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Change to read:

⟨855⟩ NEPHELOMETRY ▲AND▲ (USP 1-May-2019) TURBIDIMETRY ▲▲ (USP 1-May-2019)

Add the following:

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▲1. INTRODUCTION

Nephelometry and turbidimetry are analytical techniques that are based on the principles of light-scattering phenomena. Light scattering is the physical phenomenon in which a beam of light changes its direction of propagation (known as deflection) as a result of interaction with sufficiently small matter particles. It has been established from the Maxwell electromagnetic theory that a prerequisite for scattering to occur is that the refractive indexes of the suspended particles must be different from those of the suspending liquid. The larger the difference, the more intense the scattering becomes. There are two types of light scattering: 1) elastic scattering, in which the wavelength of the scattered light and incident light are the same; and 2) inelastic light scattering, in which the wavelength of the scattered light and incident light are different. Only the first type of light scattering (elastic) is relevant to nephelometry and turbidimetry.

In turbidimetry, the intensity of the transmitted light is measured and the attenuation of the intensity of incident light as a result of scattering is measured at the direction of incident light (i.e., 0°) and compared to the intensity of incident light (blank measurement). The measured property is an indirect measurement of the scattering effect of the suspended particles and is referred to as turbidance. Any absorbance of light by the suspended sample will result in additional attenuation of light intensity (see *Ultraviolet-Visible Spectroscopy* ⟨857⟩ and *Ultraviolet-Visible Spectroscopy—Theory and Practice* ⟨1857⟩). Hence, it is important to ensure that the material being measured does not absorb light at the measurement wavelength. Indeed the equations governing absorption and turbidimetry are the same (albeit with different values for the attenuation constants). In nephelometric techniques, the intensity of the scattered light at a 90° angle from the propagation direction of the incident light is measured. Therefore, a nephelometric measurement is a direct measurement of the scattering effect of suspended matter.

2. TERMS AND DEFINITIONS

Terms commonly used in describing turbidimetric and nephelometric techniques are:

- Turbidance (symbol, S): A measure of the decrease of the transmitted incident light beam intensity as a result of the light-scattering effect of suspended particles. The amount of suspended matter may be measured by observation of either the transmitted light (turbidimetry) or the scattered light (nephelometry).

$$\log I_0/I_t = kbc = T$$

I_0 = intensity of incident light

I_t = intensity of transmitted light

k = molar turbidity coefficient

b = cell path length

c = concentration

T = turbidance

- Turbidity (symbol, τ): In turbidimetric measurements, the turbidity is the measure of the decrease in incident beam intensity/unit length of a given suspension. The International Organization for Standardization defines turbidity as “the reduction of transparency of a liquid caused by the presence of undissolved matter”.
- Turbidity Measurement Units: The turbidity units are stated using a descriptor which indicates the method of measurement.
- Nephelometric Turbidity Units (NTUs): When the turbidity is measured using a nephelometer, which measures the scattered light at a 90° angle from the direction of propagation of incident light, the units of turbidity are called nephelometric turbidity units (NTUs). The magnitude of NTU is defined based on the turbidity generated by primary formazin standard (a suspension made by mixing solutions of hydrazine sulfate and hexamethylenetetramine in water). Safer polymer-bead suspensions are now commercially available and are recognized as an acceptable alternative. However, all those standards are traced to formazin. The primary formazin standard solution has been assigned a turbidity of 4000 NTUs.

Other recognized units for turbidity include the formazin turbidity unit (FTU) and the formazin nephelometric unit (FNU). These units are equivalent to NTU for the range from 0–40 NTUs.

3. APPLICATIONS

Turbidimetric and nephelometric techniques have applications that include 1) concentration determination of solutions and/or suspensions (determination of several cations and anions by precipitating and suspending the resulting precipitate at well-controlled reaction parameters); 2) measurement of the degree of turbidity of turbid solutions or suspensions; 3) determination of weight-average molecular weights and dimensions of polydisperse systems in the molecular weight range from 1000 to several hundred million; 4) measurement of immunoassays’ reaction kinetics or kinetics of immunoprecipitations (rate nephelometry); 5) monitoring of cell and bacteria growth; and 6) particle size distribution determination of suspended material, particle counting, etc.

Rate nephelometry is widely used for vaccine components assays and/or quantitation of components in blood serum. It is also used for host cell protein qualification in recombinant biopharmaceuticals. When using the technique, the measurement of the change in the light-scattering response by antigen–antiserum or antigen-purified antibody complexes is used to calculate the amount of antigen (Ag) or antibody (Ab) responsible for the immunological Ab-Ag precipitation reaction or agglutination reaction. Often the antigens under consideration are linked covalently or adsorbed to polymeric microspheres to increase the scattering efficiency; the resulting technique is known as "particle-enhanced immunoassay". Although the technique is described as nephelometry, usually both scattered and transmitted light are measured using the ratio instruments.

Nephelometric measurements are more reliable in low turbidity ranges (relatively low concentration of the scattering medium). In this range, a linear relationship is observed between the sample concentration and the detector’s signal intensity expressed as NTU. As the concentration increases, so does the incidence of multiple scattering that deviates the response from the linearity. The maximum NTU value, which supports a reliable linearity relationship, is in the range of 1750–2000 NTUs. Turbidimetry is preferred for higher turbidity ranges (concentrations of the scattering media). To achieve consistent results, all measurement variables must be carefully controlled. Where such control is possible, extremely dilute suspensions may be measured.

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4. INSTRUMENTATION

Instruments used for turbidimetric and nephelometric measurements are called turbidimeters and nephelometers, respectively. Generally, these instruments consist of a mercury lamp with filters for the strong green or blue lines, a shutter, a set of neutral filters with known transmittance, and a sensitive photomultiplier, which can be mounted fixed at 0° or at a 90° angle from the incident light propagation direction, or on an arm that can be rotated around the solution cell and set at any angle from −135° to 0° to +135° by a dial outside of the light-tight housing. Solution cells are of various shapes, such as square for measuring 90° scattering; semioctagonal for 45°, 90°, and 135° scattering; and cylindrical for scattering at all angles (see *Figure 1*).

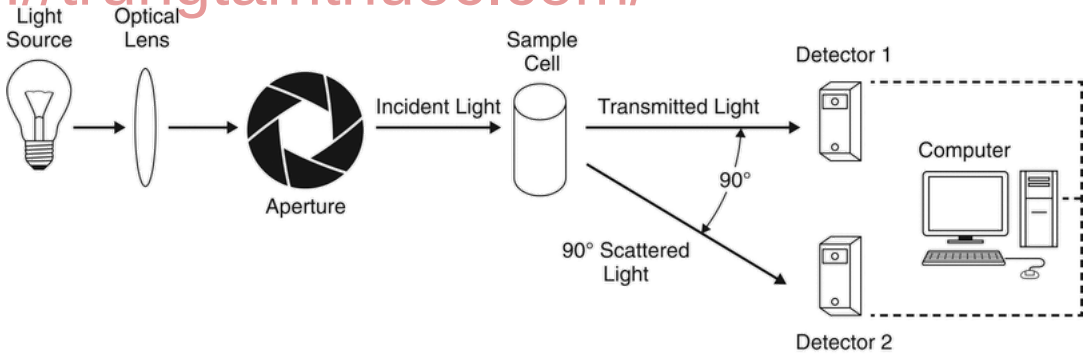

Figure 1. Representative nephelometric (turbidimetric) instrument. Note that Detector 2 may be mounted on a movable arm.

Turbidity also can be measured with a standard photoelectric filter photometer or spectrophotometer, preferably with illumination in the blue portion of the spectrum. Nephelometric measurements require an instrument with a photocell placed so as to receive scattered, rather than transmitted, light. Because this is the same geometry used in fluorometers, they can be used as nephelometers by proper selection of filters. A ratio turbidimeter combines the technology of 90° nephelometry and turbidimetry. It contains photocells that receive and measure scattered light at a 90° angle from the sample as well as receiving and measuring the forward scatter in front of the sample. It also measures light transmitted directly through the sample. Linearity is attained by calculating the ratio of the 90° angle scattered light measurement to the sum of the forward scattered light measurement and the transmitted light measurement. The benefit of using a ratio turbidimetric system is that the measurement of stray light becomes negligible. In addition, the determination of turbidity of colored suspensions is done exclusively using turbidimetric or nephelometric instruments with ratio mode because this procedure compensates for the attenuation of light as the result of the suspension color. Typically, the light source in these instruments is a tungsten lamp with most of the light intensity at about 550 nm operating at the filament temperature of 2700 K. Other suitable light sources are also available. Typically, the detectors are ▲silicon diodes▲ (ERR 1-May-2019) and photomultipliers. An alternative for eliminating the color effect involves using an infrared light-emitting diode as a light source, which yields an emission maximum centered at about 860 nm and a spectral bandwidth of 60 nm. When laser light sources are also used, especially in nephelometric instruments, the technique is commonly known as "laser nephelometry". The advantage of using laser nephelometers is the significant improvement in signal-to-noise ratio at very low detection levels. Usually the light source is a laser diode with a working wavelength at 660 nm. The high-power density of the laser beam gives rise to higher scattered intensity from smaller particles. Combined with a light trap, which absorbs the unscattered light, the system lowers the stray light significantly. When the use of a nephelometer or turbidimeter is indicated for a procedure in a monograph, instruments working in ratio mode may be used instead.

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5. FORMAZIN TURBIDITY STANDARDS

Formazin is the only known primary turbidity standard. All other standards are secondary and must be traced to formazin. The primary standard is defined in the ▲*IUPAC Compendium of Chemical Terminology,*▲ (ERR 1-May-2019) 2nd ed. (the Gold Book) as one that is prepared by the user from traceable materials using well-defined methodologies and conditions.

Formazin suspension has many features that ensure its suitability as a primary standard. It can be consistently and accurately prepared from reagent-grade starting materials. The suspension consists of random polymers with different lengths and of random configurations, which result in moieties of varying shapes and sizes ranging from less than 0.1 µm to more than 10 µm. Although the polymer chain length distribution has been shown to vary from preparation to preparation, the overall resulting turbidity has been very reproducible.

5.1 Preparation of the Formazin Standards

[Note—All procedures described below must be performed at 20 ± 2° (see *Volumetric Apparatus* ⟨31⟩.]

- **Hydrazine sulfate solution:** Dissolve 1.000 g of ACS grade hydrazine sulfate ($N_2H_4 \cdot H_2SO_4$) in particle-free water in a 100-mL Class A volumetric flask and dilute with particle-free water to volume. Allow this solution to stand for 4–6 h.
- **Primary formazin standard:** Dissolve 2.50 g of analytical grade hexamethylenetetramine [$(CH_2)_6N_4$] in 25.0 mL of particle-free water in a 100-mL flask. Add 25.0 mL of hydrazine sulfate solution using a Class A 25-mL "to deliver" pipette and mix thoroughly. Allow the preparation to stand for 48 h at 25 ± 1° before using. The resulting suspension is stable for 2 months.
- **Formazin stock standard suspension 1:** Using a 15-mL Class A "to deliver" pipette, transfer 15 mL of the *Primary formazin standard* to a 1-L volumetric flask, and dilute with particle-free water to volume and mix. The resulting suspension has a turbidity of 60 NTU.
- **Formazin stock standard suspension 2:** Using a 50-mL Class A "to deliver" pipette, transfer 50 mL of *Primary formazin standard* to a 200-mL volumetric flask, and dilute with particle-free water to volume and mix. The resulting suspension has a turbidity of 1000 NTUs.
- **Formazin reference suspensions:** Prepare by mixing in a 100-mL volumetric flask, portions of the respective *Formazin stock standard suspension* and particle-free water according to *Table 1*.

Table 1. Formazin Reference Suspensions Preparations

Formazin Reference Suspensions	Formazin Stock Standard Suspension 1 Volume (mL)	Formazin Stock Standard Suspension 2 Volume (mL)	Particle-Free Water Volume (mL)	Turbidity Value (NTU)
Reference suspension I	5.0	—	95.0	3
Reference suspension II	10.0	—	90.0	6
Reference suspension III	30.0	—	70.0	18
Reference suspension IV	50.0	—	50.0	30
Stock standard suspension 1	100	—	0	60
Reference suspension VI	—	10.0	90.0	100
Reference suspension VII	—	20.0	80.0	200
Reference suspension VIII	—	40.0	60.0	400
Reference suspension IX	—	70.0	30.0	700
Stock standard suspension 2	—	100	0	1000

6. QUALIFICATION OF TURBIDIMETERS AND NEPHELOMETERS

The suitability of a specific instrument for a given procedure is ensured by a stepwise life cycle evaluation for the desired application from selection to instrument retirement. The qualification comprises three components: 1) installation qualification (IQ), 2) operational qualification (OQ), and 3) performance qualification (PQ) (see *Analytical Instrument Qualification* ⟨1058⟩).

The purpose of this section is to provide test methods and acceptance criteria to ensure that the instrument is suitable for its intended use (OQ), and that it will continue to function properly over extended time periods (PQ). As with any spectrometric device, a turbidimetric and nephelometric spectrometer must be qualified for both wavelength (*x*-axis, if not fixed) and photometric (*y*-axis, or signal axis) accuracy and precision, and meet the requirements for the stray light. OQ is carried out across the operational ranges required within the laboratory for both the absorbance and wavelength scales.

Acceptance criteria for critical instrument parameters that establish “fitness for purpose” are verified during IQ and OQ. Specifications for particular instruments and applications can vary depending on the analytical procedure used and the desired accuracy of the final result. Instrument vendors often have samples and test parameters available as part of the IQ/OQ package.

Wherever possible in the procedures detailed as follows, primary reference standards or certified reference materials (CRMs) are to be used. Formazin is the only primary reference standard used in turbidimetry and nephelometry. All the other standards, including the CRMs, must be correlated to formazin. The CRMs should be obtained from a recognized accredited source and include independently verified traceable value assignments with associated calculated uncertainty. CRMs must be kept clean and free from dust. Recertification should be performed periodically to maintain the validity of the certification.

6.1 Calibration

All of the turbidimetric and nephelometric instruments are calibrated against standards of known turbidity. The instrument must be calibrated using formazin turbidity standards prior to its first time use and at least every 3 months or as specified by the vendor. Calibration is performed using at least four formazin turbidity standards whose turbidity proportionally covers the range of interest. Many instrument manufactures provide calibration verification standards. They usually consist of sealed sample cells filled with a latex suspension or with metal oxide particles in polymer gel. These standards must be used only for checking the calibration in the time intervals between the instrument recommended calibrations.

6.2 Stray Light

Stray light (stray radiant energy) is a very significant error source, especially for measurements in the range of the lower turbidity readings. It is defined as external light that reaches the detector without being scattered from the sample. There are several sources of stray light including the inherent cell surface imperfections, reflections from within the cell that are unaccounted for, optical system parts, light sources, and, to a smaller degree, the electronics fluctuations. Although there are many design features that instrument vendors use to minimize the stray light, a complete mitigation of the stray light cannot be achieved. Unlike spectrophotometric measurements, the stray light cannot be compensated for in turbidimetry. The stray light must be measured and the values should be within the specification range set by the vendor

of the particular instrument or <0.15 NTUs for the measurement in the range of 0–10 NTUs and 0.5 NTUs for the measurements in the range of 10–1100 NTUs, whichever is smaller.

6.3 Range of Measuring Capability

The instrument must be able to measure the turbidity in the range of 0.01–1100 NTUs or from 50%–200% of the target turbidity. To demonstrate the linearity for the intended measurements range, choose at least four appropriate reference suspensions from *Table 1*.

6.4 Resolution

Instrument resolution must be 0.01 NTU or less for the measurements range of 0–9.99 NTUs; 0.1 NTU or less for the measurements range of 10–99.9 NTUs; and 1 NTU for the measurements above 100 NTUs.

6.5 Accuracy

The instrument reading accuracy must be ±10% of the reading + 0.01 NTU for the measurement range from 0–19.9 NTUs, and ±7.5% of the reading for the measurement range from 20–1100 NTUs.

6.6 Performance Qualification

The instrument PQ is accomplished periodically or as needed between the calibrations. Primary turbidity standards (formazin) or secondary calibration verification standards (latex suspensions or metal oxide particles in polymer gels contained in sealed sample cells) supplied by instrument manufacturers may be used.

7. PROCEDURES

7.1 Turbidimetric Procedures

SAMPLE CELL PREPARATION

The sample cells for sample measurements must be clean. Follow the sample cell or instrument manufacturer recommendations for cleaning the sample cells appropriately. For low turbidity measurements it is a good practice to use a single-indexed sample cell or a flow cell, which help ensure adequate precision and repeatability of the measurements. Using particle-free water, find the sample cell orientation in the sample cell holder that gives the lowest reading. For higher values of turbidity, different sample cells may be used. However, the sample cells must be matched (the difference in readings for a standard prepared at nominal sample concentration from two different sample cells must be within ±0.005 NTU or below the measurement precision requirement, whichever is lower).

SAMPLE PREPARATION

Prepare the samples as prescribed in the individual monograph. Carefully mix the samples thoroughly by swirling or inverting the volumetric flask slowly several times. Avoid shaking or stirring since it may introduce bubbles. Degassing the samples helps to improve the measurements. For degassing, the samples could stand for several minutes or a vacuum could be applied, or they could be gently sonicated using an ultrasonic bath. After degassing, let the samples stand for several minutes and mix again by carefully inverting two to three times. Transfer the sample to the sample cell and take the readings.

USE OF FLOW CELLS

Flow cells are mainly used for low turbidity measurements for samples with small particles. When such cells are used, the sample is introduced by carefully pouring it down the interior edge of the inlet reservoir.

In practice, it is advisable to ensure that settling of the particles being measured is negligible. This is usually accomplished by including a protective colloid in the liquid-suspending medium. It is important that results be interpreted by a comparison of readings with those representing known concentrations of suspended matter, produced under precisely the same conditions.

7.2 Nephelometric Procedures

Nephelometric procedures are performed similarly to turbidimetric procedures for both direct measurements and measurements in the ratio mode as described above.

RATE NEPHELOMETRIC PROCEDURES

The overall procedure for monitoring the progress of the reaction consists of three well-defined steps: 1) record a baseline reading of the turbidity of the medium (blank); 2) record the turbidity after the first reagent (antigen) is added, which results in an increase of the turbidity until a plateau is reached; and 3) add the second reagent (antibody), which results in another turbidity increase and a second plateau followed by a final turbidity increase that continues until a third plateau is reached. The measurement zone is selected from the addition of the antibody until the third plateau, depending on the purpose of the assay and the respective component concentrations. *Kinetic nephelometry* and *Endpoint nephelometry* are two general procedures that are used for quantifying the immune complexes formed in the immunoassay methods (also known as immunonephelometry because the measured turbidity is due to immunocomplexes that are formed). For each procedure, there are several parameters that need to be optimized in each individual application. The main parameters are 1) with or without particle enhancement; 2) particle types, sizes, and respective optimum wavelength, if applicable; 3) monitoring reaction kinetic or endpoint; 4) antibody/antigen under consideration and, related to that, the optimum level of antigen loading; 5) buffers and other ionic species and respective optimal pH; 6) type and concentration of polymers used to modify the solubility of proteins; and 7) temperature and other environmental factors. Generally these parameters are optimized during the method development and the values are given in specific monograph(s) and/or chapter(s) as applicable.

Kinetic nephelometry: The kinetic nephelometry is advantageous compared to the endpoint nephelometry mainly because of the capability to take a sample blank reading in addition to a reagent blank reading. This procedure assesses the rate of the immunocomplex formation based on the increased intensity response of the scattered light of the chosen wavelength. The reaction kinetic may be monitored continuously or a certain number of data points may be taken, depending on the time response of the instrument used and the type of application. At times it may involve only two data points; however, proper care must be exercised because the choice of point selection can influence the overall accuracy in cases where differences in reaction kinetics exist between samples and calibrating standards. Careful consideration should be given to the appropriate choice of specificity control strategy.

Endpoint nephelometry: In this method, an initial measurement is performed before adding the reagent, which represents the blank reading. A second measurement is performed after the immune complex is formed after approximately 60 min. The difference between these two measurements is proportional to the content of the component being assayed.

8. VALIDATION AND VERIFICATION

8.1 Validation

Validation is required when a nephelometric/turbidimetric method is intended for use as an alternative to the official procedure for testing an official article. The objective of nephelometric/turbidimetric method validation is to demonstrate that the measurement is suitable for its intended purpose, including quantitative determination of the main component in a drug substance or a drug product (Category I assays), quantitative determination of impurities or limit tests (Category II), and identification tests (Category IV). Depending on the category of the test (see *Validation of Compendial Procedures* ⟨1225⟩, *Table 2*), the analytical method validation process for nephelometry/turbidimetry requires testing for accuracy, precision, specificity, detection limit (DL), quantitation limit (QL), linearity, range, and robustness. These analytical performance characteristics apply to externally standardized procedures and those that use standard additions.

Validation of Compendial Procedures ⟨1225⟩ provides definitions and general guidance on analytical procedures validation without indicating specific validation criteria for each characteristic. The intention of the following sections is to provide the user with specific validation criteria that represent the minimum expectations for this technology. For each particular application, tighter criteria may be needed in order to demonstrate suitability for the intended use.

ACCURACY

For Category I, II, and III procedures, accuracy can be determined by conducting recovery studies with the appropriate matrix spiked with known concentrations of the analyte. Analysts can also compare the assay results obtained using the nephelometric/turbidimetric procedure under validation to those from an established analytical procedure.

Validation criteria: 98.0%–102.0% mean recovery for the drug substances, 95.0%–105.0% mean recovery for the drug product assay, and 80.0%–120.0% mean recovery for the impurity analysis. These criteria are met throughout the specified range.

PRECISION

Repeatability: The repeatability of the analytical procedure is assessed by measuring the concentrations of six independently prepared sample solutions at 100% of the assay test concentration. Alternatively, it can be assessed by measuring the concentrations of three replicates of three separate sample solutions at different concentrations. The three concentrations should be close enough so that the repeatability is constant across the concentration range. If this is done, the repeatability at the three concentrations is pooled for comparison to the acceptance criteria.

Validation criteria: The relative standard deviation is NMT 1.0% for the drug substance, NMT 2.0% for the drug product assay, and NMT 20.0% for the impurity analysis.

Intermediate precision: The effect of random events on the analytical precision of the method must be established. Typical variables include performing the analysis on different days, using different instrumentation, and/or having the method performed by two or more analysts. At a minimum, any combination of at least two of these factors totaling six experiments will provide an estimation of intermediate precision.

Validation criteria: The relative standard deviation is NMT 1.5% for the drug substance, NMT 3.0% for the drug product assay, and NMT 25.0% for the impurity analysis.

SPECIFICITY

In nephelometric/turbidimetric measurements, specificity is demonstrated by the lack of interference from other components present in the matrix (other components of the matrix produce a true solution).

DETECTION LIMIT

The DL can be estimated by calculating the concentration of a solution that would give the signal-to-noise ratio of ≥3.3. The estimated DL must be confirmed by analyzing samples at the calculated concentration.

QUANTITATION LIMIT

The QL can be estimated by calculating the concentration of a solution that would give the signal-to-noise ratio of ≥10.0. The estimated QL must be confirmed by analyzing samples at the calculated concentration. Measurement of a test solution prepared from a representative sample matrix spiked at the required QL concentration must be performed to confirm sufficient sensitivity and adequate precision. The observed signal-to-noise ratio at the required QL should be >10.

Validation criteria: For the estimated limit of quantitation to be considered valid, the measured concentration must be accurate and precise at a level ≤50% of the specification.

LINEARITY

A linear relationship between the analyte concentration and measured turbidity response must be demonstrated by preparation of at least four standard solutions at concentrations encompassing the anticipated concentration of the test solution. The standard curve is then evaluated using appropriate statistical methods such as a least-squares regression. Deviation from linearity results from instrumental or sample factors, or both, can be reduced to acceptable levels by reducing or increasing the analyte concentration, thereby respectively decreasing or increasing the turbidity readings to within the nephelometer/turbidimeter instrument linearity range.

Validation criteria: The correlation coefficient (*R*) must be NLT 0.995 for Category I assays and NLT 0.99 for Category II quantitative tests.

RANGE

The operational range of an analytical instrument (and the analytical procedure as a whole) is the interval between the upper and lower concentrations (amounts) of analyte in the sample (including these concentrations) for which it has been demonstrated that the instrumental response function has a suitable level of precision, accuracy, and linearity.

Validation criteria: For Category I tests, the validation range for 100.0% centered acceptance criteria is 80.0%–120.0%. For non-centered acceptance criteria, the validation range is 10.0% below the lower limit to 10.0% above the upper limit. For Category II tests, the validation range covers 50.0%–120.0% of the acceptance criteria.

ROBUSTNESS

The reliability of an analytical measurement is demonstrated by deliberate changes to experimental parameters. For nephelometry/turbidimetry this can include, for example, measuring the stability of the analyte under specified storage conditions, varying pH, and adding possible interfering species. Robustness is determined concurrently using a suitable design for the experimental procedure.

8.2 Verification

Current U.S. Good Manufacturing Practices regulations [21 CFR 211.194(a)(2)] indicate that users of analytical procedures described in the *U.S. Pharmacopeia* and *National Formulary* are not required to validate these procedures if provided in a monograph. Instead, they simply must verify their suitability under actual conditions of use.

The objective of nephelometric/turbidimetric procedure verification is to demonstrate the suitability of a test procedure under actual conditions of use. Performance characteristics that verify the suitability of a nephelometric/turbidimetric procedure are similar to those required for any analytical procedure. A discussion of the applicable general principles is found in *Verification of Compendial Procedures* (1226). Verification is usually performed using a reference material and a well-defined matrix. Verification of compendial nephelometric/turbidimetric procedures includes, at minimum, the execution of the validation parameters for specificity, accuracy, precision, and QL, when appropriate, as indicated in *8.1 Validation*.▲ (USP 1-May-2019)

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

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