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GMP FOR RASAUSHADHIES, RASAMARUNTHUKAL AND KUSHTAJAT

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ABSTRACT

Herbo-mineral-metallic formulations such as Rasaushadhies or Rasamarunthukal and Kushtajat are popular because of efficacy, smaller dose, and shelf life. These formulations are prepared from processed metals, minerals, alloys, or their compounds. Compliance to GMP is an essential requirement for manufacturing Ayurveda, Siddha and Unani (ASU) medicine. Schedule "T" under the Rule 157 of Drug and Cosmetics Rule 1945, prescribes the GMP guidelines. In Schedule "T" there is supplementary guideline for manufacturing of mineral/metal-based formulations. The factory premises of ASU manufacturing plant should have adequate space for receiving and storing raw materials, manufacturing process areas, quality control section, finished goods store, rejected goods/drugs store and office. The manufacturing area should be designed with proper ventilation, exhaust and chimney providing special attention to process that generate toxic fumes like SO_2, arsenic, mercury vapor etc. Batch manufacturing record of each batch of product shall provide an account of the list of raw materials, their quantities obtained from the store, tests conducted during the various stages of manufacture, in process record of various shodhana, bhavana, burning in fire, specific grindings, record of date, manpower, machine and equipments used, details of transfer of manufactured drug to the finished products store, quantity, packaging, testing report of the finished product and any other records as required. The release of Rasaushadhis should be under the control of a person who has been trained in the specific features of the processing and quality assurance of Rasaushadhis.

Keyword: Schedule T, Ayurvedic, Siddha & Unani, Drug and Cosmetics Act and Rules

INTRODUCTION

The manufacture, sale and distribution of Ayurvedic, Siddha and Unani (ASU) drugs are regulated under the Drug and Cosmetic Act 1940 and Rules 1945. A valid manufacturing licence is the prime requirement for the manufacturing of ASU drugs for sale. An application for the grant or renewal of a licence to manufacture for sale of any ASU drugs is made in Form 24-D (or, Form 24-E in case of loan licence) to the Licensing Authority along with documents such as declaration, site plan, key plan, ownership deed of the land, non-conviction affidavit, organization chart, authorized signatory, list of machineries, list of books, SOPs, proof of the premises, MOA, documents regarding medicines etc. varying state to state or area to area. Rule 157 of the Drugs and Cosmetics Rules, 1945 provides the requirement of GMP compliance for grant or renewal

of license to manufacture ASU product since March, 2003. The objectives of GMP are to produce authentic, quality standard and contamination free product; the manufacturing process is as has been prescribed to maintain the standards; adequate quality control measures are adopted; the manufactured drug which is released for sale is of acceptable quality; each licensee shall evolve methodology and procedures for following the prescribed process of manufacture of drugs; methodology and procedures should be documented as a manual and kept for reference and inspection and so on. Schedule "T" under Rule 157 prescribes the GMP guidelines in Part-I & II as shown in Table 1.

Herbo-mineral-metallic formulations such as Rasaushadhies or Rasamarunthukal and Kushtajat of ASU have significant role. Herbo‑metallic formulations are prepared from processed metals (mercury, gold, iron, arsenic, etc.), minerals, alloys, or their compounds. These formulations are popular because of its efficacy, smaller dose, and shelf life but safety and safe uses of herbo- metallic or mineral formulations are subject of great concern in present era. Considering these there was requirement that there should be a guideline for quality assurance and control in manufacturing of these formulations. In 2009 supplementary guidelines for manufacturing of herbo-mineral-metallic compounds of ASU were included in Schedule T dealing with Bhasmas, Sindura, Pishti, Kajjali, Khalviya Ras, Kupipakwa, Rasayan, Parpati, Potali Rasa, Satwa (of Metals and Minerals origin) Druti Parpam, Karpu, and Kushta etc. The present study is focussed to understand the manufacturing requirement for herbo-mineral-metallic compounds as in supplementary and parent guideline of Schedule "T".

Table 1: Schedule T

Part-I	**Part-II**
1.1 General Requirements: A. Location and surroundings B. Buildings C. Water Supply D. Disposable of Waste E. Container 's Cleaning F. Stores G. Working space. H. Health Clothing, Sanitation & Hygiene of Workers I. Medical Services: J. Machinery and Equipments K. Batch Manufacturing Records L. Distribution Records M. Record of Market Complaints N. Quality Control. **1.2. Requirement for Sterile Product:** A. Manufacturing Areas: B. Precautions against contamination and mix	A. List of recommended machinery, equipment and minimum manufacturing premises required for the manufacture of various categories of Ayurvedic, Siddha system of medicines B. List of machinery, equipment and minimum manufacturing premises required for the manufacture of various categories of Unani system of medicines C. List of equipment recommended for in-house quality control section D. Supplementary guidelines for manufacturing of Rasaushadhies or Rasamarunthukal and Kushtajat (herbo-mineral-metallic compounds) of Ayurveda, Siddha and Unani medicines

GMP/ SCHEDULE T

Factory Building and its surroundings: GMP requires that ASU manufacturing unit shall be so situated and shall have such construction as to avoid contamination from open sewerage, drain, public lavatory, from any factory which produces disagreeable or obnoxious odour or fumes or excessive soot, dust and smoke. The factory building itself should not be source of contamination, their floor and the walls should not be damp or moist. Interior surface such as walls, floors and ceilings shall be smooth, free from cracks and permit easy cleaning and disinfection. The walls of the room in which the manufacturing operations are carried out shall be impervious to and be

capable of being kept clean. The flooring shall be smooth and even and shall be such as not to permit retention or accumulation of dust or waste products. There should be fire safety measures and proper exits should be there. The factory building should be so designed, constructed and maintained to prevent entry of insects and rodents and shall be free from cobwebs and insects/rodents. It should have adequate provision of light and ventilation. The premises used for manufacturing, processing, packaging and labelling will be in conformity with the provisions of the Factory Act and shall be compatible with other manufacturing operations that may be carried out in the same or adjacent premises.

Pipework, Water Supply, Lightening etc.: Electrical supply, lighting, temperature, humidity and ventilation should be appropriate. Pipework, light fittings, ventilation points and other services should be designed and sited to avoid the creation of recesses that are difficult to clean. As far as possible, for maintenance purposes, they should be accessible from outside the manufacturing areas. The water used in manufacture shall be pure and of potable quality. Adequate provision of water for washing the premises shall be made. From the manufacturing section and laboratories, the wastewater and the residues which might be prejudicial to the workers or public health shall be disposed off. In factories where operations involving the use of containers such as glass bottles, vials and jars are conducted, there shall be adequate arrangements separated from the manufacturing operations for washing, cleaning and drying of such containers.

Premises Area and Working Spaces: The manufacturing plant should have adequate space for receiving and storing raw material, manufacturing process areas, quality control section, finished goods store, office and rejected goods/drugs store. The manufacturing area shall provide adequate space for orderly placement of equipment and material used in any of the operations for which these employed so as to facilitate easy and safe working and to minimize or to eliminate any risk of mix-up between different drugs, raw materials and to prevent the possibility of cross contamination of one drug by another drug that is manufactured, stored or handled in the same premises. The requirement of machinery, equipments, space for an applicant companies only to have GMP of Rasaushadhis or Rasamarunthukal and Kushtajat of ASU medicines are as shown in Table 2. These requirements are subject to the modification if the Licensing Authority is of the opinion that having regard to the nature and extent of the manufacturing operations it is necessary to relax or alter them in the circumstances in a case.

The equipments/machines must be properly installed and maintained ensuring adequate space between two machines or rows of machines for ease in movement of workers and operations. Proper Standard Operational Procedures (SOPs) for cleaning, maintaining and performance of every machine should be laid down. Access to manufacturing areas shall be restricted to minimum number of authorized personnel only. The manufacturing processing should be as per the conditions described in the authoritative books specified in the First Schedule of Drug and Cosmetics Act. The manufacturing area should be designed with proper ventilation, exhaust and chimney providing special attention to process that generate toxic fumes like SO_2, arsenic, mercury vapor etc.

The size and dimensions of each Bhatti Section would be so designed to suit the batch size or quantity of materials to be processed. In addition to the fuels prescribed in the schedule books, use of other heating devices is permitted if objective of heating is achieved. Drying shall be done in a space which is covered by glass or other transparent material to allow entry of sunrays on the material to keep for the purpose. If drying is being done in oven the temperature of the same may be selected specific temperature.

Table 2: *Requirement of machinery, equipments, space for Rasaushadhis*			
Sr. No.	**A**	**B**	**C**
1.	Pisti / grinding area for Bhasma, Pishti, Kushtajat	100 sq. ft.	Kharal/mechanized/motorized Kharal, End runner / Ball-Mill Sieves / Sifter.
2.	Powdering area for raw drugs of plant origin giving in Rasaushadhis (Herbo-metalic formulations)	200 sq. ft.	Grinder / Distintegrator /Pulverisor / Powder mixer / Sieves / Sifter
3.	Pills / Vati/ Gutika Matrica and tablets / Habb making area	100 sq. ft.	Ball Mills, Mass Mixer/ Powder mixer, Granulator, drier, tablet compressing machine, pill/ vati cutting machine, stainless steel trays / container for storage and sugar coating, polishing pan in case of sugar coated tablets, mechanized chatoo, (for mixing of guggulu) where required.
4.	Kupi pakva / Ksara / Parpati /Lavana Bhasma Satva /Sindura Kapu / Uppa / Param / Qushta / Jawhar	150 sq. ft.	Bhatti, Karahi / stainless steel vessels /patila flask, Multani Matti / Plaster of Paris, Copper Rod, Earthen container, Gaj PutBhatti, Muffle furnace (electrically operated) End / Edge Runner, Exhaust Fan, Wooden, S.S. Spatula.
5.	Receiving and storing raw material	200 sq. ft.	
6.	Quality Control Section	150 sq. ft.	
7.	Quarantine / observation	50 sq. ft.	
8.	Finished goods store	150 sq. ft.	
9.	Rejected goods store	50 sq. ft.	
10.	Bhatti-putta area	200 sq. ft.	
11.	Area for water and washing etc.	50 sq. ft.	
12.	Office	100 sq. ft.	
	Total	1500 sq. ft	
A: Category of Medicine / Manufacturing area; B: Minimum Manufacturing space required. C: Machinery equipment recommended			

Stores – The layout of storage areas should be such that there is segregation of independent adequate spaces for storage of different types of material, such as raw material, packaging material and finished products. Special attention should be paid to cleanliness, and good maintenance and the area should have proper ventilation and shall be free from dampness. An area should be identified for quarantine of all incoming raw materials. An area of 150 sq. feet is required for Rasaushadhi related store.

Raw Material Store: If certain raw materials require specific controlled environmental conditions, the raw materials stores may be sub-divided with proper enclosures to provide such conditions by suitable cabinization. While designing such containers, cupboard or areas in the raw materials store, care may be taken to handle different categories of raw materials such as raw material of metallic origin, raw material of mineral origin, raw material from animal source, fresh herbs, dry herbs or plant parts, volatile oils/perfumes and flavours, plant concentrates/ extracts and exudates/resins, excipients etc. The areas should be well labelled, and materials stored in such a way as to avoid any risk of cross-contamination. All the raw materials shall be sampled and got tested either by the in-house or laboratory approved by the government and shall be used only after approval. Each container used for raw material storage shall be properly identified

with the label which indicates name of the raw material, source of supply, Batch No. or Lot No. and the date of receipt of the consignment. Furthermore, the label clearly states the status of raw material such as "UNDER TEST" or "APPROVED" or "REJECTED". Procedure of "First in first out" should be adopted for raw materials wherever necessary. Records of the receipt, testing and approval or rejection and use of raw material shall be maintained.

Packaging Material Store: All packaging materials such as bottles, jars, capsules etc. shall be stored properly. All containers and closure shall be adequately cleaned and dried before packing the products. Controls on the issue and use of these packaging materials should be adequate to ensure that incorrect labels and cartons are not used. There should be adequate information on the label. The label of finished products should have declaration of name of drug, net quantity, name and address of manufacturer, manufacturing licence number, batch number, date of manufacture, date of expiry, true list of ingredients and other specific particulars as required.

Finished Goods Store. - The finished goods transferred from the production area after proper packaging shall be stored in the finished goods stores within an area marked "Quarantine". After the quality control laboratory and the experts have checked the correctness of finished goods with reference to its packing/labelling as well as the finished product quality as prescribed, then it will be moved to "Approved Finished Goods Stock" area. Only approved finished goods shall be dispatched as per marketing requirements. Distribution records shall be maintained as required. If any ASU drug needs special storage conditions, finished goods store shall provide necessary environmental requirements.

Workers (Health, Medical Services, Clothing, Sanitation and Hygiene: All workers employed in the factory shall be free from contagious diseases. The manufacturer shall provide medical examination of workers at the time of employment and periodical check-up thereafter at least once a year by physician, with particular attention being devoted to freedom from infections as well as for any adverse effect of the drug during manufacturing process. For the adverse effect necessary investigations shall be carried out for ensuring that there is no effect of material on the vital organs of the employees. Records thereof shall be maintained. There shall be adequate facilities for first aid, personal cleanliness such as clean towels, soap and scrubbing brushes shall be provided. Separate provision shall be made for lavatories to be used by men and women, and such lavatories shall be located at places separated from the processing rooms. The clothing of the workers shall consist of proper uniform suitable to the nature of work and the climate and shall be clean. The uniform shall also include cloth or synthetic covering for hands, feet and head wherever required. Workers will also be provided facilities for changing their clothes and to keep their personal belongings.

Dosage form: The permitted excipients can be used in Rasaushadhis to transform into acceptable dosage forms such as churna, vati, guti, tablet or capsules etc. provided that their label must indicate the quantity of Ayurveda, Siddha and Unani medicines in one Tablet or Pill or Capsule in addition to the filler (excipient). All the Rasaushadhis or Rasamaruthukal or Kushtajat shall be packed in a dosage form which is ready for use for the consumer. Grinding and weighing of individual dose of potentially poisonous products will not be permissible in-patient consumer pack. The crystalline product may be grinded before packing in the individual dispensing size. However, for hospital bulk pack, it will not be applicable, and label will clearly indicate the ―Hospital pack.

BMR (Batch Manufacturing Records): BMR is a document designed to provide a complete *record* of the *manufacturing* history, actual data and step by step manufacturing process from issuance of raw materials to the final packing of a *batch* of product. GMP requires that BMR of each batch of classical preparation as well as patent and proprietary medicines shall provide an account of the list of raw materials and their quantities obtained from the store, tests conducted during the various stages of manufacture, in process record of various shodhana, bhavana, burning in fire, specific grindings, record of date, manpower, machine

and equipments used, details of transfer of manufactured drug to the finished products store including dates, quantity, packaging, testing report of the finished product and any other records as required. Records shall be maintained specially for temperatures attained during the entire process of Bhasmikaran, using appropriate temperature measuring instrument such as pyrometer and, pyrograph for manual reading or recording by heat sensors, connected to computer as the case may be. These records shall be duly signed by Production and Quality Control Personnel respectively. A register should exclusively be maintained for ready reference of following process (as in Table 3).

Table 3: Process Register

Sl. No.	Process Register	Required Details
1.	**Shodhan Register**	➢ Sl No. ➢ Batch No. and Size ➢ Date, time and duration ➢ Name of the Raw-material with Quality reference and quantity ➢ Quantity of Shodhana Dravya ➢ Book Reference followed ➢ Methodology
2.	**Bhavana and Putta Register**	➢ Sl No. ➢ Batch No. ➢ Date, time ➢ Name of the material and quantity of starting materials ➢ Quantity of Nirvapya Dravya ➢ Quantity of Bhavana Dravya ➢ Date and time of Starting and completion of Bhavana or Mardana and duration ➢ Type and Number of Puttas ➢ Time and Date of completion of Puttas ➢ Color and texture of the product or standards ➢ Inprocess tests followed (Bhasma Pariksha and any other tests) ➢ In case heating at a particular temperature is required, record of attainment of that temperature.
3.	**Grinding Record Register**	➢ Sl. No. ➢ Batch No. ➢ Date and time ➢ Name of the material and quantity ➢ Name of the equipment (SS/granite) ➢ Duration of grinding ➢ Repeat the grinding if required (Number of repetition)
4.	**Packing details**	➢ Name of Rasaushadhi ➢ Type of Dosage Form (e.g. Powder, pill, tablet etc) ➢ Weight of Rasaushadhi in each unit

Competent Technical Staff:

The competent technical staff to direct and supervise the manufacture of Ayurvedic drugs shall have qualifications in Ayurveda. Similarly, the competent technical staff to direct and supervise the manufacture of Siddha drugs and Unani drugs shall have qualification in Siddha or Unani respectively.

Personnel dealing with the production and quality assurance of Rasaushadhis manufacturing section should have an adequate training in the specific subject

of Rasaushadhis manufacturing. He will be at least a degree holder in Ayurvedic, Siddha / Unani medicines or B. Pharma degree holder in Ayurvedic / Siddha / Unani medicines. The release of Rasaushadhis should be under the control of a person who has been trained in the specific features of the processing and quality assurance of Rasaushadhis.

Distribution Records, Market Complaints and Product Recall:

Sale and distribution record of each batch of product shall be maintained and the duration of record keeping should be the date of expiry of the batch. A register shall be maintained by manufacturer to record all reports of market complaints of their products sold in the market. The manufacturer shall enter all data received on such market complaints; investigations carried out by the manufacturers regarding the complaint as well as any corrective action initiated to prevent recurrence of such market complaints shall also be recorded. Once in a period of six months the manufacturer shall submit the record of such complaints to the licensing authority. The Register shall also be available for inspection during any inspection of the premises. Literature inserted inside the product package should indicate the name, address of the manufacturing unit and telephone number for reporting of any adverse drug reaction by physicians or patients. On receipt of such Adverse Drug Reaction report, it will be the responsibility of the manufacturer to ensure the recall of the product from the market.

Standard Operating Procedures (SOP) should be included for storage of recalled Rasaushadhies in a secure segregated area, complying with the requirements specified for storage till their final disposal.

Reports of any adverse reaction resulting from the use of ASU drugs shall also be maintained in a separate register by each manufacturer. The manufacturer shall investigate any of the adverse reaction to find if the same is due to any defect in the product, and whether such reactions are already reported in the literature or it is a new observation.

Quality Control: As per Schedule T, every licensee is required to provide facility for quality control section in his own premises or through Government approved testing laboratory. Specification is the established quality criteria to which a product should conform to be considered acceptable for release or use. The specifications for finished Rasaushadhi should focus on those characteristics found to be useful in ensuring the quality. The manufacturer will ensure in-house standards for the uniform quality of product. Quality testing will be carried out as per official Pharmaceutical or Schedule books for texts namely, color, taste, *varitaratwa, Rekhapurnatwa, Laghutva, Nirdhumatwa, Dntagre Kachakacha, Niruttha, Apunarbhava and Nischandratwa*. Required physio-chemical characterization of the product should be undertaken by appropriate analytical equipment. The Particle size of the product should be tested by adopting microscope fitted with micrometer or particle size analyzer or any appropriate other techniques. The disintegration time of pills-vati and tablets should also be recorded.

Preferably for quality control section, there will be a separate expert. Quality control section must be staffed with persons who are trained academically such as Expert in Ayurveda or Sidha or Unani medicine (recognized under Schedule II of Indian Medicine Central Council Act 1970), Chemist (at least Bachelor Degree in Science or Pharmacy or Pharmacy (Ayurveda), awarded by a recognized University) and Botanist / Pharmacognosist, (at least Bachelor Degree in Science (Medical) or Pharmacy or Pharmacy (Ayurveda) awarded by a recognized University). Table 4 shows the list of equipments recommended for in-house quality control. QC section requires150 sq. feet area, reference books and reference samples for identification of raw drugs, controlled samples of finished products of each batch will be kept till the expiry date of product. Manufacturing record should be maintained for the various processes. QC must supervise and monitor adequacy of conditions under which raw materials, semi- finished products and finished products are stored, keep record in establishing shelf life and storage requirements for the drugs.

Table 4: List of Equipment Recommended for In-house Quality Control Section

Chemistry Section

1. Alcohol Determination Apparatus (complete set)
2. Volatile Oil Determination Apparatus.
3. Boiling Point Determination Apparatus.
4. Melting Point Determination Apparatus.
5. Refractometer.
6. Polarimeter.
7. Viscometer.
8. Tablet Disintegration Apparatus.
9. Moisture Meter.
10. Muffle Furnace.
11. Electronic Balance.
12. Magnetic Stirrer.
13. Hot Air Oven.
14. Refrigerator.
15. Glass/Steel Distillation Apparatus.
16. LPG Gas Cylinders with Burners.
17. Water Bath (Temperature controlled.)
18. Heating Mantles/ Hot Plates.
19. TLC Apparatus with all accessories (Manual)
20. Paper Chromatography apparatus with accessories.
21. Sieve size 10 to120 with Sieve shaker.
22. Centrifuge Machine.
23. Dehumidifier.
24. pH Meter.
25. Limit Test Apparatus.

Pharmacognosy Section

1. Microscope Binoculor.
2. Dissecting Microscope.
3. Microtome.
4. Physical Balance.
5. Aluminium Slide Trays.
6. Stage Micrometer.
7. Camera Lucida (Prism and Mirror Type).
8. Chemicals, Glassware etc.

DISCUSSION

There are numerous factors such as manufacturing process, storage condition, purpose of administration, dosing, patient related factors etc which make a drug safe and effective. Herbo- metallic-mineral formulations are more popular because of its efficacy, smaller dose and longer shelf life. Efficacy as well as safety (quality) are the prime requirement for drugs. From the viewpoint of manufacturing, quality product means the product which contains claimed ingredient and is free from contamination resulting from any source such man, material or processing. The role of Indian drug regulatory system is important in facilitating access to good quality and safe medical products. The Indian drug regulatory system originated in 1940, when the Drugs & Cosmetics Act passed and from then various legislative texts such as The Pharmacy Act, The Drugs and Magic Remedies (Objectionable Advertisements) Act, The Narcotic Drugs and Psychotropic Substances Act 1985, The Medicinal and Toilet Preparations (Excise Duties) Act, The National Pharmaceutical Pricing Policy, The Patent Act, The National Health Policy and so on have been passed to regulate the import, manufacture, distribution and sale of drugs in India. Manufacture of Ayurvedic, Siddha and Unani drugs for sale is regulated under Drugs and Cosmetic Acts and Rules. Adopting GMP is the key for manufacturing quality medicines and Schedule T provide the GMP guideline for Ayurveda, Siddha and Unani Medicine. Under the schedule there is supplementary guidelines for *Bhasmas, Sindura, Pishti, Kajjali, Khalviya Ras, Kupipakwa, Rasayan, Parpati, Potali Rasa, Satwa Druti Parpam, Karpu*, and *Kushta*. The supplementary guideline is exclusively for the above but itself it is not an independent guideline rather it should be read in conjunction with the parent guidelines. The guidelines are to provide general and minimum technical requirements for quality assurance and control in manufacturing of *Rasaushadhis* or *Rasamarunthukal* and *Kushtajat* (Herbo-mineral-metallic formulations) covering all aspects of the manufacturing process, validated critical manufacturing steps, suitable premises, storage facility, qualified and trained personnel for production and quality control, adequate laboratory facilities, approved written procedures and instructions, maintenance of records to show all steps of defined procedures, full traceability of a product

through batch records and distribution records, systems for recall and investigation of complaints. Schedule E (1) under the Rule 161 of Drug and Cosmetic Rule 1945 enlist poisonous substances used in Ayurvedic, Siddha and Unani Systems of Medicine. If an internal drug for human use contains any ingredient specified in Schedule E (1), its label is compulsory required to have secondary label as 'Caution: To be taken under medical supervision' both in English and Hindi language. This is precautionary is meant for avoiding misuses and adverse effect. Good Manufacturing Practice is the step for manufacturing of quality standard *Rasaushadhies, Rasamarunthukal* and *Kushtajat.* There are many challenges in complying to GMP for Herbo-mineral-metallic formulation such as investment for creation and maintenance of required infrastructure, lack of qualified and trained technical and regulatory manpower, inconsistent quality of raw materials, limitations of conventional manufacturing technology, quality testing tools restrictions in international market.

CONCLUSION

Compliance to GMP is essential requirement for grant or renewal of license to manufacture ASU product. Schedule T prescribe the GMP guideline for ASU and covers all aspects of production from the starting materials, premises and equipment to the training and personal hygiene of staff. Detailed written procedures for each process that could affect the quality of the finished product and systems to provide documented proofs that correct procedures are consistently are to be followed at each step in the manufacturing process - every time a product is made.

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