Installation and Operation Qualification Certificate

EXPEC6500 Inductively Coupled Plasma Emission Spectrometer

Company name_____Company address _____

Contact person_____Contact information _____

Installation date_____Serial number of instrument _____

Installation engineer_____Time _____

Contents

1. Overview

EXPEC 6500 inductively coupled plasma emission spectrometer is a brand-new ICP-OES product launched by Expec Technology based on years of experience in the development of spectral instruments. An installation and operation qualification certificate (IQ/OQ/PQ) is specially drafted and formulated in order to validate and calibrate the correctness of the installation and operation of EXPEC6500 and the qualification of its performance indicators. Methods of the complete installation and operation of the instrument and its performance test are detailed in its instructions and software operation guidelines. Relevant persons in charge can refer to the documents above for operation.

The installation and operation qualification certificate is prepared by the manufacturer. Customers can also use this certificate for the installation and operation of the instrument and the validation of its performance.

The installation and operation qualification certificate should be drafted on the premise that users are very familiar with the instrument. To promote the implementation of the IQ/OQ specification, please be familiar with the operation guides of the instrument and software as well as the theory, knowledge, analysis method and technology of the inductively coupled plasma mass spectrometer before you complete this agreement.

2. Validation purpose

To confirm that EXPEC6500 inductively coupled plasma emission spectrometer can meet GMP standards and design requirements and that the established standards and documents conform to GMP requirements and to ensure the accuracy of test data of the instrument.

3. Validation scope

Table 1 Validation scope

Instrument name	EXPEC6500 inductively coupled plasma emission spectrometer
Test method	Validation reference including test devices and the test method
Acceptance criteria	The test results in the test report are consistent with the expected results. To successfully complete IQ/OQ, the equipment must be installed correctly and operated in the right way.
Test Item	Design qualification, installation qualification, operation qualification and performance qualification.

4. Validation reference

This certificate is formulated based on the Enterprise Standard of Hangzhou Puyu Technology Development Co., Ltd. Q/EXPEC 01-2020 and the Verification Specification of Emission Spectrometer JJG 768-2005 issued by the General Administration of Quality Supervision, Inspection and Quarantine of China.

5. Design qualification

5.1 Qualification and service of manufacturer

5.1.1 The equipment manufacturer should have good production and operation conditions and no production in violation of national or local regulations.

5.1.2 The number and qualification of technicians for on-site guidance or training can be provided during installation, and maintenance can be provided in daily use in the future.

5.2 Equipment

5.2.1 Equipment conditions

5.2.1.1 Equipment parts are in good condition without damage;

5.2.1.2 The inner and outer surfaces are smooth, flat and easy to clean;

5.2.1.3 Equipment parts are easy to disassemble and maintain.

5.2.2 Equipment features: The inductively coupled plasma emission spectrometer is composed of a sampling system (an atomizer, an atomizing chamber, a connecting pipe of the atomizing chamber and a peristaltic pump), a plasma torch, a cold cone, a slit, a prism, echelle, a collimating imaging system, a CCD detector and a data acquisition system, etc. Another auxiliary device is a circulating cooling water system.

5.3 See Table 2 for acceptance criteria.

Table 2 Acceptance criteria

Test Item	**Acceptance quality standard**					
Limit of detection	Zn213.856	Ni231.604	Mn257.610	Cr267.716	Cu324.754	Ba455.403
	<0.5 ppb	<1 ppb	<0.5 ppb	<1 ppb	<1 ppb	<0.3 ppb
Short-term stability	≤0.5%					
Long-term stability	≤1%@2hrs					

6. Installation qualification

6.1 Purpose of installation qualification

To prove that the specification of the supplied equipment meets the requirements and the technical data required for the equipment are complete. The out of box inspection should be passed and should confirm that the installation conditions (or place) and the whole installation process meet the design requirements. See Table 3 and Table 4.

Table 3 Qualification of out of box inspection

	Out of box inspection	**Operation**	**Result**		**Remarks**	**Date**
			Pass	**Fail**		
	After unpacking the instrument, check whether the main frame, accessories, spare parts and instructions are complete one by one according to the packing list.	Inspection				
	Check the appearance of the instrument for any damage, and report any problem found to the manufacturer in time.	Inspection				
	Read the instructions carefully, and be familiar with the principle, structure, installation steps and usage of the instrument.	Qualification				

Table 4 Installation qualification

	Environmental requirements of laboratory	**Operation**	**Result**		**Remarks**	**Date**
			Pass	**Fail**		

	The working environment of the laboratory should be far away from the following areas:					
	Strong heat radiation area	Inspection				
	Strong light irradiation area	Inspection				
	Corrosive, flammable and explosive gases	Inspection				
	There should be no equipment that can produce violent vibration near the laboratory.	Inspection				
	The laboratory must be separated from the chemical treatment room so as to prevent corrosion.	Inspection				
	The internal environment of the laboratory should be kept clean.	Inspection				
	The optimum temperature is 18-28℃, and the temperature remains stable.	Measurement				
	The relative humidity is less than 60% and remains stable.	Measurement				
	Exhaust equipment must be installed above the instrument, and the wind speed at the exhaust outlet measured by an anemometer should be greater than 9 m/s. An adjustable air valve should be provided.	Inspection				
	The main frame of the instrument is 930 mm long, 700 mm wide and 560 mm high. The test bench must have enough space to install the instrument and other equipment such as computers. It should be firm and stable, and flat on the surface. It is recommended that its height should be about 0.75 m. A space for maintenance not less than 0.5 m wide should be kept behind the test bench.	Inspection				
	Gas source requirement					
	Argon: Argon is used as plasma gas, the purity of which should be greater than 99.999%. A special gas pressure reducing valve must be used.	Inspection				
	Power distribution requirement					
	The laboratory should be equipped with an AC 220V and 50Hz power supply and reliable grounding wires. If the voltage changes beyond the specified requirements, a stabilized voltage supply with power greater than 10KV should be provided.	Inspection				

	An independent circuit (220V±10%/16A, power > 5KW) should be used for the inductively coupled plasma spectroscopy. A purifying voltage regulator should be provided when the voltage changes beyond the specified requirements.	Inspection				
	Auxiliary equipment such as the circulating water machine should use one circuit (220V/10A, power > 1.5KW).	Inspection				
	There should be a good ground wire system in the instrument operation room. If not, please make a ground wire according to the national standard.	Inspection				

6.2 Qualification of software configuration

Purpose: To confirm that the application software installed meets the requirements of computer systems and peripheral equipment, as shown in Table 5.

Table 5 Qualification of software configuration

No.	Description	Validation result
1	Turn on the power switch of the computer and start the computer system.	
2	Turn on the ICP-OES power switch, and install the software ElementV and the database.	
3	Double click the software icon on the desktop	
4	Confirm that the instrument and the software are connected properly.	
5	Enter the main screen of the software.	

6.3 Qualification of maintenance service

Purpose: To confirm that failures of the instrument can be handled in time after occurrence without affecting the operation.

Simple maintenance methods are available in each operation manual. Operators who have received training in the instrument can perform simple maintenance and parts replacement according to the instructions.

Customers can call the manufacturer's maintenance engineer if there are other complex problems that cannot be solved by them.

7. Operation qualification

7.1 Purpose: To prove that the software and hardware functions of ICP-OES run normally and meet the design and test requirements.

7.2 Content of operation qualification

7.2.1 Inspection of light intensity value

7.2.2 Test method

Choose the wavelength 257.610 for Mn and establish a method. Inject 0.5 ppm Mn standard solution for 3 repeated tests, and calculate the absolute intensity of Mn at 257.610.

7.2.3 Acceptance criteria

Intensity>250WCPS

7.2.4 Test records

Element and spectral line	Content ($mg \cdot L^{-1}$)	Data of 3 measurements (wcps)			Mean (wcps)
Mn257.610	0.5	1	2	3	

8. Performance qualification

8.1 The purpose of performance qualification: The standard or reference or the tested sample should be used for performance qualification to confirm that the instrument meets the use requirements if the functional test of the instrument is passed after completion of its operation qualification.

8.2 Content of performance qualification

8.2.1 Qualification of limit of detection

8.2.1.1 Test method: When the instrument is in normal working condition, suck and spray a series of standard solutions, make a working curve, and measure the blank solution for 10 consecutive times. The concentration corresponding to three times the standard deviation of the 10 blank values is the limit of detection.

Calculation of the limit of detection:

$$s = \sqrt{\frac{\sum_{i=1}^{n} (x_i - \bar{x})^2}{n - 1}}$$

Where, s - standard deviation;

x_i - single measured value;

$\bar{x}$ -mean of measured values;

n - number of measurements, n=10.

$$DL=3s/b$$

Where, DL - limit of detection of element, mg/L;

s - standard deviation;

b - slope of working curve.

8.2.1.2 Acceptance criteria

Limit of detection	Zn213.856	Ni231.604	Mn257.610	Cr267.716	Cu324.754	Ba455.403
	<0.5 ppb	<1 ppb	<0.5 ppb	<1 ppb	<1 ppb	<0.3 ppb

8.2.1.3 Test records

Element	Content ($mg \cdot L^{-1}$)	Data of 10 measurements (cps)					Mean (mg/L)	Standard deviation s	Limit of detection DL (mg/L)
Zn213.856	0	1	2	3	4	5			

		6	7	8	9	10			
		1	2	3	4	5			
Ni231.604	0	6	7	8	9	10			
		1	2	3	4	5			
Mn257.610	0	6	7	8	9	10			
		1	2	3	4	5			
Cr267.716	0	6	7	8	9	10			
		1	2	3	4	5			
Cu324.754	0	6	7	8	9	10			
		1	2	3	4	5			
Ba455.403	0	6	7	8	9	10			

8.2.3 Qualification of short-term stability

8.2.3.1 Test method: When the instrument is in normal working condition, suck and spray a series of standard solutions, make a working curve, measure the standard solution for 10 consecutive times, and calculate the relative standard deviation RSD (%) of the 10 measured values to obtain the short-term stability of the instrument.

Calculation of short-term stability:

$$RSD = \frac{1}{\bar{x}}\sqrt{\frac{\sum_{i=1}^{n}(x_i - \bar{x})^2}{n-1}} \times 100\%$$

Where, RSD - relative standard deviation, %

$\bar{x}$ - mean of measured values, mg/L;

xi - measured value;

n - number of measurements, n=10.

8.2.3.2 Acceptance criteria

Short-term stability	Zn213.856	Ni231.604	Mn257.610	Cr267.716	Cu324.754	Ba455.403
	<0.5%					

8.2.3.3 Test records

Element	**Content ($mg \cdot L^{-1}$)**	**Data of 10 measurements (cps)**					**Mean (mg/L)**	**Standard deviation s**	**Short-term stability RSD%**
Zn213.856	1	1	2	3	4	5			
		6	7	8	9	10			
Ni231.604	1	1	2	3	4	5			
		6	7	8	9	10			
Mn257.610	0.5	1	2	3	4	5			
		6	7	8	9	10			
Cr267.716	1	1	2	3	4	5			
		6	7	8	9	10			
Cu324.754	0.5	1	2	3	4	5			
		6	7	8	9	10			

Ba455.403	0.5	1	2	3	4	5			
		6	7	8	9	10			

8.2.4 Qualification of long-term stability

8.2.4.1 Test method: After the instrument is turned on and becomes stable, suck and spray the standard solution, make a working curve and measure the standard solution. Make 6 repeated measurements at an interval of over 15 min within no less than 2 hours, and calculate the relative standard deviation (RSD) of the 6 measured values to obtain the stability.

Calculation of long-term stability:

$$RSD = \frac{1}{\bar{x}}\sqrt{\frac{\sum_{i=1}^{n}(x_i - \bar{x})^2}{n-1}} \times 100\%$$

Where,

RSD - relative standard deviation, %

$\bar{x}$ – mean of measured values, mg/L;

xi - measured value;

n - number of measurements, n=6.

8.2.4.2 Acceptance criteria

Long-term stability < 1%

8.2.4.3 Test records

Element	**Content ($mg \cdot L^{-1}$)**	**Data of 6 measurements (cps)**					**Mean (mg/L)**	**Standard deviation s**	**Short-term stability RSD%**
Zn213.856	1	1	2	3	4	5			
		6							
Ni231.604	1	1	2	3	4	5			
		6							
Mn257.610	0.5	1	2	3	4	5			

		6							
Cr267.716	1	1	2	3	4	5			
		6							
Cu324.754	0.5	1	2	3	4	5			
		6							
Ba455.403	0.5	1	2	3	4	5			
		6							