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**Diploma in Pharmacy 2<sup>nd</sup> Year**  
**Pharmacy Law & Ethics**  
**Chapter 2 : Pharmacy Act & Pharmacy Practice Regulation**

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## Chapter 2

# Pharmacy Act & Pharmacy Practice Regulation Rules Pharmacy Act 1948 and

- Pharmacy Act 1948 And Rules is a set of rules in which Pharmacy profession ,practices , course , duration , qualification , penalties and things are related to pharmacy mentioned.
- Before independence there was no rule for the pharmacy practice and education.
- The drug enquiry committee recommend the Government that pharmacy practitioner should have a proper knowledge , in the same way Health Survey and Development Committee also recommended for that , and Government made Pharmacy Act and It came into force in 1948.

## Objectives of Pharmacy Act, 1948

- The pharmacy act 1948 is passed with the main objects to regulate the profession and practice of pharmacy are as follows
  - To make better provisions for regulating profession and practicing of pharmacy.
  - To rise the status of "Profession of Pharmacy" in India.
  - To constitute "Pharmacy Council of India" For setting new standards in pharmacy education.
  - To regulate pharmacy institution specially "Diploma in Pharmacy" through education regulations with registration of pharmacist.

## Definitions

- **Central Council** : It means PCI , it is created under Section 3 Of the Pharmacy Act 1948.
- **State Council** : It means State Pharmacy Council , created under section 19 , and also includes Joint State Pharmacy Council created under section 20.
- **Registered Pharmacist** : A person whose name is entered ( written ) in the Register of Pharmacists of the state in which he / she is living presently or doing his pharmacy practice.
- **First register** : It means the register of pharmacists prepared under chapter 5th of the Pharmacy Act , by the state government before constitution of State Pharmacy Council.
- **Central Register** : It means the register of pharmacists Maintained by the central Council.
- **Displaced Person** : It means a person who was living in that area of India which is now in Pakistan , He has left that area Because of any reason ( civil disturbance , fear ) after March 1947 , and now living in India.
- **Repatriate** : It means a person who was living in that area of India which is now in Burma ,Sri Lanka Or Uganda , He has left that area Because of any reason ( civil disturbance , fear ) after April 14, 1957 , and now living in India.
- **UGC ( University Grant Commission )** : It is made up under the University Grant Commission Act 1956 . It gives approval the Universities and determine and maintain the standard of teaching , examination ,and research in universities.

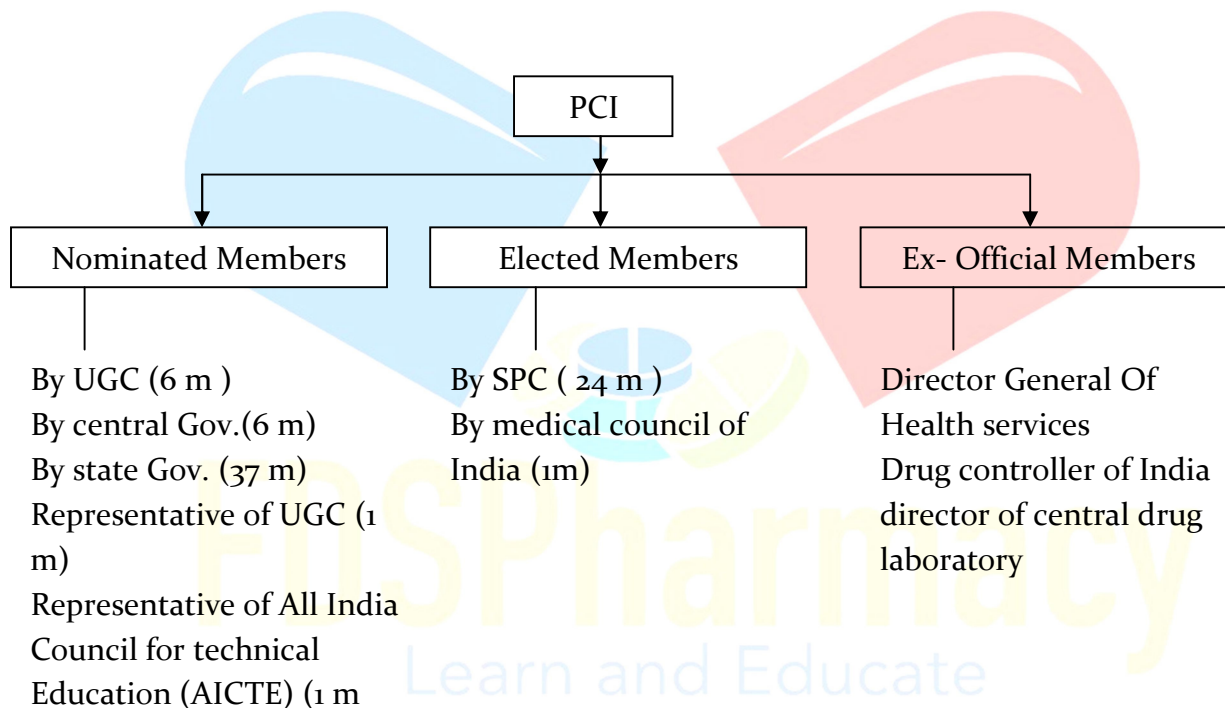
# PCI ( Pharmacy Council Of India )

→ PCI was constituted ( created ) under Section 3rd of pharmacy Act 1948. First time it was created by Central Government in 1949, to regulate Pharmacy practice and profession .

→ It is reconstituted over every 5 years.

→ It consist of Following types Of members.

- 1) Nominated Member
- 2) Elected Member
- 3) Ex - Official Member



## Constitution of PCI and methods used

### 1. Nominated Members ( 51 )

- ❖ **By UGC** : 6 members are Nominated by UGC From among the teachers are working in Indian Universities or college affiliated ( joined ) to Indian universities . Out of 6 teachers at least one should be specialist of Pharmacology , Pharmaceutical chemistry , and pharmacognosy.
- ❖ **By Central Government** : 6 Members are nominated Central government , out of 6 at least 4 should have minimum qualification , diploma in pharmacy.
- ❖ **State Government** : 37 members are nominated by state government . One nominee of each state government . They should be registered pharmacist.
- ❖ 1 representative of UGC.
- ❖ 1 representative of AICTE ( All India Council of Technical Education ).



## 2. Elected members (25)

- ◇ **State Pharmacy Council** : 24 members are elected by SPC. Each state Pharmacy council select one registered Pharmacist from themselves.
- ◇ **MIC** : Medical Council of India select 1 member from themselves.

## 3. Ex - Official Members ( 3)

- ▲ The director general of health services.
- ▲ The Director of Central Drug laboratory.
- ▲ The Director of drug Controller of India.

## Function of PCI

- ✓ To regulate pharmacy institution specially Diploma in Pharmacy through education regulation.
- ✓ To frame periodically "Education Regulation" with approval of central government for setting new standard for pharmacy education.
- ✓ To approve or disapprove course of study and examination in pharmacy.
- ✓ To recognise foreign qualification in pharmacy for purpose of registration.
- ✓ To maintain central register of pharmacist.

# Education Regulation , 2020 for Diploma in Pharmacy

## Chapter 1

- **Qualification for Pharmacist** : The minimum qualification required for registration as a Pharmacist is to be passed in D. Pharma Part 1st , Part 2nd and part 3rd ( hospital training )
- or any other qualification approved by PCI

## Chapter 2

- **Admission In D Pharmacy** : The minimum qualification for admission in D Pharmacy is 10+2 examination , with Physics , chemistry , biology or mathematics.
- **Duration of Course** : The duration of d pharma is 2 academic year , and each academic year should not be less than 180 working days , and 500 hours for Hospital training and it should not be less than 3 months.
- **Course Of Study** :

Subject	Number of Hours		
	Theory	Practical	Tutorial
Pharmaceutics	75	75	25
Pharmaceutical Chemistry	75	75	25
Pharmacognosy	75	75	25
Human Anatomy & Physiology	75	75	25
Social Pharmacy	75	75	25
<b>Total</b>	<b>375</b>	<b>375</b>	<b>125</b>

Subject	Number of Hours		
	Theory	Practical	Tutorial
Pharmacology	75	50	25
Community Pharmacy & Management	75	75	25
Biochemistry & Clinical Pathology	75	50	25
Pharmacotherapeutics	75	25	25
Hospital & Clinical Pharmacy	75	25	25
Pharmacy Law & Ethics	75	--	25
<b>Total</b>	<b>450</b>	<b>225</b>	<b>150</b>



→ **Approval of the authority / Institution conducting the course :**

- No one can conduct D Pharma course in a state without the approval of PCI . and PCI do not approve any Institution unless it provide appropriate arrangements for teaching like buildings , accommodation , equipment and teaching staff etc.

→ **Examinations :**

- Annual exam Theory and practical at end of the academic year.
- Supplementary exam ( back paper )
- Sessional exam ( theory and practical )

Subject	Maximum Marks for Theory			Maximum Marks for Practicals		
	Examination	Sessional	Total	Examination	Sessional	Total
Pharmaceutics	80	20	100	80	20	100
Pharmaceutical Chemistry	80	20	100	80	20	100
Pharmacognosy	80	20	100	80	20	100
Human Anatomy & Physiology	80	20	100	80	20	100
Social Pharmacy	80	20	100	80	20	100
			<b>500</b>	<b>+ 500 = 1000</b>		

Subject	Maximum Marks for Theory			Maximum Marks for Practicals		
	Examination	Sessional	Total	Examination	Sessional	Total
Pharmacology	80	20	100	80	20	100
Community Pharmacy & Management	80	20	100	80	20	100
Biochemistry & Clinical Pathology	80	20	100	80	20	100
Pharmacotherapeutics	80	20	100	80	20	100
Hospital and Clinical Pharmacy	80	20	100	80	20	100
Pharmacy Law & Ethics	80	20	100	-	-	-
<b>600</b>				<b>+400</b>	<b>+100</b>	<b>= 1100</b>

- **Eligibility for Appearing at the exam** : The percentage of presence in class should not be less than 75%.
- **Minimum Passing Marks** : Minimum 40% marks should be obtained in each subjects including sessional marks , separately in theory and practical.
- **Eligibility for Promotion to D pharma second year** : If a student is fail in more than two subjects he / she will not be promoted to second year.

### Chapter 3

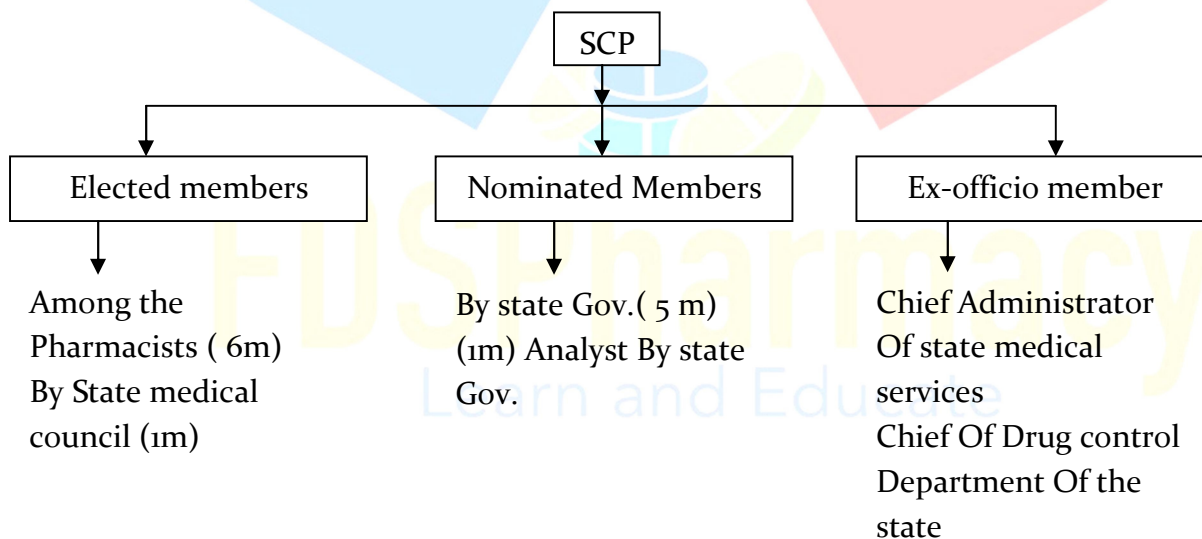
- Diploma In pharmacy Part 3rd ( Practical training )
  - **Procedure for practical training** : The institution issue the Practical Training Contract Form , It will be in will in five sections.

### Chapter 4

- **Certificate of Diploma In Pharmacy** : On completing successfully all the 3 Parts , the student granted a certificate of Diploma In Pharmacy
- Now he can apply for Exit Exam . after passing the exit exam he can apply for drug license.

# State and Joint State Pharmacy Council ( SPC)

- According to the Pharmacy Act , a State Pharmacy Council is constituted under each state government .
- This council Maintains a register for the Pharmacists of the state , and monitor their activities regarding the profession .
- These members hold their positions for five years , from themselves a president is nominated by Gov. and vice - President is elected by themselves.
- Section-19 of pharmacy Act 1948 provides for constitution and composition of state council. Every state government has to constitute state council accordingly which consists of following members.
  1. Elected members
  2. Nominated Members
  3. Ex-officio member



1. **Elected members** : Six members elected from among themselves by registered Pharmacist of state. One member elected by the state Medical council from amongst its member.
2. **Nominated Members** : Five members are nominated by the state government of whom atleast three should be degree are D.Pharma or pharmaceutical chemistry or should be registered Pharmacist.
3. **Ex-officio members** : The chief administrative medical officer of the state ex-officio.
  - The officer incharge of drug controller department of State.
  - The government analyst deputed by the state government.
  - President and Vice President of shall be elected by the members from amongst themselves.
  - Subject to membership they hold office for the five years and are also eligible for re-election



# Joint State Pharmacy Council

- Under the Joint State Pharmacy Council , two or more states do an agreement , and according to this agreement , State Pharmacy Council of one state help and fulfill the needs of other state/ states.
- Member of Joint State Pharmacy Council are nominated by each state governments.
  - 3- 5 members from state Pharmacy council
  - 2-4 other members from each state ( not from state council )
  - 1 member from medical council
  - and chief administrative medical officer , Government analyst ,drug controller.

## Registration of Pharmacist

- The pharmacy act provides for registration of the pharmacist to regulate the entry of person in "Pharmacy professions" only person having requisite, qualifications, training, and experience are allowed to enter the professions. Name of registered Pharmacist are entered in the Register maintain by state council and central council.
- The register include particulars
  - Full name and residential address of registered Pharmacist.
  - Date of first admission to register.
  - Qualification for registration
  - Professional address,
  - Name of employer if employed.
  - Such other particulars are may be prescribed

### First register :

- For preparation of 1st register the state government constitutes a "Registration Tribunal" by notification in the official gazette.
- The tribunal consists of three person and a register. The registered act as secretary of tribunal.
- The state government by notification specify the date for submission of applications for registration. The applications for registration along with prescribed fee should be made on or before this date registration tribunal.
- The state government by notification specify the date for submission of applications for registration. The applications for registration along with prescribed fee should be made on or before this date registration tribunal.

## Qualification for entry on 1st register :

- A person above 18 years of age who resides or carries business or professions of pharmacy in the state on payment of prescribed fee is entitled for entry of the name in the 1st Register.
- Hold degree or diploma in Pharmacy of pharmaceutical chemistry or a "chemist" and "druggist" "Diploma of Indian University or state government". A qualification granted outside of India approved under section-14.
- Hold degree of and Indian University other than degree in pharmacy or pharmaceutical chemistry and has been engaged for a total period of time is more than than 3 years in compounding of drug in hospital or dispensary in other place.
- Passed an examination recognised as adequate by the state government for compounding or dispensing

## Procedure for Registration of Pharmacist :

- Under provisions for section-33 of act state pharmacy council register name, Address, and, Qualifications of the Pharmacist in the state register an application in prescribed pro-forma is to be submitted to the register of respective State pharmacy council.
- The application should be accomplished by the prescribed fee and following document.

## Document required for Registration of Pharmacist (P.C.I. Registration) :

- 5 recent passport size photo
- ID proof
- Address proof
- Hospital training certificate
- Mark sheet of 1st year and 2nd year D.Pharma, If you want to get the registration of B.Pharma then its complete mark sheet all year.
- Provision certificate
- 10+2 marksheet

## Renewal of Registration :

- First registration continued till 31 December of year following the year in which it is granted there after registered Pharmacist should annually renew registration by the due date to retain his name on register of pharmacist.
- On failure to remit renewal fee before due date 1April of subsequent year.
- The name defalter pharmacist is remove from the registered on payment of renewal fee the register issues receipt therefore.
- This stand as a proof of renewal of Registration in order to avoid such situation, pharmacist may voluntarily remit advance renewal fee in Lump Sum (ARFL).

# Offences and Penalties

- ❖ **Falsely claiming to be a registered Pharmacist** : If a person who is not a registered Pharmacist , and he claims to be registered pharmacist or uses such words which signify ( show ) that he is a reg. Pharmacist , he can be punished with a fine up to 500 rupees.
- ❖ **Dispensing drug without registration** : If a person is not reg. Pharmacist and dispensing prescribed drugs , he could be punished with a fine of Rs 1000 . or imprisonment up to six months or with both.
- ❖ **Failure to surrender the Certificate Of registration** : If some ones name has been removed , and he has not surrendered his certificate to the registrar without a reason ,he can be punished with Rs 50.

## Pharmacy practice regulations , 2015

### Chapter 1

#### Definitions

- Act : means Pharmacy Act 1948.
- Practice Of Pharmacy : Means
  - a) Interpretation , evaluation and implementation of medical orders , dispensing of prescriptions , drug orders.
  - b) Participation in drug and device selection , drug administration.
  - c) Provisions of patient counseling and the provision of those acts or services necessary for patients

#### Compounding

- Compounding means the preparation, mixing, packing or labeling of a drug or device.

#### Dispensing

- “Dispensing” Means delivery of drugs or devices to a patients or patients attendant , according to prescription or without prescription.

#### Patient Counselling

- It means the oral guidance by Pharmacist to the patient regarding drugs or devices.

#### Pharmaceutical Care

- It means to provide health care services with the help of Pharmaceuticals ( drugs and devices ).

#### Pharmacy Practitioner

- It means a registered Pharmacist which can be classified as :
  - **Community Pharmacist** : It is a registered Pharmacist who provides health care services in a community with the help of a community pharmacy.



- **Hospital Pharmacist** : It is a registered Pharmacist who provides health care services in a hospital.

## **Clinical Pharmacist**

- ▲ It is a registered Pharmacist which provides health care services through his Clinical Pharmacy. Clinical Pharmacist provides his services with the help of physicians and other health care professionals.

## **Prescription**

- It means a written or electronic direction from a registered Medical Practitioner to a Pharmacist to deliver drugs.

## **Chapter 2**

### **Code of Pharmacy ethics**

- 1) **Declaration** : When a person apply for the registration , he is provided a copy of declaration in which he declares with oath that I will follow all the rule and regulation.
- 2) **Displaying name of owner and registered pharmacist** :
  - (a) Name of the owner of pharmacy business shall be displayed.
  - (b) Name of the registered pharmacist along with his registration number and qualification along with his/her
  - (c) photograph shall be displayed adjacent to the area where dispensing is carried on in the pharmacy. Registered

### **Duties and responsibilities of the registered pharmacist in general :**

#### **1) Character of registered pharmacist :**

- The main objectives of Pharmacy profession is to provide services to humanity. financial Gain should not be main target.
- A pharmacist should care about the dignity and honour of his profession.

### **Renewal of Registration**

- It is the responsibility of pharmacist to renew his registration , after one year of registration and then after 5 years.

### **Dispensing against prescription of Registered Medical Practitioner only**

- It is the responsibility of pharmacist to dispense only those medicines which are prescribed and will not substitute the prescription.

### **Practical training to student pharmacists**

- The owner of pharmacy should get the approval of PCI before practical training to students. and during he should handle them with good manner and should pay best of his efforts.

## Pharmacy Inspectors to Inspect the Pharmacists

- The owner / registered Pharmacist should allow co- operate with the inspectors are pointed by state Pharmacy council to inspect the premises where the drugs are compounded or dispensed.

## Maintaining Good Pharmacy Practice

- 1) **Membership In Association** : For advancement of his profession he should join with association and society of allopathic pharmacy professions , and should attend their meetings.
- 2) **Maintenance of Patient record** : He should maintain the prescription record of patients for 5 years.
- 3) **Highest Quality Assurance in Patient Care** : The Pharmacist avoid those persons whose moral character and educational level is low.
- 4) **Exposure of Unethical conduct** : He should expose , without fear and favor, the corrupt , dishonest , and unethical things of the members of profession.
- 5) **Payment of professional services** : A Pharmacist should announce his fees before paying service not after.

## Application of other Laws not Barred

- The registered pharmacist shall obey the laws of country and convinced others to follow them also.

## Chapter 3

### Duties of Registered Pharmacist to their Patients

#### Obligations to the Sick

- 1) It is not necessary for pharmacist to provide his services to every person asking his services , but he should pay his best of effort for those who are under his care.
- 2) A pharmacist should review the patient record and each prescription , for purpose of promoting appropriate therapeutic care by identifying :
  - Overutilisation or underutilization.
  - Drug -disease interaction
  - Drug - drug interaction
  - Incorrect dosage or duration of drug administration.

#### Patience , Delicacy and Secrecy

- A registered Pharmacist should have Patience and delicacy in his character , and defects of patient observed during medical attendance should never be reveal to anyone unless it is required by state gov

#### Prognosis

- A Pharmacist will neither exaggerate not minimize the real condition of a patient .

## The patient must not be neglected

- A Pharmacist is free to choose whom he will provide services , but he should neglect anyone in emergency condition.

## Chapter 4

### Duties of registered Pharmacist

- a) **Dispensing / supply of drugs** : The actual dispensing of drugs to patients should only by a registered Pharmacist , if it is not possible , then the various activities be performed under super- vision of a registered pharmacist.
- b) **To promote rational use of drug** : It is also a duty of pharmacist to promote rational ( appropriate ) use of drugs ( quality , safety , drug related information ).

### Patient Counselling

- At the time of delivery of drug the pharmacist should provide important information orally such as
  - Route of administration
  - Duration of administration
  - Dose
  - Drug storage

## Chapter 5

### Responsibilities of registered Pharmacists to each other

- 1) **Conduct In counseling** : A junior Pharmacist should get suggestion from a senior Registered Pharmacist , and should not be jealous , dishonesty and disrespect to each other.
- 2) **Appointment of substitute** : Whenever a registered pharmacist request another to attend his patients during his temporary absence, he should accept the request.

## Chapter 6

### Duties Of Registered Pharmacist to public and to the profession

- 1) **Registered Pharmacist as citizen** : He should play his role in enforcing the laws of community and should conduct the institution and programs that increase the humanity
- 2) **Public And Community Health** : It is a duty of pharmacist to promote the public health and try to prevent diseases . He should teach about diseases and their transmission , especially communicable diseases.

## Chapter 7

### Unethical Acts

- A registered pharmacist should avoid the unethical acts are following :
  - a) **Advertising** : A pharmacist should avoid Advertising for the purpose of attraction of patients to him, directly or indirectly , in the same way he should avoid printing of self - photograph or any such material of publicity.
  - b) **Rebates and Commission** : A registered pharmacist should avoid rebates ( discount on buying ) and commissions.
  - c) **Secret Remedies** : The prescribing or dispensing of drugs which ingredients are unknown is unethical.
  - d) **Human rights** : A pharmacist should care the human rights and should avoid mental and physical torture.

## Chapter 8

### Misconduct :

- A registered Pharmacist should avoid unacceptable and improper behaviour such as :
  - Violation of Regulations Of Pharmacy Act.
  - Substitution of prescription without approval of prescriber.
  - Giving His certificate to use a pharmacy owner without attending the pharmacy.
  - Giving the certificate to use to more than one pharmacy.
  - Not displaying the certificate in the pharmacy.
  - Not allowing the inspectors from inspection the pharmacy.
  - Disclosing ( exposing ) the secrets of patients which he observed during medical profession.
  - Using agents for seeking patients.
  - Working in pharmacy, to work in another place like industry , college etc is understood a misconduct.

## Chapter 9

### Punishment and disciplinary Action

- Any complaint regarding profession can be submit before the PCI or State Pharmacy council.
- In the case of removal from register for a limited time may also be restore by state pharmacy council.
- Any decision on complaint against a registered pharmacist should be taken within 6 months.
- During the pendency of decision the state pharmacy council may stop the pharmacist from pharmacy practice until the decision sdeclared.

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