Checklist for cosmetics GMP

1	**Personal Hygiene**
	Facility should undertake periodic Personal Hygiene Awareness programs for all its employees.
MJ	All people working at different work-stations should be appropriately dressed (Is the Operators use overhead and shoes, musk, gloves when needed)
MJ	All employees should undergo annual health check-up programs & when needed.(if medical insurance is applied)
MJ	Hygiene stations should be provided at entrance to and near critical areas (Manufacturing & Filling).
MJ	Rest room and canteen facilities should be provided in the facility seperated from manufacturing area
	Basic personal hygiene practices should be followed while handling raw and packaging materials.
	Jewelry / personal belongings should not be allowed in manufacturing areas.
MJ	Toilets and change-rooms should be kept clean and tidy.
C	Is toilets separated from changing rooms before entering to process area
2	**Personnel**
MJ	Is there list of personnel organogram & job responsibilities?
C	Is the factory manager graduated from a scientific faculty & studied pharmacology OR chemistry? Is there qualified personnel available for manufacture & quality departments?
C	Are the responsibilities of the quality control & manufacturing unit independent from each other?
	Is there a list of personnel available with qualification, experience & department?
	Job responsibilities of production head
	Job responsibilities for quality control / assurance head
	Are there SOPs related to personnel, including professional qualification & training?

MJ	Training calendar available & approved by Mfg Head / CQA Head?
MJ	Training records available as per the training Calendar?
3	**Housekeeping**
	A well-defined house-keeping program should be in place for the facility.
	There should be adequate number of scrap/ dust-bins across the facility and properly located.
	All scrap/ dust-bins should be clearly identified, kept enclosed and emptied on a regular basis.
	The facility should have a scrap disposal procedure.
MJ	Different types of scrap should be properly segregated and disposed off as per the procedure.
	There should be a designated place for storing of housekeeping equipment.
	The adequacy of housekeeping program should be ascertained by conducting periodic reviews.
MJ	There should not be any hard-to-reach areas inside the facility that render housekeeping difficult.
4	**Pest Control (MUST BE CONTRACTED WITH A COMPANY)**
	A well-defined Pest Control program should be in place for the facility.
	Pest Control treatment should be carried out at adequate frequency. as per SOP given by CQA)
	The adequacy of treatment should be ascertained by conducting periodic reviews of Pest Control system.
	Adequate number of insectocutors should be appropriately located across the facility.
MJ	All wooden pallets should be treated to prevent termite infestation and fungal growth Not allowed in production areas.(while buying)
	Pest Control records should be maintained.
	The chemicals used for Pest Control should be safe for the products.
	MSDS for chemicals used for Pest Control should be readily available.

MJ	The facility should be designed in such a way so as not to allow ingress of pests.
	There should not be any open soil or stagnant water inside the facility premises that could be a breeding ground for insects.
	There should not be any plants touching the walls of the facility from inside.
	There should not be any insect-preferred vegetation within the facility compound.
MJ	There should not be any open drains in and around the facility.
MJ	All the septic tanks should be properly closed.
	Exhaust fan openings should be covered with either wire mesh or louvers.
5	**Facility**
	General
C	Shop-floor area should be adequate for intend use.(Production line should be clearly seperated)
	Different areas on the shop floor should be clearly demarcated for different activities.
	Toilets and wash-rooms should be at a proper distance from the production floor.
	Is there step over bench before production area(or cored)
	Doors
MJ	Air locks should be provided at the entrances to critical manufacturing areas.
	Walls
MJ	Walls should be smooth, painted properly with no peeling of paint.
MJ	There should not be any cracks, crevices or dents in the walls.
MJ	Walls should not be wet and should be without any mould growth on them.

	Walls should be easily cleanable.(with curved end bet) impervious between wall&floor.
	Floor
MJ	Floors should be smooth and without any cracks or dents.
MJ	Floors should be easily cleanable.(with curved end bet)
	Ceiling
	Ceiling should be without any cracks and leakages.
MJ	Ceiling should not be wet and should be without any mould growth on it.
	Windows
MJ	Windows should either be properly sealed or provided with a mesh to prevent entry of insects and pests.
	Illumination
	Lighting should be adequate in every area of the facility.
	Lights should be properly located to provide uniform illumination in the facility. (>100 lux illumniation is to be maintained)
	Drainage
MJ	There should not be any open drains inside and around the facility(GMP covered drains(u-shaped or twisted)
6	**Cleaning and Sanitization**
C	A well-defined and documented C & S plan should be available for every equipment and utensils as well as for special formula.
MJ	C & S SOP should be maintained, for production tanks and equipment.
MJ	The adequacy of cleaning should be ascertained by checking and recording whether the surface to be cleaned is visually clean & free from odour
	The effectiveness of sanitization should be ascertained by testing for microbial count post sanitization.

	Cleaned and sanitized equipment and utensils should be stored properly to prevent any contamination & recleaned if not used within one week.
7	**Receipt, Storage and Handling of Materials:**
	A well-documented system should exist for:
	Unloading of raw and packaging materials
	Loading of Finished products
	Handling of Out-of-specification material
	Status labeling of materials
	Storage of materials and products
MJ	Tracking the expiry of raw materials
	Areas should be demarcated for storage of raw and packaging materials, receiving,rejected semi-finished and finished goods.
	Materials and products should be segregated in such a way as to prevent any accidental self-reactions.
	All the stocks should be stored on pallets 20 cm off the floor.
	All the stocks should be stored sufficiently away from the walls and prevented from exposure to direct sunlight.
	There should be sufficient space left around the stocks to allow ease of cleaning and for inspection.
	Stack height norms should be maintained.
MJ	Stocks should be labeled according to status. Details on labels should be legible and correct.
MJ	All stocks should be segregated as per lot numbers. FIFO / FEFO should be followed for stocks(in case of raw material)
	Finished goods should be handled carefully while loading to avoid any damage to the goods.
	MSDS for raw materials should be available wherever required.
	Personnel handling hazardous raw materials should be provided with adequate training on MSDS.

	Hot room/ air-conditioned room facility should be available for raw materials requiring ambient temperature for storage.(Is the temperature being monitored?)
	The material handling equipments should be available in adequate numbers and should be maintained properly.
MJ	Packs opened for sampling or half-used packs should be closed and stored properly.
	Handling equipment such as scoops, barrel pumps, etc. should be cleaned and stored in a designated area.
8	**Quality Assurance:**
	Laboratory testing
	Is there separate area for QA/QC
	Testing should be done by qualified Chemistry professionals.
MJ	Analytical testing laboratory should be adequately equipped to perform all mandatory testing.(Is there dedicated equipments available for all assays & tests dedicated?)(in- house specification)
	All material used in cosmetic grade and food grade in case of it carried on lip or oral cavity MSDS for all raw materials and chemicals/ reagents should be available in the laboratory.
MJ	All laboratory equipment should be calibrated and verified as per the pre-defined frequency and records maintained.
MJ	Records of testing of raw materials and finished products should be maintained.
	Is there sealable containers for storage of materials to be tested?
	Is there dedicated equipment available for calibration?(or external contracts)
	Is there dedicated equipment available for measuring/ weighing/ sampling?(or external contracts)
	Is there dedicated equipment available for validation?
MJ	Is there LOG book for each equipment?(or batch file record)
MJ	Is over printing is reviewed by an authorized person & check it with the instructions contained in the batch packaging instruction?

	Are there records of testing results of retained samples?
MJ	Is there test methods for testing the retain samples from both raw & finished products?(retained samples for each batch)
	Is there test procedures(ITPs)?
	Is there SOPs for testing and sampling?
	Is the test methods (ITPs)validated?
	Packaging material testing
	All inspection and testing should be done by trained technicians.
	Packaging testing laboratory should be adequately equipped to perform all mandatory testing.
MJ	All laboratory equipment should be calibrated and verified as per the pre-defined frequency and records maintained.
	Records of testing of packaging materials should be maintained.
	Is there SOPs for cleaning & operating of a packaging lab equipment?
MJ	Is each packaging and labeling line is internally inspected for clearance prior to each new operation?
	Are the packaging materials & labels related to the approved label & packaging from registration department?(according to EU STANDARDS)
	Microbiological testing
MJ	All testing should be done by qualified microbiologists.If not is there a contract with approved micro lab
	Microbiological laboratory should be segregated and access controlled.
	There should be a Microbiological Control plan available for the facility.
	The laboratory should be adequately equipped to perform all mandatory tests. Is there laminar air flow in the micro lab
MJ	All the chemicals, glassware, equipment, etc. should be exclusive to the laboratory.
	Records of testing of raw materials,BULK and finished products should be maintained.

	MSDS for all raw materials and chemicals/ reagents should be available in the laboratory.
	The laboratory water should be tested for microbial contamination prior to use for testing.
	Is there gowning area before micro lab? Is there air lock before this area?
9	**Processing (Batch-making)**
MJ	All processing equipment should be cleaned, sanitized, maintained, calibrated and records maintained.
MJ	All personnel working in processing areas should be appropriately dressed.
MJ	All processing areas should be access controlled.
MJ	All processing areas should be clean and tidy.
MJ	Eating and drinking should not be allowed in processing areas.
	There should be disinfection stations before the processing areas.
C	Hoses and pipes used for transferring product should be of food-grade material and should be cleaned, sanitized and maintained properly and records maintained.(should not react with the product)
C	There should not be any dead legs in the pipelines (cream production line to filling line)
	Environmental count monitoring should be carried out for processing areas at regular intervals.
	Is there air curtains before production area?
	Is there air interlock in clean places?
MJ	Is there a retained samples chamber?
MJ	If powders used in preparation is there a dust collector?
MJ	Is there records of in-process control?
MJ	records of on –line inspection should be maintained for future references

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10	**Finishing Operation**
MJ	There should be a system for on-line inspection of finished goods.
	On-line inspectors should be trained on the on-line inspection procedure.
	Is there SOPs for production, cleaning? Is it clear & easy for the operator to reach?
MJ	Is there a log book used on each production line?
C	Is the area with air handling unit(cream production) or closed system?
MJ	Is the pressure measured in the area?
	Is the receiving warehouse containing sampling room with the adequate balances?Is it containt collector in case of using powders?
	Is there a quarantine (under test) area for finished products till their release by QC?(specified area)
	Check the retest policy & what happens at retest date? & does it comply with MOH retest polocy?
MJ	Is there adequate record keepng (either manual or electronic) in case of electronic records Is there a back up system?
C	All rejected products physically or electronically segregated And all containers labeled as rejected? Is the deviation report, cause of rejection,(in batch file) investigation & remedial action present?
MJ	Is there coloured visual status identification on lots (Green, Yellow, Red)
	Is only plastic pallets used?(in processing department)
	Is there adequate fire alarm equipments & does it get calibrated on regular basis?
	Is there dedicated equipments for maintenance/ lubrication according to schedule?
	Is there dedicated equipments & instruments available for cleaning equipments?

	Are there sealable containers for storage/ transfer of products or bulk from production area to packaging area
	Assuring periodic cleaning of warehouses?
11	**Water System**
MJ	A block diagram of Water system should be available with the facility.
MJ	A maintenance and regeneration schedule should be defined for the water system.
	There should be procedure available for regeneration of water system.
	Sampling ports should be available at specified locations in the water system.
C	The output of water system should be validated for physical, chemical and microbiological parameters under normal and challenged conditions.
	There should be a defined procedure, including frequency, for cleaning and sanitization of water system.
	Records of maintenance, regeneration, C & S and testing should be maintained.
	On-line data should be recorded and stored for reference.
	Results of water system output should be reviewed periodically.
12	**Documentation**
C	Is there proceedures & Sops for description of work/tasks done in each department?(in production department)
MJ	Is there correct QA/QC final product testing including samples, tests , documentation for each batch to have desired chemical/physical properties and meet final approval standards? Is there documenting that QC/QA has approved materials?
	Is records found for ensuring critical steps checked by 2nd person?
C	Is there master batch record available?(tracebililty)