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REVIEW ARTICLE **OPEN ACCESS**

A Review on Standard Operating Procedures and Calibration of Analytical Instruments

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ABSTRACT
The article is based on the review of standard operating procedures and calibration of Analytical instruments. It describes the perspectives of calibration and SOP from different viewpoint while indicates it's importance for medical field and pharmaceutical services. Calibration is the note able prepare utilized to bolster instrument precision. This review is discussing that to determine a response for sample which falls within an appropriate range and precision of the instrument interpretation and problems caused by a lack of SOP include misreading of information, technical mix-ups, etc. In conclusion, SOP is implemented and materialised as a part of an efficient management system, standard operating procedure promotes visible functions, implements measures to prevent errors, makes it easier to take remedial actions, and transfers knowledge and expertise. This contains details on the evaluation procedures and acceptance standards used to calibrate various analytical instruments. During analysis, out of calibration is the main factor. It also provides detailed information about the out of calibration.
Keywords: UV, IR, PH meter, HPLC, HPTLC, Analytical Balance.

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INTRODUCTION

Instrumental analysis study how to working process and verified the use of scientific instruments to study systems. Typical topics that are included within this area are UV spectroscopy, IR spectroscopy, PH meter, Analytical Balance, high performance liquid chromatography (HPLC) and high-performance thin layer chromatography (HPTLC). Analytical instruments are commonly used in the fields as very different from with each other as pharmaceutical industry, QA (Quality assurance) for validate raw materials and used for validated the finished drug products by quality control (QC), material science healthcare, forensics, Environmental sciences, quality test equipment, water testing and fluid analyzers. Analytical instruments are plays a significant role in production and evaluation of new drug products. The instrumentation affords the decrease detection limits required to assure safe meals, tablets, water and air. The manufacture of materials whose composition must be regarded precisely, which include the substance used in incorporated circuit chips, is monitored by analytical instruments. In routine Overall performance verification are made to ensure that the contraptions used in analytical cause have to be properly demonstrated &calibrated. "To demonstrate that it is suitable for its intended purpose."[1] It is able to described as analytical chemistry is to analyze of separation ,quantification and chemical additives identity of and herbal substances constituted with one or greater compounds or factors. Pharmaceutical analysis plays a incredible function within the examination of pharmaceutical formulations and bulk drugs concerning the QA and qc. Speedy boom in pharmaceutical industries and production of drug in and around the sector convey ahead a upward push in inevitable call for to are looking for novel and systematic analytical strategies inside the pharmaceutical industries. Analytical method improvement in the end effects in respectable test strategies. Therefore, quality controls laboratories used the techniques to test the efficacy, identification, purity, protection in addition to performance of drug substances. The high objective of any pharmaceutical plant is to fabricate products of needful attribute and excellent continuously at the lowest viable price. [2].

Calibration also called for new or advanced eq uipment. After an tool has been repaired or modified. Then a targeted time period has elapsed. While a distinct usage (working hours) has elapsed before and/or after a crucial dimension.[5] which means that process of comparing the reading of one instrument with a standard instrument. Example: (pH meter reference equipment compared with standard PH meter).The reference device is already calibrated and referenced to a known set of parameters. The reference instrument need to itself be directly traceable to equipment this is calibrated. Uncertainty in measurement by ensuring the accuracy of test equipment. Calibration is an operation which is accomplished to show that the instrument readings are corrected on the subject of the mounted requirements. The aim of the calibration program is to make sure that all measuring and testing system included within the program are calibrated in the manufacturers accuracy specs or the tolerance required for the application. It is done to check the zero-error deflection by using standard reference.[4]

SOP- A General running process is a fixed of written route that describes the step-by means of-step motion that should be taken to properly carry out a ordinary interest.[3] and It provides clear-cut directions.

Desk of contents is affords easy get entry to to one of a kind sections in larger SOPs.

Step-by means of-step listing of procedures consists of dialogue of assignment goals, roles and obligations, regulatory requirements, terminology, description of obligations to be executed to finish each step, and choices to be made. This phase will make up most of the SOP.

Once a draft is written, it must be reviewed, edited, and tested several instances. This manner have to be repeated till an SOP is written which is approved by way of all of the stakeholders.

At this point, it can be allotted to every person who needs it to do their task.[5]

Elements of analytical balances:

- Main elements of an analytical instruments are as below:
- Chemical information source, transducer, signal conditioner, display.

Chemical information source:

- This means that, disseminating recorded information. Information source from where one can get information. It represents as results. In chemistry, is that science concerned with the substance of matter is composed, the investigation of their properties and reactions.[6]

Transducer:

- Transfer of one form of energy to other form is called transduction. The conversion is accomplished through sensing is carried out and transducing the bodily quantities like temperature, pressure, sound, etc.[7]

Signal conditioner:

- It is process of data acquisition and instrument called signal conditioner. When one type of electric signal (input –signal) into another type (output-signal). The purpose is to amplify and convert this signal into an easy to read and compatible form for machine control. It helps to provide clear measurements, which are essential for accurate data acquisition and machine-control. These instruments can perform an additional number of different functions.[7]

Display:

- A display is a laptop output surface and projecting mechanism that shows text and often graphic images to the computer user, using cathode ray tube (CRT), liquid crystal display (LCD), light-emitting diode, gas plasma, or other image projection technology. The display is usually considered to include the screen or projection surface and the device that produces the information on the screen. [7]

SPECTROSCOPY

- Spectrographic analysis is a method used to estimate the amount of an analyte in solution.[8]Spectroscopy or Spectrophotometry is a branch of electromagnetic spectroscopy. which are used for the transmission property of drug sample as a function of wavelength and quantitative measurement of the reflection.[9]
- Photometer that can degree the depth of a mild beam at exclusive wavelengths. Spectrographic analysis is a tool that hinges on the quantitative analysis of molecules depending on amount of light is color absorbed on colored compound.
- Spectrographic analysis are the spectral Bandwidth (the peak range of colors it can transmit through the test drug sample), the percentage of sample-transmission, the logarithmic range of sample-absorption, and sometimes a % of reflectance measurement.
- If biochemical are colored, as in they absorb visible light and therefore can be measured by Colorimetric procedures, even colorless bio chemicals can be converted to Colored compounds suitable for chromogenic color-forming reactions to yield compounds suitable for Colorimetric analysis.It can also be designed to measure the Diffusivity on any of the listed light ranges that usually cover around 200–2500 nm using different controls and calibrations.[10]

- Within these ranges of light, calibration is required on the machine using standards that differ depending on the wavelength of the photometric determination.

Working principle:

- Absorption Spectrographic analysis works with the principle of Beer–Lambert law.
- The Beer–Lambert regulation states that the absorbance of a solution is directly proportional to the attention of the soaking up species in solution and the direction period. As a consequence, for a given path duration, UV/Vis spectroscopy may be used to determine the attention of the absorber in solution.[11],[16].

IR SPECTROSCOPY

IR means 'infrared'. The examination of infrared light's intelligent with atoms is known as infrared spectroscopy.[12].It is described by Speedy, squat pattern volume (a one or two micrograms to a one or two milligrams), strong characterization (various substances have their own specific infrared spectrum), tests capable of inspect various states (gas, liquid, solid) without damaging the specimens.[13]

OPERATING PROCEDURE:

- Turn on the instrument's main power switch. After hearing the buzzer sound, turn on the computer.
- Click the [IR solution] icon twice. Username and password must be entered.
- Select Measurement from the menu bar, then select Initializes. On the status monitor on the left side of the screen, check the instrument status.
- The entire display should be green, including the light source, laser, beam splitter, and any attachments. In the window for the scan parameters, click [Data Tab], then enter the values as displayed below.
  1. %Transmittance as the measurement mode
  2. Happ Genzel's "Apodization"
  3. There were 16 scans.
  4. 4 cm-1 resolution.

Select the Instrument tab, then enter the values as displayed below.

1. Internal Beam
2. Standard Detector
3. Mirror velocity 2.8 mm/sec
4. Select the More tab, then enter the values as displayed below.

Regular:

1. a) Gain Auto
2. b) Auto Aperture Monitor.4000 to 400 cm**.**

To change the scan parameters, go to the Files Tab and uncheck the [locked] box. Check the option next to View circumstances in the quantifying file section to ensure that the condition spectrum is displayed after the measurement is complete. A message dialogue box will appear on the screen when you click [BKG] in the measurement file section. [14] Please put together the pattern compartment for the history experiment" Cancel OK. Click OK to view the background spectrum. Prepare the sample and place it in the test chamber using the specimen holder. By clicking ON. Button, Enter the schema ID to scan in the description and the data call to store the fact in the Document Report. Click Example to experiment with the template. Spectra can be viewed on the screen and stored close to the recorded data. Use the [View] tab window to view the index at the top and bottom of the window. The upper window is called the calibration window and the lower window is called the zoom window.

To change the spectrum in absorbance mode, right-click on the test or zoom window and click on the vertical axis. Open the reference spectrum file of the relevant sample from D:\Data\Reference Spectra\Product Name. Drag a reference spectrum from the tree view window on the left side of the screen and place it above the sample in the zoom window. Click document, then Print Preview, then choose the needed record template and print via pressing the print button. [14]

For liquid sample:

Prepare the sample solutions according to the SPECTROSCOPY instructions. Using a syringe, inject the test solutions into the cell. Rinse the cell twice with the solution before filling it, taking care not to trap any air bubbles inside. [14]

A liquid sample in mineral oil dispersion:

Triturate 200 to 300mg of sample in a clean mortar with small amount of liquid paraffin(8 to 10 drops).to make a smoothy slurry ,compress a portion slowly and carefully between the two sodium chloride plates. The placed the sample holder in the sample compartment and record the spectra. [14]

- Record and then fill the form annexure.

CALIBRATION OF IR SPECTROSCOPY

- Switch ON instrument and properly connected with power supply.
- Set instrument parameter as follows:

RESOLUTION 2.0
APODIZATION STRONG
RANGE 4000-400 cm-1
MODE RATIO
NUMBER OF SCAN 16

- Allow the machine to warm for 30 Minutes.
- Operate the instrument as per operation SOP.
- Open the specimen compartment cover of IR 1600 and place the polystyrene film in the specimen holder and the close the cover.
- Click OK in the SCAN MODE.
- The spectrum of the polystyrene film is displays on the screen. PRINT the spectrum by going to print Function.
- When the printer of the spectra is completely go to DATA and then to PEAK.
- The peak data's of the spectra of the polystyrene film is displays on the screen.
- PRINT out these data's by going to print function.
- When the spectra printer is finished, go to DATA and then to PEAK. The peak data of the polystyrene film spectra is displayed on the screen.
- Subject to the following restrictions. Accuracy of wave number limit 3060.0 (±1.5) 2849.5 (±1.5) 1942.9 (±1.5) 1601.2 (+1.0) 1583.0 (±1.0) 1154.5 (±1.0) 1026.3 (+1.0)
- The apparatus's resolution performance Take a spectrum of the 0.04 mm thick polystyrene film. The distinction x among the proportion transmittance at the transmission most A at 2870 cm-1 (3.48 m) and the proportion transmittance at the transmission minimal B at 2849.5cm-1(3.51m) should be more than 16 .[refer by British pharmacopeia B.P] Y is the difference between the percentages .Transmittance at the time of transmission C at 1589 cm-1 (5.29 μm) and that at the transmission minimum D at 15−1 (5.32 Mm) should be greater than 12.
- Record the reading in the calibration record (Annexure) form. Affix a "CALIBRATION LABEL "on the instrument. Report any discrepancy observed during calibration or operation of the instrument to QA Manager and notify the defect to Engineering. Dept / Service. Affix an 'UNDER MAINTANCE:
- Label on the instrument. Frequency of Calibration Once in three months and after each maintenance job.[15]

ULTRAVIOLET-VISIBLE SPECTROPHOTOMETRY

UV-Vis Spectrophotometer is one of the most widely used methods in drug analysis. It involves measuring the amount of ultraviolet or visible radiation from chemicals in solution. The instrument that measures the contrast or ratio of the intensity of two light beams in the UV-Vis region is called the UV-Vis spectrophotometer. In quality analysis, a spectrophotometer can be used to identify organic compounds if records are available, and quantitative analysis can be used to determine the number of molecular species that absorb electricity. Spectrophotometry is simple, fast, neutral and suitable for small compounds. The basic law governing multi spectrophotometric analysis is the Beer-Lambert law.(previously explained this law)

Principle:

Molecules or ions exhibit absorption in the visible or ultraviolet region when radiation causes electronic changes in their structure. Therefore, the absorption of light by the sample in the ultraviolet or visible region is accompanied by a change in the electronic state of the molecules in the sample. The energy provided by the light will push electrons from ground state orbitals to higher energy state orbitals or antibonding orbitals. Three types of ground state trajectories may be involved.

- **σ** (Bonding) molecular
- ***π*** (Bonding) molecular
- **n** (non-Bonding) atomic orbitals.

Also, there can be two antibonding orbitals involved in the transition

- **σ*** (sigma star) orbital
- ***π**** (pi star) orbital

There are n electrons such that n * antibonding does not form commitment. Therefore, the absorption of ultraviolet and visible light can cause the following energy changes.

- **σ – σ***
- n - **σ***

- n - π^*
- π - π^*

σ-σ^* and n - σ^* transitions require a lot of energy, so they appear weak in the far ultraviolet region or the 180 -240nm region. Therefore, saturated groups do not show strong absorption in the UV region.
Then π^* and π to * transitions occur in molecules with neutral regions, require less energy and occur at longer wavelengths than transitions to σ^* anti-bonding orbitals. Many organic compounds in solution are also absorbed in the visible region. This absorption occurs as a result of the transfer process in which the energy provided by the light passes from one part of the body to another. [17]

Standard operating procedure for ultraviolet-visible spectrophotometer:

1. Start the computer system and UV machine and Now use password on comp system: uv123.
2. Put reference solvent in both curettes in UV machine. andthen, Click on carry win UV (software on desktop).Set up – visible to UV up – baseline up – baseline correction up – ok up – baseline – yes
3. Put reference inner portion and put sample front portion the UV chamber. Next to Click on start button (green button).
4. After getting complete graph click on finish option. Now click on trace reference baseline – removed by selection – new get single UV graph of sample without baseline on display. Now click on print per view – print select cute PDF writer – OK and saved.Then,Toshut down the computer - click on close button in software. After shutting down the computer close back switch of machine. [18]

Calibration:

- Absorption Cell
- Absorbance Control
- UV region
- Visible Region
- Photometric Linearity
- Stray Light Limitation
- Resolution
- Wavelength Control. [20]

SOP AND CALIBERATION OF HIGH PERFORAMANCE LIQUID CHROMATOGRAPHY

Description:

- HPLC is an effective type of chromatography which is used in pharmaceuticals its also used to determine the assay of related drug substances. mainly used to separate the components of a drug substances.

Principle:

- A high pressure reservoir pump takes mobile phase through an injector then it travels through a reverse phase for component separation through C18 packed column the amount of time takes to travel from the injector to detector is called retention time.[21]

SOP OPERATIONAL PROCEDURE

Preparation of mobile phase:

- Prepare mobile phase as per IP/BP/USP
- Filter through the 0.45µ using filtration
- Sonicate the mobile phase <Submerge inlet of line filter in mobile phase <STARTUP<Switch(on)the main button<Start the on/off button in HPLC<Display will showed on screen
- SHIMADZU RIGHTS RESERVED
- Above all the conditions are done, then put ID admin &password and press OK<After all are ready start the computer, select user and password will appear on the monitor<Double click on lab solution icon, login window<Enter username and password click on login<Lab solution software will open
  RUN METHOD
- Select the project and click'' OK '' REALTIME ANALYSIS window will appear<To select click on'' FILE'' then select'' OPEN METHOD FILE '' and choose method click DOWNLOAD and CLOSE
  RUN SEQUENCE
- Create new sequence →click on window →select realtime batch→click on sequence→select table style→select following options
- Vial→enter the number vial is kept→tray name→enter the name where sample is kept→sample name→name of product→sample ID →identification of sample eg.blank ,standard solution etc →method file→select required method →data file→given suitable data file name →inj.volume→sve file→start batch sequence.
- CREATE PROJECT→CREATE METHOD FILE→CREATE REPORT FORMAT[22]

Calibration:

- Ensure the instrument is ready for calibration and start up the procedure
- The instrument is set according to the chromatographic conditions
- Following the procedure, inject each of the solutions in triplicate and record the chromatograms
- Take the print out the chromatograms and attach to the calibration log
- Record the area and retention time of the benzene and toluene peaks in the calibration log
- Make entry usage of the instrument and HPLC column in the instrument usage log register and column usage log register
- Calculate the area ratio of benzene to toluene find out the mean value of the ratios and record in the calibration log
- Find out the correlation coefficient r2 from the mean area ratios values of the three levels, and record the calibration log
- Plot the curve for area ratio corresponding to benzene to toluene peaks v/s concentration, find out the RSD (REPRODUCIBLITY) and record in calibration log
- Prepare calibration status label and display on the instrument at the designated place
- In case of non-compliance, follow the maintenance program[23]

SOP AND CALIBRATION OF HIGH PERFORMANCE THIN LAYER CHROMATOGRAPHY

Description:

HPTLC is a superior automated model of thin layer chromatography with superior and excessive separation efficiency and detection limits. It is also referred to as computer (planar chromatography) or excessive stress thin layer chromatography(HPTLC).A separation can end result from the partition,adsorption,or both it's miles bases at the sort of adsorbents uses for improvement.

Principle:

Thin layer chromatography is a stable liquid method wherein the two phases are a stationery segment [solid]and mobile phase [liquid]. It depends upon each adsorbent and its treatment and nature of the solvents hired.

- Widespread OPERATIONAL technique

Education of plates:

- Reap HPTLC plate silica gel 60 F254(200cm) file the batch wide variety
- Look into plate underneath UV 254nm for any harm of the layer, if any harm is detected discard plate.
- Use with gentle pencil to label the plate within the higher right nook together with your initials and date (dd/mm/yy)-consecutive number of the day instance:03/06/10-001
- At the right facet of the plate mark developing distance at 70 mm from decrease edge of plate.
- Practice of chamber:
- Reap a dual via chamber for 20x10 cm plates
- Suit the rear through a chamber with clear out paper.[24]
- Pour 20ml of prepared solvent over a filter paper into arear via making sure whole wetting.
- Pour a sufficient amount of growing solvent. Close the lid of the chamber and allow to 20 minutes for saturation.[25]
- PLATE CONDITIONING(guide improvement handiest)
- After pattern application area the plate for 45 min in appropriate desicator containing a saturated solution of magnesium chloride.
- Documentation:
- After development, take one image under UV254nm, UV 366nm, and white (transmission reflection)
- After derivatization, take one image each under UV 366nm and white light (transmission +reflection)
- Reporting
- Creating a copy of software based report or use own reporting documents.[26]

CALIBRATION

Procedure:

Take a look at the performance of the tool in phrases of linearity of recognizing (ANNEXURE I)<Reproducibility of recognizing (ANNEXURE II)<Put together the cell section as in step with the method in given in annexure I<Put together the solution as mentioned in annexure-I<Use 10x10cm HPTLC plate (kiesel gel 60F254 or equal).[27]

Linearity of spotting:
Apply 2µl, 4 µl, 6µl, eight µl, and 10 µl, of solution on the HPTLC plate with a spotter. Dry the plate with a drier and Scan the plate with the scanner. Check the linearity and correlation coefficient &Fill inside the records.
Reproducibility of spotting:
Observe 10 µl, solution on the HPTLC plate for five times in collection. Permit the plate to run within the cellular phase. Dry the plate with drier. Scan the plate with the scanner. Calculate the RSD cost for 5 tracks (RSD restrict: N.M.T.3 zero %) Fill the records in the (ANNEXURE -II).[30]

STANDARD OPERATING PROCEDURE FOIR ANALYTICAL BALANCE
Purpose:
This procedure providing instructions to weigh substances or sample or chemical using the analytical balance.
Scope:
It is used for operating the analytical balances in TRACES centre and UG Laboratories
Responsibility:
User
Accountability:
TRACES Manager/Course Instructor

STANDARD OPERATING PROCEDURE OF ANALYTICAL BALANCE:
Balance operation:
The laboratory instructor should select the method to be used for conducting analytical balances at TRACES center and UG laboratories
Before you start:
- Level and zero the analytical balance
- Make sure the leveling bubble is centered. If it is not centered, center it by adjusting the leveling screw at the bottom.
- Before pressing 0 button, close all the sliding doors and wait until the balance show zeros. It indicates the balance is ready to use

Direct weighing:
- Use beaker to weigh the samples. Check the units
- Weight to container must be placed on the balance pan and close the doors
- Make sure the container is tarred .Add sample to container without spilling or spilling. and close the doors, note the displayed reading.[30]

Indirect weighing:
- To weigh the difference in the tarred sample before and after the removal of a specified amount of sample .Sample is then transferred to the container and the lid and mass is recorded. Then, Take out the sample and transfer it to the secondary container, record the new mass. Continue the process until the sufficient mass is acquired.

Cleaning up:
- After weighing is completed, you must clean the balance.[31]
- And then fill the annexure form1&2.

CALIBRATION OF ANALYTICAL BALANCE
Bubble level check:
- Rotate levelling screws in order to adjust air bubble. Air bubble must weigh the material.

Zero error check:
- The entry of the weighing scale closed and the deduction key is clicked to check the zero error.

Holding of Weight Box:
- Make sure that the handed-down weights are estimated on a constant method. The tongs are used to keep it at pan.To avoid variations in the results the weights should be handled carefully without dropping. After each and every use the weights used in the calibration must be cleaned with tissue paper

p**H METER:**
What is pH?
pH is the term used to signify the power of hydrogen ion concentration.
Theory:
It is based on water dissociation. Water dissociates spontaneously into its H+ and OH- components. In pure water, the concentration of H+ ion is 1 x 10-7. This H+ ion concentration is neutral, meaning it is neither

acidic nor alkaline. The concentration of H+ ions that are greater than 1 x 10-7 indicates the solution is acidic. The concentration of H+ ions that is less than 1 x 10-7 indicates the solution is alkaline[32].

SOP for pH meter:

Switch on the pH meter. The ATC indicator becomes visible at bottom right corner in order to show automated temperature remuneration. In order to remove impurities, the electrode should be rinsed with de-ionized or distilled water. The temperature of the sample should be maintained at 25Â°C t+ 2Â°C.Wait for few minutes the reading to stabilize. To measure the reading, click HOLD and click ENTER in order to verify the calculated value. The observed values of pH and temperatre are recorded in the test data sheet. Then the electrode should be washed in the de-ionized water and stored in the storage solution.

Calibration of pH meter:

Manufacturer's instructions should be referred for calibration.[37] Calibrate the pH Meter daily.[38] It is necessary in order to use freshly dispensed buffer for calibration.[37] Make all standards and samples to 25EC before use.[37] When the meter so indicates, rinse the apparatus with reagent water and then buffer 10. A pH 7.0 buffer is kept at instrument and the stand key is clicked. [47]Note that calibration will likely involve drying the probe between sample readings. This is usually done by blotting the probe dry with lint-free tissue paper.It is important not to rub the probe with the tissue since this may physically damage the delicate membrane of the probe and/or generate a static charge that can damage the probe or interfere with accurate pH measurements. After calibration, check the accuracy of the meter by testing the pH of a standard buffer solution, such as a pH 4 buffer. A pH 10.01 buffer is kept at instrument and the slope key is clicked. [38] Once the standardization is done, the meter will show it.

CONCLUSION

SOP is implemented and materialised as a part of an efficient management system, standard operating procedure promotes visible functions, implements measures to prevent errors, makes it easier to take remedial actions, and transfers knowledge and expertise. This contains details on the evaluation procedures and acceptance standards used to calibrate various analytical instruments. During analysis, out of calibration is the main factor. It also provides detailed information about the out of calibration.

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AUTHOR'S CONTRIBUITION

Mr. N. Premkumar, Mr. P. Keerthi Vasan, Mr. R. Karthik, and Ms. C. Harini gathered analyzed those review data and necessary inputs were given towards the designing of the manuscript. Ms. K. Kaviya and Mr. P. Sakthi, Mr. S. Sridhar and Ms. B. Parameshwari provided valuable inputs toward designing of the manuscript. Dr.N.Astalakshmi guided the preparation and correction in the review manuscript. Dr.M.Surendra kumar provided valuable suggestion for the preparation of the manuscript. All authors read and approved the final version of manuscript.

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