













4.3 The Agreement on Trade Related Intellectual Property Rights (TRIPS) sets minimum standards in the field of intellectual property (IP) protection.

4.3.1 Define the term "intellectual property." List **five (05)** components included under Intellectual Property Rights. **(15 marks)**

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4.3.2 State main TRIPS standards related to pharmaceuticals. **(10 marks)**

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4.4 Sri Lankan National Drug Policy (NMDP) was implemented to ensure the availability of efficacious, safe and good quality medicines.

What are the major elements discussed in NMDP? **(25 marks)**

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5.1.4 Schedule III

(15 marks)

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5.2 List **five (05)** conditions that apply for the retail pharmacy under the CDDA regulations.

(20 marks)

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5.3 State mandatory labeling information to be indicated in the container of a drug.

(20 marks)

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6.1 As per the CDDA regulations every person desires to register a drug with the Drug Regulatory Authority shall make an application.

6.1.1 Indicate details to be included in the applications. *(15marks)*

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6.1.2 List **five (05)** situations where a certificate holder should notify the Authority.

*(20 marks)*

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6.2

6.2.1 State **three (03)** main categories of license required to import drugs. *(15 marks)*

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