

Con. 2374-10.

Sem VIII

Pharmaceuticals

(2 Hours)

MX-8500

[Total Marks : 35

2009-10

N.B. : (1) Questions No. 1 is compulsory.

(2) Attempt any four questions out of the remaining six questions.

(3) Figures to the right indicate full marks.

(4) Draw sketches wherever required.

1. Attempt any two :- 7
 - (a) Write on QC Charts. ✓
 - (b) What is F_0 ? Give its relevance in the validation of steam sterilization.
 - (c) Show importance of the process of scale up for a tablet manufacturing plan via wet granulation.

 2. Submit a sketch of an brief discussion on layout plan of a typical manufacturing section designed for small volume parenterals. 7

 3. (a) Write on ABC concept. 4
(b) Give details of Elements of cost. 3

 4. Write on the important points to be considered during preparation of a BMR. Show a BMR for an ophthalmic semisolid formulation. 7

 5. (a) Referring to cGMP write on Building and associated facilities. 4
(b) Discuss on IQ and OQ for Dry heat sterilizer. 3

 6. (a) Write on in process quality assessment protocol for chewable tablets. 3
(b) How will you validate the process of powder mixing in a rotocube ? 4

 7. (a) How do you plan for space requirement in a pilot plant ? 3
(b) Write on Sampling and Sampling plans. 4
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