THE DRUGS AND COSMETICS RULES, 1945 1[***] THE DRUGS AND COSMETICS RULES, 1945

1[76. Form of licences to manufacture drugs specified in Schedules C and C (1) , excluding those specified in 2[Part XB and] Schedule X, or drugs specified in Schedules C, C(1) and X and the conditions for the grant or renewal of such licences.—3[A licence to manufacture for sale or for distribution of drugs specified in Schedules C and C(1) other than 4[Large Volume Parenterals, Sera and Vaccines and Recombinant DNA (r-DNA) derived drugs,], drugs specified in Part XB and Schedule X shall be issued in Form 28 and a licence to manufacture for sale or distribution of drugs specified under Schedule C and C(1) (other than 4[Large Volume Parenterals, Sera and Vaccines and Recombinant DNA (r-DNA) derived drugs,], drugs specified in Part XB) and Schedule X shall be issued in Form 28B. A licence to manufacture for sale or for distribution of 4[Large Volume Parenterals, Sera and Vaccine and Recombinant DNA (r-DNA) derived drugs] shall be issued in Form 28D. Before a licence in Form 28 or Form 28B or Form 28D is granted or renewed, the following conditions shall be complied with by the applicant:—]]

(1) The manufacture will be conducted under the active direction and personal supervision of competent technical staff consisting at least of one person who is a whole-time employee and who is—

(a) a graduate in Pharmacy or Pharmaceutical Chemistry of 5[a University established in India by law or has an equivalent qualification recognised and notified by the Central Government for such purpose] and has had at least eighteen months' practical experience after the graduation in the manufacture of drugs to which this licence applies, this period of experience may, however, be reduced by six months if the person has undergone training in manufacture of drugs to which the licence applies for a period of six months during his University course; or

(b) a graduate in Science of 5[a University established in India by law or has an equivalent qualification recognised and notified by the Central Government for such purpose] who for the purpose of his degree has studied Chemistry 6[or Microbiology] as a principal subject and has had at least three years' practical experience in the manufacture of drugs to which this licence applies after his graduation; or

(c) a graduate in Medicine of 7[a University established in India by law or has an equivalent qualification recognised and notified by the Central Government for such purpose] with at least three years' experience in the manufacture and pharmacological testing of biological products after his graduation; or 8[(d) a graduate in Chemical Engineering of a University recognised by the Central Government with at least three years' practical experience in the manufacture of drugs to which this licence applies after his graduation; or

(e) holding any foreign qualification the quality and content of training of which are comparable with those prescribed in clause (a), clause (b), clause (c) or clause (d) and is permitted to work as competent technical staff under this rule by the Central Government:]

Provided that any person who was approved by the licensing authority as an expert responsible for the manufacture of drugs for the purpose of rule 76 read with rule 78 as these rules were in force immediately before the 29th June, 1957, shall be deemed to be qualified for the purposes of this rule: 9[Provided further that for the drugs specified in Schedules C and C (1) meant for veterinary use, the whole time employee under whose supervision the manufacture is conducted may be a graduate in Veterinary Science or General Science or

Medicine or Pharmacy of a University recognised by the Central Government and who has had at least three years' experience in the manufacture of biological products:] 10[Provided further also that for the medical devices specified in Schedule C, the whole time employee under whose supervision the manufacture is conducted may be a Graduate in Science with Physics or Chemistry or Microbiology as one of the subjects; or graduate in Pharmacy; or Degree/Diploma holder in Mechanical or Chemical or Plastic Engineering of a University recognised by the Central Government for such purposes.]

(2) The factory premises shall comply with the conditions prescribed in Schedule M 10[and Schedule M III in the respect of Medical devices].

(3) The applicant shall provide adequate space, plant and equipment for any or all the manufacturing operations; the space, plant and equipment recommended for various operations are given in Schedule M 10[and Schedule M III]. 11[(4) The applicant shall provide and maintain adequate staff, premises and laboratory equipment for carrying out such tests of the strength, quality and purity of the substances as may be required to be carried out by him under the provisions of Part X of these rules including proper housing for animals used for the purposes of such tests, the testing unit being separate from the manufacturing unit and the head of the testing unit being independent of the head of the manufacturing unit.] Provided that the manufacturing units which before the commencement of the Drugs and Cosmetics (Amendment) Rules, 1977,12 were making arrangements with institutions approved by the licensing authority for such tests to be carried out on their behalf may continue such arrangement up to the 30th June, 1977: Provided further that for tests requiring sophisticated instrumentation techniques or biological or microbiological methods other than sterility the licensing authority may permit such tests to be conducted by institutions approved by it 13[under Part XV (A) of these rules] for this purpose.] 14[(4A) The head of the testing unit referred to in condition (4) shall possess a degree in Medicine or Science or Pharmacy or Pharmaceutical Chemistry of a University recognised for this purpose and shall have experience in the testing of drugs, which in the opinion of the licensing authority is considered adequate.]

(5) The applicant shall make adequate arrangements for the storage of drugs manufactured by him. 15[(6) The applicant shall furnish to the licensing authority, if required to do so, data on the stability of drugs which are likely to deteriorate for fixing the date of expiry which shall be printed on the labels of such drugs on the basis of the date so furnished.] 16[(7) The applicant shall, while applying for a licence to manufacture patent or proprietary medicines, furnish to the licensing authority evidence and data justifying that the patent or proprietary medicines—

(i) contain the constituent ingredients in therapeutic/prophylactic quantities as determined in relation to the claims or conditions for which the medicines are recommended for use or claimed to be useful;

(ii) are safe for use in the context of the vehicles, excipients, additives and pharmaceutical aids used in formulations, and under the conditions in which the formulations for administration and use are commended;

(iii) are stable under the conditions of storage recommended; and

(iv) contain such ingredients and in such quantities for which there is therapeutic justification.] 17[(v) have the approval, in writing, in favour of the applicant to manufacture drug formulations falling under the purview of new drug as defined in rule 122E, from the

licensing authority as defined in clause (b) of rule 21.] 18[(8) The licensee shall comply, with the requirements of "Good Manufacturing Practices" as laid down in Schedule M.] 19[Explanation.—For the purpose of this rule, "Large Volume Parenterals" shall mean the sterile solutions intended for parenteral administration with a volume of 100 ml. or more (and shall include anti-coagulant solutions) in one container of the finished dosage form intended for single use.]