

اسم المصنع	
الخطوط	

pics/-annex-1/ 009-14 + 2011-who- من اصدار

اي فقرة لا تثبت بوثائق تعتبر غير منفذة

PREMISES in general	
1	Is there site master plan? مخطط معماري محدث يمثل واقع حال المصنع متضمن حركة المواد والاشخاص- يجب ان يتوفر في الادارة او تعلق نسخته بمدخلها
2	Is there a green area around the building?
3	Is there any protection against the entry of rodents, insects, birds and other animals? مكافحة القوارض WHO-(12.9)
4	Which substance is used for pest control and how it is handled? is carried out as per the SOP?
5	Is there a map& monitoring record for the rodent and pest control?
6	Rodenticides, insecticides, and fungicides shall not be used unless be accordance with Regulatory هل المواد المستخدمة موافق عليها من السلطة المعنية?
7	pest control (including details of any pest control program implemented, records of observations made as part of that program & any casual sightings, & details of any corrective action taken);
8	Does ensure the avoidance of contamination of starting materials ,packaging materials, in process-products & finished products with rodenticides& insecticides &/or fumigant agents?// is there sqp to improve that?
Sewage and Refuse & (ETP)	
9	- Is there a sewage treatment? (ETP)
10	If "YES", is there a specific area for waste treatment, completely separated from manufacturing areas?
11	Is there waste treatment program covering the entire factory?
12	Sewage, refuse, and other waste (e.g., solids, liquids, or gaseous by-products from manufacturing) in & from buildings and the immediate surrounding area should be disposed of in a safe, timely, & sanitary manner.
13	Does the company comply with the legislation on fire control & prevention?
14	Are maintenance areas physically separated from production areas? (Should be),
15	- The premises are secured against entry of unauthorized personnel or materials.
16	- Visitors to the premises, including external maintenance workers & contractors, are supervised & restricted to an appropriate level of access.
17	اللوندي :
18	-Is there a laundry area for uniforms which is separate from production areas?=-
19	Are there SOP's for washing uniforms separately depending on the type of area (sterile, non sterile, maintenance, special products)?
20	If Is this outside laundry facility periodically audited & the audit recorded? في حال متعاقدين مع لوندري خارجي
21	Containers and/or pipes for waste material should be clearly identified. Is this in compliance? & in a safe and sanitary manner?
22	Is the building exterior in good conditions? المظهر الخارجي للبنية and /مثلا ابدون تشققات
23	Is the area of factory enough for easy movement for persons & materials?
24	Is there an electricity generator for maintenance of critical systems & processes to be used in case of problems with the electricity supply occur?/ IS generator connected to(critical equipment) such as autoclave, lyophilizer ...etc?
25	What the capacity of electricity generator? المولدة هل طاقتها كافية؟ لتغطية الاماكن المهمة والواجب عدم انقطاع التيار فيها؟
26	Do its performance tested & the time it starts work after electricity drop is suitable? مالوقت المستغرق بين تشغيل المولدة وانقطاع الوطني ؟ لانه قد يتسبب بفشل وجبة ومشاكل وتلوث ان كان طويلا

معلومات عن فصل الابنية	
27	Are the free& non productive areas belonging to the company in good clean & orderly conditions?
28	Production & Q.C areas are not used as passageways by personnel who do not work in them, or for the transport of materials not being currently used in them. They are not used as storage areas for obsolete materials or equipment.
29	Staff amenities استراحة, including lunch rooms, are separate from storage, production & quality control areas. (معلومة)
30	Is there a staff library and meeting room?(معلومة)