



Centre for cGMP



PHARMACEUTICALS EXPORT PROMOTION COUNCIL OF INDIA  
(Set up by Ministry of Commerce & Industry, Govt. of India)



**MANIPAL**  
ACADEMY of HIGHER EDUCATION  
(Institution of Eminence Deemed to be University)



Our Inspiration

Founder : Dr. T M A Pai,  
Padmashree awardee

Manipal College of  
Pharmaceutical Sciences

In Association with IDMA and Pharmexcil

## Centre for cGMP presents to you "cGMP AWARENESS SERIES" (2024/05)

**\*THINK cGMP – cGMP is LIFE\***

Commitment

Adherence

Creating Quality Culture



### Topic: Medical examination of employees in the pharmaceutical industry



#### Procedure for medical checkup

- All the employees working in the manufacturing facility shall undergo a medical examination.
- The administration/HR department shall prepare the list of employees for medical examination.
- The list shall be sent to the company authorized medical hospital by the administration department.
- The dates of medical examination shall be finalized after consultation with the company authorized doctors.
- Medical checkup shall be conducted in the factory premises and the medical team visits the site on a date agreed upon with the medical team. In case of anyone missed out, such employee shall visit the hospital for checkup.
- The reports shall be provided by the hospital as per the prescribed format with the recommendations (if any), doctor's signature and date.

#### Procedure and general requirements

- Employees who are found not suitable during the medical examination shall not be allowed to work in the manufacturing facility.
- However, if the employee is found to be medically fit after treatment, he/she shall be allowed to work in the manufacturing facility after certification by the doctor.
- The medical examination shall be conducted once in a year by the company authorized hospital / doctors.
- The medical reports shall be received and reviewed by QA department.
- The medical reports shall be filed department wise by QA and shall be stored in the QA department.
- The tests to be performed during the medical examination shall be described in the approved format of the company.
- Eye checkup of personnel performing visual inspection is usually done twice yearly.

#### MEDICAL CHECKUP AND REPORTS:

##### The report shall contain the following information.

- Complete employee details.
- Details like Height, Weight, Blood Pressure, Vital capacity etc
- The tests shall be performed as per the prescribed format.
- The report shall contain the details of examining doctor and certifying doctor.
- The reports shall be kept confidential

#### EYE CHECKUP:

Eye check-up is mandatory for all the staff and most importantly for the operators involved in product inspection during manufacturing operations. Eye check-up will help us to recognise the person who is color blind. This will help the company to identify such cases.

##### Examples include,

- Operators involved in inspection of parenteral products
- Operators involved in inspection of liquid orals, solid dosage forms prior to primary packing etc

#### Penicillin and Cephalosporins Sensitivity Tests:

These tests are mandatory for all the employees working in the penicillin and cephalosporin manufacturing facility.



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