Code No: E-12477/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Regulatory Affairs) II Semester (PCI) (Main & Backlog) Examination, November 2023

Subject: Regulatory Aspects of Herbal & Biologicals

Time: 3 Hours **Max Marks: 75**

Note: Answer any five Questions. All Questions carry equal Marks.

1. (a) Describe the content and format of labeling for human prescription drug and biological products in US. [9+6]
   (b) Differentiate the Biologics and Biosimilars.

2. (a) What is Reference product, interchangeable product? Write the potential benefits of biosimilars and advantages of biosimilars. [9+6]
   (b) Differentiate the generics and biosimilars.

3. Give an informative note on
   (a) International society of blood transfusion (ISBT) [8+7]
   (b) International Haemovigilence network (HIN)

4. (a) Describe the regulations of blood and blood products in India. [8+7]
   (b) Write about development and approval of biosimilars in the EU.

5. Write about [8+7]
   (a) Data requirement for clinical trial application in India.
   (b) Post market data for similar biologics.

6. Discuss in detail about the good manufacturing practices in India. [15]

7. Describe the safety and legislations about the herbal drugs in India and USA. [15]

8. (a) Describe the data requirement for preclinical studies of biologicals in India. [7+8]
   (b) Write about development and approval of biosimilars products in US.

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Code No: E-12478/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Regulatory Affairs) II Semester (PCI) (Main & Backlog) Examination, November 2023

Subject: Regulatory Aspects of Medical Devices

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. (a) Define Medical Device. Describe in detail about the risk based classification of Medical Devices. [8]
   (b) Write a note on history of Medical Device Regulation. [7]

2. (a) Write Quality Principles and essential principles of Medical Devices & IVDs. [9]
   (b) Write about Quality System Regulations of Medical Devices: ISO 13485. [6]

3. (a) Write a note on Quality Risk Management of Medical Devices: ISO 14971. [8]
   (b) Write a note on clinical investigation of Medical Devices. [7]

4. (a) Write the regulatory approval process for Medical Devices (510k). [8]
   (b) Write about Investigational Device Exemption (IDE). [7]

5. (a) Write about the Labelling requirements 21 CFR Part 801. [8]
   (b) Write the Classification of Medical Devices & IVD as per US FDA & EU & ASEAN. [7]

6. (a) Write the regulatory approval process for In vitro Diagnostics (In Vitro Diagnostics Directive). [8]
   (b) Write a note on CE Certification process. [7]

7. (a) Write the Quality System requirements and clinical evaluation and investigation for Medical Devices for ASEAN. [15]

8. (a) Write a note on IMDRF Study groups. [7]
   (b) Describe the Quality System Requirements 21 CFR Part 820. [8]

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Code No: E-12479/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Regulatory Affairs) II-Semester (PCI) (Main & Backlog) Examination, November 2023

Subject: Regulatory Aspects of Food & Nutraceuticals

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. (a) What are Functional and Medical Foods? Write a detailed note on the importance, scope and role of Functional and Medical Foods. [9]
   (b) Write about the Scope and Opportunities in Nutraceutical Market. [6]

2. (a) Discuss about the NSF Standards for Food and Dietary Supplements. [8]
   (b) Write briefly about GMP for nutraceuticals. . [7]

3. (a) Describe the organization and functions of food safety and standards authority of India. [8]
   (b) Write a note on Recommended Dietary Allowances (RDA) in India. [7]

4. Summarize the USFDA Food Safety and Modernization Act regulations with respect to dietary supplements and ingredients. [15]

5. (a) Discuss European Regulation on Novel Foods and Novel Food Ingredients. [8]
   (b) Write a note on Recommended Dietary Allowances (RDA) in Europe. [7]

6. Give an overview of the WHO guidelines on daily iron and folic acid supplementation in pregnant women. [15]

7. Explain the salient features of Food Safety and Standard Act 2006. [15]

8. Write short notes on
   (a) Recommended Dietary Allowances (RDA) in USA [7.5]
   (b) History of Food and Nutraceutical Regulations [7.5]

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Code No: E-12476/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Regulatory Affairs) II Semester (PCI) (Main & Backlog) Examination, October 2023

Subject: Regulatory Aspects of Drugs and Cosmetics

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. (a) Write a note on regulatory approval process for Investigational New Drug. [8]
   (b) Write a note on history and evolution of United States Federal Food Drug and Cosmetics Act (FFDCA). [7]

2. Write in detail about Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA. [15]

3. (a) Describe content and approval process of IMPD. [7]
   (b) Write a note on Marketing Authorization Procedures in EU. [8]

4. (a) Explain the Legislations and regulations for manufacture and sale of cosmetics in Australia. [9]
   (b) Write a note on Eudralex directives for human medicines. [6]

5. (a) Write a note on Pharmaceutical Laws and regulations in Japan. [9]
   (b) Write a note on Organization of PMDA. [6]

6. (a) Explain Emerging Market. Discuss about various committees across the globe. [8]
   (b) Write a note on Certificate of Pharmaceutical Product (CoPP). [7]

7. (a) Write a note on ACTD. [8]
   (b) Describe the regulatory requirements for registration of drugs in ASEAN region. [7]

8. (a) Write a note on marketing authorization requirements for drugs in GCC countries. [8]
   (b) Write a note on legislations and regulations for import and sale of cosmetics in CIS countries. [7]

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Code No: E-12260/PCI

FACULTY OF PHARMACY

M. Pharmacy (Regulatory Affairs) II-Semester (PCI) (Backlog) Examination,
April / May 2023
Subject: Regulatory Aspects of Drugs and Cosmetics

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks. (5 x 15 = 75 Marks)

1. (a) Write a note on regulatory approval process for New Drug Application. [8]
   (b) Write a note on Hatch-Waxmann Act. [7]

2. (a) Write a note on Drug Master Files system in US. Add a note on Orange book and Purple Book. [8]
   (b) Write a note on legislations and regulations for import, manufacture and sale of cosmetics in Canada. [7]

3. (a) Describe Certificate of Suitability (CoS) in EU. [6]
   (b) Write a note on Marketing Authorization Procedures in EU. [9]

4. (a) Describe the organization and structure of EMA and EDQM. [8]
   (b) Write a note on WHO GMP. [7]

5. (a) Write a note on drug regulatory approval process in Japan. [10]
   (b) Write a note on regulatory considerations for packaging and labelling in Japan. [5]

6. (a) Explain Emerging Market. Write a note on Certificate of Pharmaceutical Product (CoPP). [8]
   (b) Write a note on ASEAN, PANDRH &SADC committees. [7]

7. (a) Write a note on legislations and regulations for import and sale of cosmetics in GCC countries. [8]
   (b) Describe the regulatory requirements for registration of drugs in ASEAN region. [7]

8. (a) Write a note on marketing authorization requirements for drugs in Saudi Arabia & UAE. [8]
   (b) Write a note on ACTD. [7]

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CODE NO: E-12262/PCI

FACULTY OF PHARMACY

M. Pharmacy (Regulatory Affairs) II-Semester (PCI) (Backlog) Examination, May 2023

Subject: Regulatory Aspects of Medical Devices

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

(5 x 15 = 75 Marks)

1. (a) Differentiate medical devices, IVDs and Combination Products. [6]
   (b) Write the organization structure, purpose, and functions of IMDRF. [9]

2. (a) What are the various working groups in GHTF. [8]
   (b) Briefly describe about Global Medical Device Nomenclature (GMDN). [7]

3. (a) Write about Quality System Regulations of Medical Devices: ISO 13485. [8]
   (b) Write about Adverse Event Reporting of Medical device. [7]

4. (a) Write the regulatory approval process for Medical Devices as Per USFDA & EU. [9]
   (b) Write about Investigational Device Exemption (IDE). [6]

5. (a) Write about the Labelling requirements for 21 CFR Part 801. [8]
   (b) Describe in detail about Unique Device Identification (UDI). [7]

6. (a) Write the regulatory approval process for In vitro Diagnostics (In Vitro Diagnostics Directive. [8]
   (b) Write a note on InVitro diagnostics classification and approval process. [7]

7. Write the Regulatory Registration procedure for Medical Devices as per ASEAN, China & Japan. [15]

8. (a) Describe the Quality System Requirements for 21 CFR Part 820. [8]
   (b) Write a note on IMDRF guidance documents. [7]

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Code No: E-12261/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Regulatory Affairs) II Semester (PCI) (Backlog) Examination, April / May 2023

Subject: Regulatory Aspects of Herbal & Biologics

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. (a) Describe the data requirements in clinical trial application. [7]

   (b) What are similar biologics? Write about the present status and guidelines in India. [8]

2. (a) Write the differences between generics and biosimilars. [6]

   (b) Write about Pharmacovigilance. [9]

3. Describe the regulatory requirements and approval of biologics and biosimilars as per EU. [15]

4. Explain the procedure for approval of clinical trials, labeling and packing of similar biologics in India. [15]

5. (a) Write the regulations and safety of herbals in India. [9]

   (b) Discuss the labeling and packing of biologics in US. [6]

6. Write about:

   (a) IHN [5]

   (b) ISBT [5]

   (c) Post market data for similar biologics [5]

7. Discuss the regulations of blood and blood products in India and EU. [15]

8. (a) Describe the data requirements for preclinical studies of biologics in India. [7]

   (b) Write about development and approval of biosimilars products in US. [8]

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Code No: E-12263/PCI

FACULTY OF PHARMACY

M. Pharmacy (Regulatory Affairs) II-Semester (PCI) (Backlog) Examination, May 2023

Subject: Regulatory Aspects of Food & Nutraceuticals

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

(5 x 15 = 75 Marks)

1. (a) What are medical foods , functional foods, and Nutraceuticals? Giving examples explain their role in health care. [9]
   (b) Write about the scope and opportunities in Nutraceuticals Market. [6]
2. (a) What is NSF certification? Write the role of NSF international in Nutraceuticals Industries. [8]
   (b) Mention the critical considerations about good manufacturing practices for Nutraceuticals. [7]
3. (a) Discuss the regulations for import of Nutraceuticals according to FSSAI. [8]
   (b) Write a note on Recommended Dietary Allowances (RDA) in India. [7]
4. (a) Write a note on Labelling requirements and claims for dietary supplements in the USA. [6]
   (b) Discuss the US FDA Food Safety Modernization Act. [9]
5. (a) What is EFSA? Explain its organization and functions. [8]
   (b) Write a note on Novel food ingredients in EU. [7]
6. Give an overview of the WHO guidelines on nutrition. [15]
7. (a) Describe the functions of Chief Executive Officer of Food Authority of India. [8]
   (b) Elaborate the Differences between Recommended dietary allowances (RDA) of India & US. [7]
8. Write short notes on
   (a) Labelling requirements for dietary supplements in the EU. [7.5]
   (b) Prebiotics and probiotics. [7.5]

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Code No: E-12116/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Regulatory Affairs) II Semester (PCI) (Main) Examination, December 2022

Subject: Regulatory Aspects of Herbal & Biologics

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. Discuss in detail about good manufacturing practices and its advantages. [15]

2. (a) What are different biological products? Give the differences between generic and biosimilars. [7]
   (b) Describe about post marketing data requirements for similar biologics. [8]

3. (a) Describe the data requirements in clinical trial application. [7]

   (b) What are similar biologics? Write about the present status and guidelines in India. [8]

4. Discuss the regulations of blood and blood products in India and EU. [15]

5. Explain the procedure and data requirements for approval of clinical trial in India. [15]

6. (a) Describe the regulation and safety of herbal in India. [8]

   (b) Write about the preclinical requirements for biologics in US. [7]

7. Write about:

   (a) International Haemovigilence network (IHN) [7]

   (b) International society of Blood transfusion (ISBT) [8]

8. Discuss about the development and regulations of biologics and similar biological in EU. [15]

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Code No: E-12115/PCI

FACULTY OF PHARMACY

M. Pharmacy (Regulatory Affairs) II Semester (PCI) (Main) Examination, December 2022

Subject: Regulatory Aspects of Drugs and Cosmetics

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. (a) Write a note on regulatory approval process for Investigational New Drug. [8]
   (b) Write a note on Organisation structure and functions of FDA. [7]

2. Write in detail about regulatory considerations for manufacturing, packaging and labelling of pharmaceuticals in USA. [15]

3. (a) Describe Active Substance Master Files (ASMF) system in EU. [7]
   (b) Write a note on Marketing Authorization Procedures in EU. [8]

4. (a) Explain the Legislations and regulations for manufacture and sale of cosmetics in Australia. [9]
   (b) Write a note on Eudralex directives for human medicines. [6]

5. (a) Write a note on drug regulatory approval process in Japan. [10]
   (b) Write a note on Organization of PMDA. [5]

6. (a) Explain Emerging Market. Discuss about various committees across the globe. [8]
   (b) Write a note on Certificate of Pharmaceutical Product (CoPP). [7]

7. (a) Write a note on ACTD. [8]
   (b) Describe the regulatory requirements for registration of drugs in ASEAN region. [7]

8. (a) Write a note on marketing authorization requirements for drugs in GCC countries. [8]
   (b) Write a note on legislations and regulations for import and sale of cosmetics in CIS countries. [7]

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Code No: E-12115/PCI

FACULTY OF PHARMACY

M. Pharmacy (Regulatory Affairs) II Semester (PCI) (Main) Examination, December 2022

Subject: Regulatory Aspects of Drugs and Cosmetics

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. (a) Write a note on regulatory approval process for Investigational New Drug. [8]
   (b) Write a note on Organisation structure and functions of FDA. [7]

2. Write in detail about regulatory considerations for manufacturing, packaging and labelling of pharmaceuticals in USA. [15]

3. (a) Describe Active Substance Master Files (ASMF) system in EU. [7]
   (b) Write a note on Marketing Authorization Procedures in EU. [8]

4. (a) Explain the Legislations and regulations for manufacture and sale of cosmetics in Australia. [9]
   (b) Write a note on Eudralex directives for human medicines. [6]

5. (a) Write a note on drug regulatory approval process in Japan. [10]
   (b) Write a note on Organization of PMDA. [5]

6. (a) Explain Emerging Market. Discuss about various committees across the globe. [8]
   (b) Write a note on Certificate of Pharmaceutical Product (CoPP). [7]

7. (a) Write a note on ACTD. [8]
   (b) Describe the regulatory requirements for registration of drugs in ASEAN region. [7]

8. (a) Write a note on marketing authorization requirements for drugs in GCC countries. [8]
   (b) Write a note on legislations and regulations for import and sale of cosmetics in CIS countries. [7]

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Code No: E-12118/PCI

FACULTY OF PHARMACY

M. Pharmacy (Regulatory Affairs) II Semester (PCI) (Main) Examination, December 2022

Subject: Regulatory Aspects of Food & Nutraceuticals

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. (a) What are dietary supplements? Giving examples critically explain their role in human body. [7]

   (b) Discuss about the history of food and Nutraceutical Regulations. [8]

2. (a) Write briefly about GMP for Nutraceuticals. [7.5]

   (b) Give an account of the NSF standards for food and dietary supplements. [7.5]

3. (a) Describe the FSSAI regulations pertaining to import and sale of Nutraceutical products in India. [7]

   (b) Describe the organization and functions of food safety and standards authority of India. [8]

4. Summarize the USFDA food safety and Modernization Act regulations with respect to dietary supplements and ingredients. [15]

5. (a) Write about the organisation and functions of European Food safety Authority (EFSA). [8]

   (b) Explain EU regulations for sale of Nutraceuticals. [7]

6. (a) What are medical foods, functional foods and Nutraceuticals? Giving examples explain their role in health care. [8]

   (b) Discuss about the history of Food and Nutraceutical Regulations. [7]

7. Discuss the WHO guidelines on nutrition of pregnant women. [15]

8. Write short notes on:

   (a) Labelling requirements and claims for dietary supplements in the USA. [7.5]

   (b) Novel food ingredients in EU. [7.5]

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Code No: E-12260/PCI

FACULTY OF PHARMACY

M. Pharmacy (Regulatory Affairs) II-Semester (PCI) (Backlog) Examination,
April / May 2023
Subject: Regulatory Aspects of Drugs and Cosmetics

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks. (5 x 15 = 75 Marks)

1. (a) Write a note on regulatory approval process for New Drug Application. [8]
   (b) Write a note on Hatch-Waxmann Act. [7]

2. (a) Write a note on Drug Master Files system in US. Add a note on Orange book and Purple Book. [8]
   (b) Write a note on legislations and regulations for import, manufacture and sale of cosmetics in Canada. [7]

3. (a) Describe Certificate of Suitability (CoS) in EU. [6]
   (b) Write a note on Marketing Authorization Procedures in EU. [9]

4. (a) Describe the organization and structure of EMA and EDQM. [8]
   (b) Write a note on WHO GMP. [7]

5. (a) Write a note on drug regulatory approval process in Japan. [10]
   (b) Write a note on regulatory considerations for packaging and labelling in Japan. [5]

6. (a) Explain Emerging Market. Write a note on Certificate of Pharmaceutical Product (CoPP). [8]
   (b) Write a note on ASEAN, PANDRH &SADC committees. [7]

7. (a) Write a note on legislations and regulations for import and sale of cosmetics in GCC countries. [8]
   (b) Describe the regulatory requirements for registration of drugs in ASEAN region. [7]

8. (a) Write a note on marketing authorization requirements for drugs in Saudi Arabia & UAE. [8]
   (b) Write a note on ACTD. [7]

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CODE NO: E-12262/PCI

FACULTY OF PHARMACY

M. Pharmacy (Regulatory Affairs) II-Semester (PCI) (Backlog) Examination, May 2023

Subject: Regulatory Aspects of Medical Devices

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

(5 x 15 = 75 Marks)

1. (a) Differentiate medical devices, IVDs and Combination Products. [6]
   (b) Write the organization structure, purpose, and functions of IMDRF. [9]

2. (a) What are the various working groups in GHTF. [8]
   (b) Briefly describe about Global Medical Device Nomenclature (GMDN). [7]

3. (a) Write about Quality System Regulations of Medical Devices: ISO 13485. [8]
   (b) Write about Adverse Event Reporting of Medical device. [7]

4. (a) Write the regulatory approval process for Medical Devices as Per USFDA & EU. [9]
   (b) Write about Investigational Device Exemption (IDE). [6]

5. (a) Write about the Labelling requirements for 21 CFR Part 801. [8]
   (b) Describe in detail about Unique Device Identification (UDI). [7]

6. (a) Write the regulatory approval process for In vitro Diagnostics (In Vitro Diagnostics Directive. [8]
   (b) Write a note on InVitro diagnostics classification and approval process. [7]

7. Write the Regulatory Registration procedure for Medical Devices as per ASEAN, China & Japan. [15]

8. (a) Describe the Quality System Requirements for 21 CFR Part 820. [8]
   (b) Write a note on IMDRF guidance documents. [7]

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Code No: E-12261/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Regulatory Affairs) II Semester (PCI) (Backlog) Examination, April / May 2023

Subject: Regulatory Aspects of Herbal & Biologics

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. (a) Describe the data requirements in clinical trial application. [7]

   (b) What are similar biologics? Write about the present status and guidelines in India. [8]

2. (a) Write the differences between generics and biosimilars. [6]

   (b) Write about Pharmacovigilance. [9]

3. Describe the regulatory requirements and approval of biologics and biosimilars as per EU. [15]

4. Explain the procedure for approval of clinical trials, labeling and packing of similar biologics in India. [15]

5. (a) Write the regulations and safety of herbals in India. [9]

   (b) Discuss the labeling and packing of biologics in US. [6]

6. Write about:

   (a) IHN [5]

   (b) ISBT [5]

   (c) Post market data for similar biologics [5]

7. Discuss the regulations of blood and blood products in India and EU. [15]

8. (a) Describe the data requirements for preclinical studies of biologics in India. [7]

   (b) Write about development and approval of biosimilars products in US. [8]

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Code No: E-12263/PCI

FACULTY OF PHARMACY

M. Pharmacy (Regulatory Affairs) II-Semester (PCI) (Backlog) Examination, May 2023

Subject: Regulatory Aspects of Food & Nutraceuticals

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

(5 x 15 = 75 Marks)

1. (a) What are medical foods , functional foods, and Nutraceuticals? Giving examples explain their role in health care. [9]
   (b) Write about the scope and opportunities in Nutraceuticals Market. [6]
2. (a) What is NSF certification? Write the role of NSF international in Nutraceuticals Industries. [8]
   (b) Mention the critical considerations about good manufacturing practices for Nutraceuticals. [7]
3. (a) Discuss the regulations for import of Nutraceuticals according to FSSAI. [8]
   (b) Write a note on Recommended Dietary Allowances (RDA) in India. [7]
4. (a) Write a note on Labelling requirements and claims for dietary supplements in the USA. [6]
   (b) Discuss the US FDA Food Safety Modernization Act. [9]
5. (a) What is EFSA? Explain its organization and functions. [8]
   (b) Write a note on Novel food ingredients in EU. [7]
6. Give an overview of the WHO guidelines on nutrition. [15]
7. (a) Describe the functions of Chief Executive Officer of Food Authority of India. [8]
   (b) Elaborate the Differences between Recommended dietary allowances (RDA) of India & US. [7]
8. Write short notes on
   (a) Labelling requirements for dietary supplements in the EU. [7.5]
   (b) Prebiotics and probiotics. [7.5]

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