The Sample Examination Paper is for Reference ONLY

Pharmacy and Poisons Board of Hong Kong

Sample Examination Paper (3 hours)

Pharmacy Legislation in Hong Kong

READ THESE INSTRUCTIONS CAREFULLY
DO NOT TURN THIS PAGE OVER UNTIL YOU ARE TOLD TO DO SO

FAILURE TO COMPLY WITH THE INSTRUCTIONS MAY RESULT IN DEDUCTION IN MARKS OR DISQUALIFICATION

1. *Write your Candidate Number clearly on each answer sheet. Do not write your name on any sheet.*

2. *USE A FRESH SHEET FOR **EACH** QUESTION. THE ANSWER TO EACH QUESTION WILL BE COLLECTED SEPARATELY AT THE END OF EXAMINATION.*

3. *Read the questions very carefully. Do not waste time writing down information that is not asked for. No marks will be given for irrelevant answers.*

4. *Answer **ALL** questions.*

5. ***Do not take any question papers or writing papers, whether used or unused, out of the examination room.***

This paper consists of this page and **THREE** other printed pages.

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*Answer **ALL** questions. Each question carries 20 marks.*

1. (A) Indicate by using the abbreviations respectively shown in square brackets, the legal classifications of the following drugs showing whether they are included in Part I of the Poisons List [P1], Part II of the Poisons List [P2], the First Schedule to the Pharmacy and Poisons Regulations [S1], the Third Schedule to the Pharmacy and Poisons Regulations [S3], Part I of the First Schedule to the Dangerous Drugs Ordinance [P1DD], Part II or III of the First Schedule to the Dangerous Drugs Ordinance [P2DD], Schedule 1 to the Antibiotics Regulations [A], or none of the above [NP]: (1 mark each)

   (a) An ophthalmic cream containing 3% aciclovir

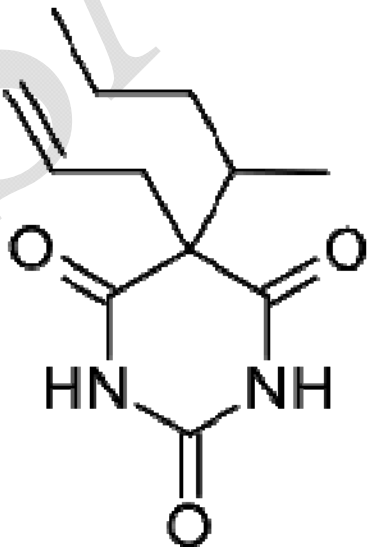
   (b) A tablet containing 100 mg theophylline

   (c) A tablet containing 4 mg nicotine intended to be used in nicotine replacement therapy

   (d) A capsule containing 6 mg melatonin intended to be used for the treatment of insomnia

   (e) A syrup containing 5 mg codeine phosphate, 300 mg paracetamol and 2 mg chlorpheniramine per 5 ml

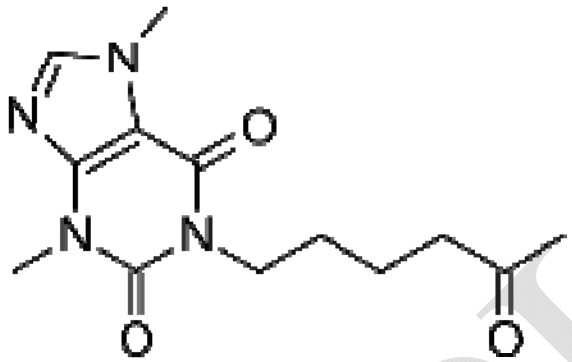
   (f) A capsule containing 100 mg quinalbarbitone sodium
   Note: Structure of quinalbarbitone is



(g) A tablet containing 2.5 mg diphenoxylate and 25 mcg atropine sulphate

(h) An injection containing 1% ivermectin

(i) A tablet containing 400 mg oxypentifylline
Note: Structure of oxypentifylline is



(j) A condom containing 1% benzocaine

(k) An injection containing 5% zolazepam hydrochloride

(l) A gel containing 0.5% piroxicam

(B) Describe the specific conditions under which the following poisons would be exempted from the provisions of the Pharmacy and Poisons Ordinance as stipulated under regulation 8 of the Pharmacy and Poisons Regulations: (1 mark each)

(a) Lignocaine

(b) Podophyllum resin

(c) Hydrochloric acid

(d) Clioquinol

(C) The Poisons List Regulations apply to certain substances and their derivatives. Give the names of two such derivatives for each of the following substances: (2 marks each)

(a) Fluorouracil; its derivatives

(b) Mustine and any other N-substituted derivative of di-(2-chloroethyl)amine; their salts

2. Describe the statutory requirements stipulated under the Pharmacy and Poisons Ordinance in relation to the storage, supply, labelling and record keeping of Part I poisons by an institution as defined under section 2 of the Ordinance. (20 marks)

3. (a) Define “medicine”, “advertisement” and “orally consumed product” under the Undesirable Medical Advertisements Ordinance. (20 marks)

(b) Describe the prohibition, and exceptions, of advertisements relating to medicine as stipulated under the Undesirable Medical Advertisements Ordinance.

4. (a) If a company wishes to import a pharmaceutical product that contains a Part I poison for sale and distribution in Hong Kong, what licence/registration/permit does the company require? Please also describe the record-keeping requirements for the company when it supplies the product to a registered medical practitioner. (20 marks)

(b) If the above company decided to change its company address, what action should be taken by the company in relation to the registration of the product?

5. Describe the statutory authority and requirements stipulated under the Dangerous Drugs Ordinance in relation to the possession, manufacturing, supply, storage and record keeping of dangerous drugs by an authorized seller of poisons. (20 marks)

END OF PAPER