Ministry of Health
Central Administration for Pharmaceutical Affairs
Pharmaceutical Inspection Department
Local cosmetics & Insecticide Inspection department.

وزارة الصحة
الإدارة المركزية للشئون الصيدلية
الإدارة العامة للتفتيش الصيدلي
ادارة التفتيش على **مصانع** التجميل
والمبيدات الحشرية

Serial: 00001/yyyy

Cosmetic GMP audit checklist

Location : **Name:**
Date: **Code:**

Item no.	Item	YES /NO	Comments	DOC. To refer
1.	**Personnel**			
1.1	IS there list of personnel organogram & job responsibilities?			
1.2	IS the factory manager a pharmacist?			
1.3	IS there sufficient number of qualified personnel available for manufacture & quality departments?			
1.4	Are the responsibilities of the quality control & manufacturing unit independent from each other?			
1.5	IS there a list of personnel available with qualification, experience, & department?			
1.6	Job responsibilities of production head?			
1.7	Job responsibilities for quality control head?			
1.8	Are there standard operating procedure related to personnel, including professional qualification & training?			
1.9	Training program available& approved?			
1.10	Training records available as per the training program?			
هفتش الإدارة :		**مسئولى المصنع:**		

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2.	**Premises**			
2.1	ARE the walls & floors smooth easily to be cleaned?			
2.2	IS there NO leak, holes, cracks in building / windows?			
2.3	IS there separate area for : -QC/QA -Raw materials warehouse -finished products warehouse			
2.4	Adequate lighting & ventilation?			
2.5	Is toilets separated from changing?			
2.6	Are the personnel flow complies with GMP? Are there different sites for entrance& exit from & to production area (unidirectional flow)?			
2.7	Are the operators use overhead & overshoes in production area?			
2.8	Is the step-over bench before production area?			
2.9	Are there air curtains in the required places?			
2.10	Is there a retained samples room?			
2.11	Is the flow of the comply with GMP (unidirectional flow)?			
3.	**Equipments**			
3.1	ARE there dedicated equipments available for laboratory for all assays & tests dedicated?			
3.2	IS there dedicated equipment & instrument available for cleaning equipment?			
3.3	IS there a sealable container for storage of materials to be tested?			
	مفتش الإدارة :			**مسئول المصنع:**

3.4	IS there dedicated equipment for maintenance / lubrication according to schedule?			
3.5	IS there dedicated equipment available for measuring/ weighing / sampling?			
3.6	IS there dedicated equipment available for calibration?			
3.7	IS there dedicated equipment available for validation?			
3.8	IS there LOG book on each equipment?			
4.Production areas **a)preparation area:**				
4.a.1	IS the walls & floors are smooth easily to be cleaned with curved end bet. Wall & floor?			
4.a.2	IS the area separated from other production areas?			
4.a.3	IF powders used in preparation IS there a dust collector?			
4.a.4	Are the pipes that transport water or product before packaging smooth & easily to be cleaned 7 not react with the product?			
4.a.5	IS there cleaning records for production tanks & equipments?			
4.a.6	ARE there records of in- process control?			
4.a.7	Is there SOPS production, cleaning? Is it clear & easy for the operator to reach?			
4.a.8	Is there a log book used on each production line?			
هفتش الإدارة :		**مسئول المصنع:**		

4.b	**Cream production area:**			
4.b.1	IS the area with positive pressure relative to the surroundings?			
4.b.2	IS the pressure measured in the area?			
4.b.3	IS there air handling system in the area?			
4.b.4	Is the wall & floor smooth easily to be cleaned with curved end bet? Wall & floor?			
4.b.5	If there is no AHU, is closed system established with air interlock in cream in cream production area?			
4.b.6	Is there secondary gowning before cream production area?			
5.	**Packaging area**			
5.1	IS there a sealable container for storage / transfer of products or bulk from production area to packaging area?			
5.2	IS there SOPs for cleaning, operating during packaging?			
5.3	Are the packaging materials & labels related to the approved label & packaging from registration department?			
5.4	IS each packaging & labeling line is internally inspected for clearance prior to each new operation?			
5.5	IS Over-printing is reviewed by an authorized person & check it with the instructions contained in the batch packaging instruction?			
هفتش الإدارة :		**مسئولى المصنع:**		

6.	**Quality department:**			
6.1	IS there separate department for QC / QA?			
6.2	IS there the required equipment in the QC lab?			
6.3	IS there laminar flow in microbiological lab. If the factory produce creams?			
6.4	IS there air handling system in the micro. Lab?			
6.5	IS there the required equipment in the micro lab?			
6.6	IS there test procedures?			
6.7	ARE there records of all tests (for raw, bulk, in-process, finished products)?			
6.8	Is there SOPs for testing & sampling?			
6.9	IS the test methods validated?			
6.10	IS there test methods for testing the retain samples from both raw & finished products?			
6.11	Are there records of testing results of retained samples?			
6.12	Are there records of testing results of retained samples?			
6.13	Is there gowning area before micro lab? Is there double door before this area?			
7	**Documentation**			
7.1	IS there procedures & SOPs for description of work / tasks done in each department?			
هفتش الإدارة :		**مسئول المصنع:**		

7.2	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?			
7.3	IS there documenting that QC/QA has approved materials?			
7.4	IS records found for ensuring critical steps checked by 2nd person?			
7.5	IS there master batch record available?			
7.6	Assuring all departments have documented procedures to follow when QA/QC tests show materials do not meet the required standards & have documented procedures for conducting investigations to determine the causes & make corrections?			
7.7	Assuring periodic cleaning of warehouses?			
8.	**Storage**			
8.1	IS there separated warehouses for raw materials, receiving, finished products, rejected products?			
8.2	Is the receiving warehouse containing sampling room with the adequate balances?			
8.3	IS the balances are calibrated periodically?			
8.4	IS there a quarantine area for finished products till their release by QC?			
هفتش الإدارة :		**مسئولى المصنع:**		

8.5	ARE there colored signed tickets, yellow for holding material & after sampling from QC & green one for approved products by QC & red ticket for rejected hold products by QC?			
8.6	IS 1/6 of the ware houses area left for ventilation?			
8.7	IS only plastic palettes used?			

Auditors:

The corrective actions will be presented to the auditing committee in……....time & it will be done in…….....….time.

Signature of audit members: **Signature of Factory manager:**

Date : / /