(661)

GUIDELINES

FOR ANALYSIS OF ASU SAMPLES IN DRUG RESEARCH LABORATORIES OF CENTRAL COUNCIL FOR RESEARCH IN UNANI MEDICINE

Preface

The Central Council for Research in Unani Medicine is the apex government organization established for fostering research and development in Unani Medicine. It conducts researches in house through a network of 23 institutes as well as in collaboration with other institutions of repute. Clinical research, drug standardization, survey and cultivation of medicinal plants and literary research are key research programmes undertaken at the CCRUM.

Standardization and toxicity evaluation of drugs is one of the most important components of medical research. Considering this, the CCRUM has established some state-of-the-art DST facilities for drug testing and preclinical studies at its institutes located in Hyderabad, Ghaziabad, Chennai, and Srinagar. In its efforts to foster research and development, the CCRUM offers services of these facilities to other government and private research organizations as well as industry at nominal charges for the larger benefits of the mankind. This booklet intends to propagate research facilities of the CCRUM in order to facilitate such organizations in the fulfillment of their needs for drug testing and toxicity evaluation. I am sure it would prove helpful in achieving the objective of undertaking, coordinating, aiding and promoting research in Unani Medicine.

(Prof. Asim Ali Khan)
Director General, CCRUM

About CCRUM

The Central Council for Research in Unani Medicine (CCRUM) is an autonomous organization under the Ministry of Ayush, Government of India. The mission of the CCRUM is to strive for excellence and global leadership in the field of Unani Medicine by comprehensive research for quality assured and cost-effective products to prevent/manage/cure various diseases and to develop a dynamic, vibrant and model research organization for undertaking, coordinating, aiding and promoting research in Unani Medicine. It aims to bring-up modern scientific knowledge technology to explore classical Unani treasure by following prevalent scientific methods through inter disciplinary approach.

Since its establishment in 1978, the CCRUM has been engaged in conducting scientific research on the applied as well as fundamental aspects of Unani Medicine. Over the past four decades of its existence, it has made significant strides in clinical research, drug standardization, survey and cultivation of medicinal plants, literary research and other research and development programmes.

Drug Research

Unani Medicine believes in purity and quality of single and compound drugs as sub-standard drugs cannot produce desired results. The drug standardization encompasses comprehensive evaluation of drugs in respect of their pharmacognostical, physiochemical and pharmacological profiles in order to study various qualitative, quantitative and characteristics of drugs. The pharmacognostical studies of plant material include the study of gross morphology, its macro and microscopical characteristics and after suitable processing enumeration of characteristics structures of cells, tissue and organs under microscope and determining their essential bio-statistical dimensions. The physio-chemical parameters of single and compound drugs include determination of organoleptic characteristics, moisture content, ash values, extractive values, pH values, presence of active constituents and HPTLC fingerprint studies, heavy/toxic metals, microbial contamination, aflatoxins and pesticide residue. These may be useful as benchmark standard for any commercial sample compared or as a reference standard. The standards shall be useful for preparation of quality Unani drugs.

Drug Research Labs of CCRUM

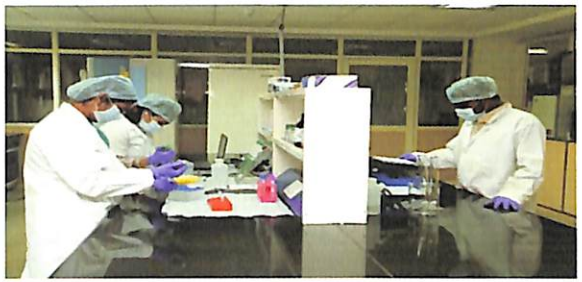
The CCRM has established drug testing and preclinical laboratories at National Research Institute of Unani Medicine for Skin Disorders (NRIUMSD), Hyderabad, Drug Standardization Research Institute (DSRI), Ghaziabad, Regional Research Institute of Unani Medicine (RRIUM), Chennai, RRIUM, Srinagar with the following objectives:

1. Evaluation of pharmacopoeial standards of Unani single drug as well as formulations included in different volumes of National Formulary of Unani Medicine and Essential Drug List.
2. Development of Standard Operating Procedures (SOPs) for method of preparation of formulations followed by their pharmacopoeial standards.
3. Estimation of heavy metals, microbial load, aflatoxin contents and pesticidal residues from single and compound drugs.
4. Shelf-life studies to evaluate the stability potential of drugs.
5. Pre-clinical or toxicity studies to determine therapeutic potential and hazards of drugs.

PHARMACOLOGY LABORATORY OF RRIUM, SRINAGAR
DEVELOPED UNDER DST PROJECT

BIO-CHEMISTRY CELL & MOLECULAR BIOLOGY LAB AT NRIUMSD, HYDERABAD

Cell Culture Laboratory



Molecular Biology Laboratory

Instruments for Genetic Studies

Gel Documentation System

DRUG TESTING LABORATORY AT RRIUM, CHENNAI

Microbiology Lab.

Instrumentation Room

Pharmacognosy Lab

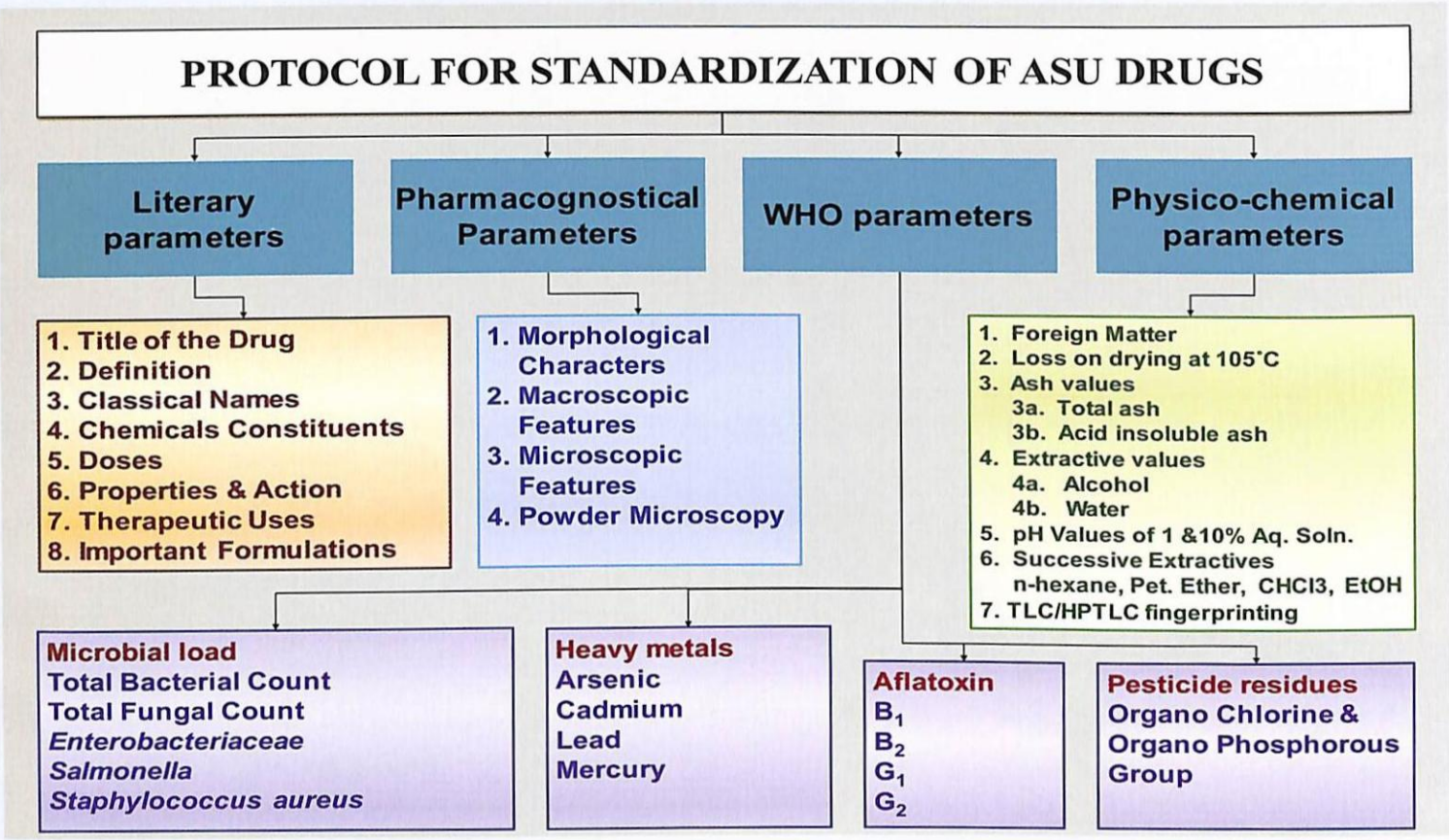
Chemistry Lab

Activities at Drug Research Labs

The CCRUM laboratories are utilized for quality control and evaluation of ASU&H drugs on DTL pattern. The activities of pharmacopoeial and preclinical studies are as follows:

- Preparation of Unani Pharmacopoeia of India (UPI) of single drugs (Part-I) and compound formulations (Part-II)
- Prescribing the working standards for raw materials as well as compound formulations including test for identity, purity, strength and quality so as to ensure uniformity of the finished formulations
- Developing standard methods for analysis, doses forms, toxicity profile, etc. for Unani formulations
- Identification of methods and procedures for publication of the standards of commonly used formulations of National Formulary of Unani Medicine in a phased manner
- Providing information on Unani formulations regarding the distinguished characteristics, methods of preparation, methods of administration with various vehicle and their toxicity
- Any other matter relating to the quality standards, shelf-life, identification, new information, etc.

Methods Followed by CCRUM Drug Research Laboratories for Standardization of ASU Drugs



Protocol for Standardization of Unani Compound Formulations

MAJUNAT (Semisolids)

2. Brief description
3. Identification - Powder microscopy
4. HPTLC/HPLC/GC profile
5. Physico-chemical parameters
   - 4a. Total ash
   - 4b. Acid insoluble ash
   - 4c. Alcohol & water soluble extractive
   - 4d. pH of 1 & 10% aq. suspension
   - 4e. Reducing sugar
   - 4f. Non-reducing sugar
   - 4g. Loss on drying
   - 4h. Bulk density
6. WHO parameters
   - 5a. Microbial load
   - 5b. Aflatoxins
   - 5c. Pesticidal residue
   - 5d. Heavy metal

RAUGHANIYAT/MARHAM (Oil/Gel)

1. Brief description
2. Identification (with GLC)
3. HPTLC/HPLC/GC profile
4. Physico-chemical parameters
   - 4a. Petroleum ether extractive (%)
   - 4b. Acid value
   - 4c. Iodine value
   - 4d. Peroxide value
   - 4e. Unsaponifiable matter
   - 4f. Refractive index
   - 4g. Weight per ml (gm)
   - 4h. Test for presence of
     - i. Arachis oil
     - ii. Cotton seed oil
     - iii. Sesame oil
     - iv. Mineral oil
1. WHO parameters
   - 5a. Microbial load
   - 5b. Aflatoxins
   - 5c. Pesticidal residue
   - 5d. Heavy metal

HUBUB/AQRAS/SAFUF
(Pills /Tablets/ Powder)

1. Brief description
2. Identification – Powder microscopy
3. HPTLC/HPLC profile
4. Physico-chemical parameters
   - 4a. Total ash
   - 4b. Acid insoluble ash
   - 4c. Alcohol & water soluble extractive
   - 4d. pH of 1 & 10% aq. suspension
   - 4e. Loss on drying
5. WHO parameters
   - 5a. Microbial load
   - 5b. flatoxins
   - 5c. esticidal residue
   - 5d. Heavy metal

ARAQ/QUTUR
(Distillate)

1. Brief description
2. Identification (with GLC)
3. HPTLC/HPLC/GC profile
4. Physico-chemical parameters
   - 4a. pH (as such)
   - 4b. Weight g/ml
   - 4c. Refractive index
   - 4d. UV-Spectroscopy profile
5. WHO parameters
   - 5a. Microbial load
   - 5b. Aflatoxins
   - 5c. Pesticidal residue
   - 5d. Heavy metal

KUSHTAJAT/KUHL (Fine Powder)

1. Brief description
2. HPTLC/HPLC profile
3. Physico-chemical parameters
   - 3a. Nature
   - 3b. Colour
   - 3c. Streak
   - 3d. Cleavage
   - 3e. Fracture
   - 3f. Lustre
   - 3g. Tenacity
   - 3h. Transparency
   - 3i. Hardness
   - 3j. Sp. gr.
   - 3k.Fluorescence
4. Chemical properties
   - 4a. Reaction with acids
   - 4b. Effect of Heat
   - 4c. Other elements
5. WHO parameters
   - 5a. Microbial load
   - 5b. Aflatoxins
   - 5c. Pesticidal residue
   - 5d. Heavy metal

SHARBAT/SHIKANJABIN (Syrup)

1. Brief description
2. Identification (with GLC)
3. HPTLC/HPLC profile
4. Physico-chemical parameters
   - 4a. Total ash
   - 4b. Acid insoluble ash
   - 4c. Alcohol & water soluble extractive
   - 4d. pH of 1 & 10% aq. suspension & as such
   - 4e. Refractive index
   - 4f. Weight per ml (g)
   - 4g. Optical rotation
   - 4h. Reducing sugar
   - 4i. Non-reducing sugar
   - 4j. Loss on drying
5. WHO parameters
   - 5a. Microbial load
   - 5b. Aflatoxins
   - 5c. Pesticidal residue
   - 5d. Heavy metal

Need for Analysis of ASU Drugs

As per the Drugs & Cosmetics Act, 1940, no person shall manufacture for sale or for distribution any ASU drugs except in accordance with such standards, if any, as prescribed in relation to that drug. Before manufacturing of ASU formulations, the industry should analyze the raw drug samples for its identity, purity, quality and strength in accordance with the Rule 160 B of the Drugs & Cosmetics Act, 1940 as well as following the format of ASU pharmacopoeia.

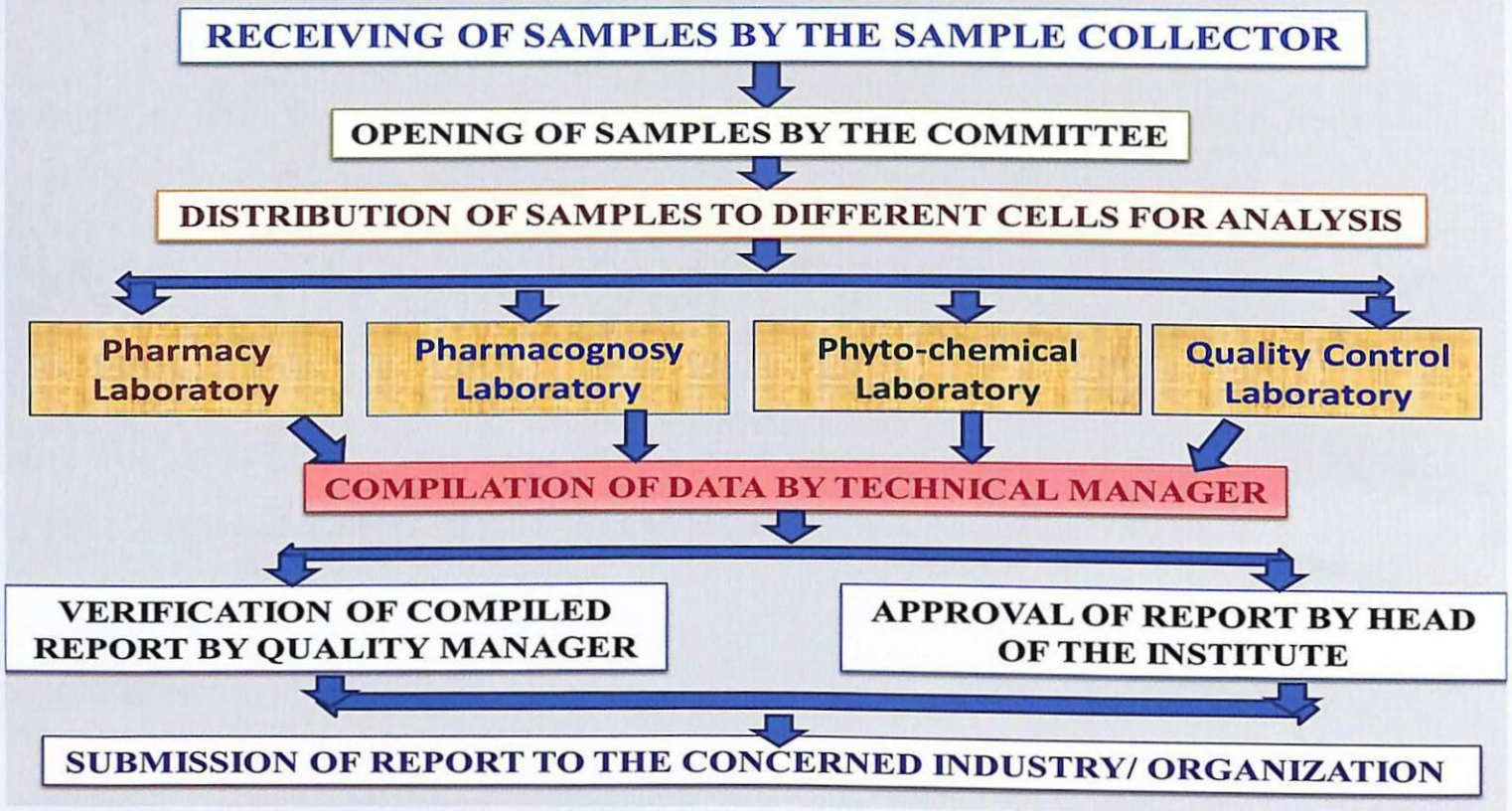
The need for analysis arises to check if a drug is deemed to be misbranded (label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular), adulterated (prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health) or spurious (an imitation of, or is substitute for, another drug or resembles another drug in a manner likely to deceive, or bears upon it or upon its label or container the name of another drug, unless it is plainly and conspicuously marked so as to reveal its true char: ter and its lack of identity with such other drug).

How to Submit Samples for Analysis

The sample to be analyzed should be properly sealed in an air-tight, moisture-proof and light-proof container made of glass or any other suitable material such as tin, can, covered metal tin which is previously sterilized. The container must have label displaying the list of all the ingredients used in the manufacture with quantity of each of the ingredients incorporated therein and a reference to the method of preparation. If the list of ingredients contained in the medicine is large and cannot be accommodated on the label, the same may be printed separately and enclosed with packing and reference be made to this effect on the label. The following conditions must be followed while sending samples to the CCRUM Drug Testing Laboratories for analysis:

- While labelling the drug, the name should be same as mentioned in the authoritative books either included in the First Schedule of the Drugs & Cosmetics Act, 1940 or mentioned in other classical references.
- The label must have the net content of ingredients in terms of weight, measure or number as the case may be. The weight and volume shall be expressed in metric system.
- Name and address of the manufacturer along with the license under which the drug is manufactured, the figure representing the manufacturing license number being preceded by the words 'Manufacturing License Number' or 'Mfg. Lic. No.' or 'M.L.' must be mentioned.
- A distinctive batch number, i.e. the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken must be recorded and available for inspection for, e.g. "Batch No." or "Batch" or "Lot Number" or "Lot No." or "Lot".
- The date of manufacture must be mentioned. It is either the date of completion of the final products or the date of bottling or packing for issue.
- The words "FOR EXTERNAL USE ONLY" must be printed on label, if the medicine is for external application.

PROCEDURE FOLLOWED IN CCRUM DTL LABORATORIES FOR ANALYSIS OF ASU DRUGS



Charges for Analysis of ASU Samples at Drug Testing Laboratories

The CCRUM laboratories at Regional Research Institute of Unani Medicine, Chennai and Drug Standardization Research Institute, Ghaziabad are testing ASU samples in accordance with DTL pattern and the charges for testing of ASU samples are as follows:

S. No.	Name of Parameter	User Charge
1.	Loss on drying at 105 °C	₹220/-
2.	Refractive index	₹220/-
3.	Acid value	₹440/-
4.	Saponification value	₹440/-
5.	Iodine value	₹440/-
6.	Fat content	₹330/-
7.	Peroxide value	₹440/-
8.	Rancidity test	₹220/-
9.	Ash value	₹220/-
10.	Acid insoluble ash	₹220/-

S. No.	Name of Parameter	User Charge
11.	pH	₹220/-
12.	Specific gravity	₹220/-
13.	Total solids	₹220/-
14.	Alcohol content	₹440/-
15.	Reducing sugar and total sugar	₹660/-
16.	Volatile matter	₹440/-
17.	Water soluble extractive	₹220/-
18.	Alcohol soluble extractive	₹440/-
19.	Microscopic examination of plant material	₹500/-
20.	Microscopic examination of raw material of compound drug	₹500/-
21.	Assay of iron	₹440/-
22.	Assay of calcium	₹440/-
23.	Assay of potassium by Flame photometer	₹440/-
24.	Assay of sodium by Flame photometer	₹440/-
25.	Assay of tin	₹440/-
26.	Assay of silver	₹440/-
27.	Assay of lead	₹440/-

S. No.	Name of Parameter	User Charge
28.	Assay of copper	₹440/-
29.	Assay of mercury	₹440/-
30.	Resin content	₹330/-
31.	Disintegration test	₹220/-
32.	Standardisation of single plant drugs as per APC/UPC format (loss on dryings at 105 C, ash value, acid insoluble ash, pH, water soluble extractive, alcohol soluble extractive, HPTLC)	₹8800/-
33.	Foreign matter	₹220/-
34.	UV spectrum	₹330/-
35.	TLC with photographs	₹880/-
36.	HPTLC – Quantitative	₹3850/-
37.	HPTLC - Quantitative (respective marker provided by the customer)	₹4400/-
38.	Assay of elements by AAS a. Lead	₹1500/-
	b. Cadmium	
	c. Arsenic	
	d. Mercury	

S. No.	Name of Parameter	User Charge
39.	Microbial load	₹2000/-
	Staphylococcus aureus, /g	
	Total plate count, cfu/g	
	E.coli, /g	
	Yeast and moulds count, cfu/g	
	Pseudomonas aeruginosa, /g	
	Salmonella, /g	
40.	Aflatoxins	₹1500/-
41.	Extraction from plant powder (per kg) by cold maceration method	₹3300/-
42.	Extraction from plant powder (per kg) by successive cold maceration method	₹6600/-
43.	Organic qualitative analysis (per extract)	₹1100/-

Preclinical or Toxicity Studies

Acute toxicity is a single-dose test that identifies symptoms and the extent to which toxicity affects animals. Sub-acute toxicity studies at repeated doses can be carried out after obtaining preliminary information from acute toxicity tests, which provide information about the animal's target tissue or organ. The preclinical research activities/facilities of only acute and sub-acute testing are available at NRIUMSD, Hyderabad and the charges for analysis of acute and sub-acute toxicity studies are given below:

Charges for Preclinical/Toxicological Studies

	Animals*	Feed & Bedding Material	Chemicals and Consumables	Histopathology**	Haematology & Biochemical Investigation	Subtotal	Overhead Charges ***	Total	Rounded
Approximate Rate	₹1500 per rat	Feed @₹100 per kg; CornCob@ ₹50 per kg	-	₹600 per tissue +18% GST for 12 organs per animal = ₹8496 per animal	-	-	At the rate of 15-20% of Subtotal	-	-
Acute Toxicity (Oral; Rat/Mouse) (Upto 20 Animals)	₹30000	₹3000	₹3000	N/A	₹7800	₹43800	₹8760	**₹52560**	**₹50000**
Sub-acute (28-day) Toxicity (Oral; Rat/Mouse) (Upto 60 Animals including Satellite Group)	₹90000	₹7500	₹20000	₹254880	₹48000	₹420380	₹84076	**₹504456**	**₹500000**

**Animal rate as per Hylasco Bio-Technology Pvt. Ltd; **As per EDARA Research Foundation rate contract considering histopathology of vehicle, high dose group including satellite group; ***Overhead charges are included @ 20% of subtotal cost of study*

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