	Checks on yields, reconcilliation of quantities to ensure no descrepancies and within limits			
	5.9	Operations on different products not carried out simultaneously/ consecutively in the same room unless no risk of cross contamination			
	5.10	Product/materials protected from microbial and other contamination at all stage of processing			
	5.12	At all time during processing, all materials, bulk containers, major items of equipment and where appropriate rooms used should be labelled or otherwise identified.			
	5.15	Access to production premises should be restricted to authorised personnel			
	5.17	Water used as ingredients/ final rinsing of equipment should be treated			
	5.18	Verification or validation needed to prove control of critical aspects of particular operations should be identified. Significant changes that may affect product quality of the product should be verified or validated.			
	5.19	Contamination of a starting material or of a product by another material or product must be avoided			
	5.20	Measures to prevent cross- contaminationand their effectiveness should be checked periodically according to set procedures			
	5.27	Only starting materials which have been released by the Quality Control Department and which are within their shelf life should be used			
	5.33	Production personnel should follow defined and authorised procedures for every stage of each manufacturing process			
	5.36	At all times during processing, all materials, bulk containers and major equipment should be labeled or otherwise identified with the name of the product or material being processed, its strength, quantity and batch number.			
	5.38	The final yield of each production batch should be recorded and shecked againtst the theoretical yield.			
	5.40	Particular attention should be paid to printed materials. They should be stored in adequately secure condition to exclude unauthorised access			
	5.43	When setting up a program for the packaging operations, particular attention should be given to minimising the risk of cross contamination, mix ups or substitution			

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	5.49	The correct performance of any printing operation (eg. Code numbers, epiry dates) to be done separately or in the course of packaging should be checked and recorded			
	5.53	On-line control of the product during packaging should include checking of genaral appearance, completion of packages, correct products and packaging materials used, correct over-printing and correct functioning of line monitors			
	5.57	Finished products should be held in quarantine until their final release under conditions established by the manufacturer			
	5.60	Rejected materials and products should be clearly marked as such and stored separately in restricted areas.			
	5.64	Products returned from the market and which have left the control of the manufacturer should be destroyed unless without doubt their quality is satisfactory.			
6. Quality Control	6.1	Quality control is concerned with sampling, specification, testing, organisation, documentation and release procedures which ensure that the necessary tests are carried out, that the materials are not released for use nor products released for sale and supply until their quality has been assessed to be satisfactory	QC is concerned with sampling, specifications and testing as well as the organisation, documentation and release procedures which ensure that the necessary and relevant tests are carried out, and that materials are not released for use, nor products released for sale or supply, until their quality has been judged satisfactory.		
	6.2	QC department should have laboratory adequately staffed and equipped to perform QC tests required before, during and after manufacture			
	6.3	In the absence of a in-house laboratory, services of external laboratory can be used			
	6.4	The quality of the final product remains the responsibility/ liability of the manufacturer			
	6.8	The identity and quality of starting materials and finished products should be tested.			
	6.9	Besides these principal duties, the Quality Control Department as a whole will also have other duties, such as to establish and implement all quality control procedures, keep reference samples, ensure correct labelling, monitoring stability, etc.			
	6.10	The stability of the bulk, intermediate, and finished product should be monitored according to a continuous appropriate program that will permit the detection of any stability issue associated with the formulation in the marketed package.			
	6.12	Sampling to be done in accordance to approved written procedures			
	6.15	Reference samples from each batch from each batch of finished products should be retained till one year after the expiry date.			
	6.18	Testing performed should be recorded and records of data kept			
	6.19	All the in-process controls, including those made in the production area by production personnel, should be performed according to approved methods and results recorded.			
7. Contract Testing	7.1	Contract production correctly defined, agreed and controlled to avoid misunderstanding resulting in product or work of unsatisfactory quality	There must be a written contract between the		
	7.5	The Contract Giver should ensure that all TMHS and materials delivered by the Contract Acceptor comply with their specifications			

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Production and	7.9	The Contract Acceptor should refrain from any activity that may adversely affect the quality of the product manufactured/ tested for the Contract Giver	contract between the Contract Giver and the Contract Acceptor which clearly establishes the roles and responsibilities of each party.		
	7.11	A contract should be drawn up between the Contract Giver and the Contract Acceptor which specifies their respective responsibilities relating to the manufacture and control of the product.			
	7.13	The contract should describe who is responsible for purchasing materials, testing and releasing materials, undertaking production and quality controls, including in-process controls, and who has responsibility for sampling and analysis.			
8. Distribution, Complaints and Product Recall	8.1	Distribution Records should be readily available to conduct a prompt, accurate and efficient recall whenever necessary	System and appropriate procedures should be in place to record, assess, investigate and review complaints including potential quality defects, and if necessary, to effectively and promptly recall medicinal products		
	8.3	All complaints should be investigated and evaluated. Written procedures established and followed. Written record of each complaint maintained.			
	8.4	A person designated to handle complaints and deciding the measures to be taken			
	8.5	Written procedues describing action to be taken, need to consider recall			
	8.10	Complaint records should be reviewed regularly for any indication of specific or recurring problems requiring attention and possibly the recall of marketed products			
	8.12	Responsibility and procedures for recall of TMHS should be established by the manufacturer to facilitate the recall of a batch from any link of the			
	8.15	There should be established written procedures, regularly checked and updated when necessary, to organise any recall activity			
	8.16	Recall activity should be capable of being initiated promptly and at any time			
	8.19	Recalled products should be identified and stored separately in a secure area while awaiting a decision on their fate			
	8.20	The progress of the recall process should be recorded and a final report issued, including reconciliation between the delivered and recovered quantities of the products			
9. Self Inspection	9.3	Written procedures for self-inspection available and followed	System is in place for the manufacturer to do self-checks or any activities that demonstrate self-inspections		
	9.4	Self inspection conducted in independent and detailed way			
	9.5	All self inspection should be recorded. Reports should contain all observations made and corrective actions done			

Reviewed by (applicant)

Signature:

E-mail/ Phone no.:
Name:
Date: