2.4.1 Appearance of Solution

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This draft proposal contains general chapter text for inclusion in the Indian Pharmacopoeia (IP). The content of this draft document is not final, and the text may be subject to revisions before publication in the IP. This draft does not necessarily represent the decisions or the stated policy of the IP or Indian Pharmacopoeia Commission (IPC).

Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Manufacturers are also invited to submit samples of their products to the IPC to ensure that the proposed monograph adequately controls the quality of the product(s) they manufacture. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

Please send any comments you may have on this draft document to lab.ipc@gov.in, with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.

Document History and Schedule for the Adoption Process

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Further follow-up action as required.	

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Insert before **Clarity of Solution**

This General Chapter has been harmonized with corresponding texts of the European Pharmacopoeia, the Japanese Pharmacopoeia and the United States Pharmacopeia.
Portions of the IP text that and are not part of the PDG harmonized text, are marked with symbols (♦♦).

Insert at the end
Instrumental method
Principle

The observed colour of an object depends primarily on its light-absorbing characteristics. However, a variety of conditions such as light-source differences, spectral energy of the illuminant, visual sensitivity of the observer, size differences, background differences and directional differences affect the perception of colour. Hue, lightness (or brightness) and saturation are 3 attributes of the colour. Instrumental measurement under defined conditions allows numerical expression of a colour. The base of any instrumental measurement of colour is that the human eye has been shown to detect colour via 3 types of receptors.

Instrumental methods for measurement of colour provide more objective data than the subjective viewing of colours by a small number of individuals. With adequate maintenance and calibration, instrumental methods can provide accurate, precise and consistent measurements of colour that do not drift with time. Through extensive colour-matching experiments with human subjects having normal colour vision, distribution coefficients (weighting factors) have been established for each wavelength in the visible spectrum, giving the relative amount of stimulation of each receptor type caused by the light of that wavelength.

The International Commission on Illumination (CIE) has developed models taking into account the light source and the angle at which the observer is looking at the target (field of view). In a visual test for coloration of solutions, there are requirements that lead to the use of a 2° angle and diffuse daylight (illuminant C). The mean sensitivity of human eye is represented by the distribution coefficients $\overline{x}_\lambda$, $\overline{y}_\lambda$ and $\overline{z}_\lambda$ (Fig. 2.4.1-1).

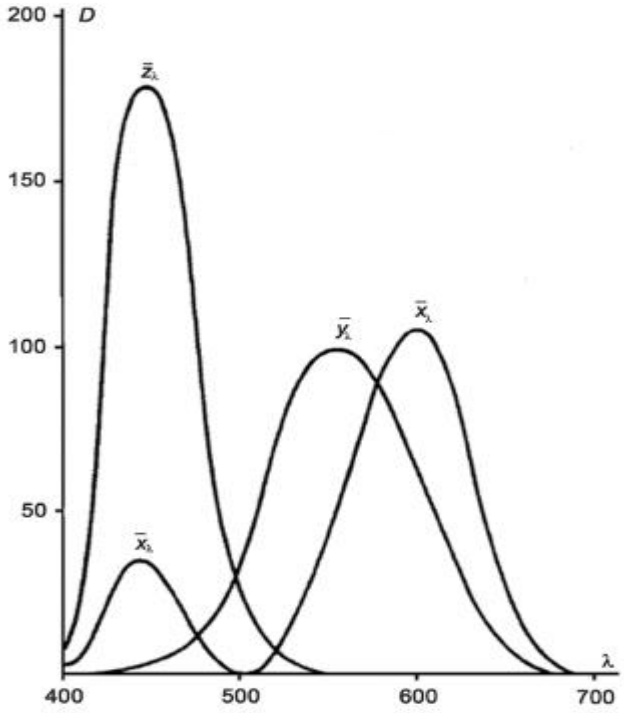

Fig. 2.4.1-1: Mean sensitivity of the human eye represented by distribution coefficients, CIE 2° Standard Observer (D = distribution coefficient; λ = wavelength in nanometers)

For any colour, the amount of stimulation of each receptor type is defined by the set of tristimulus values (XYZ).

The relationship between the distribution coefficients and the tristimulus values (X, Y and Z) is given by the following equations, expressed in terms of integrals:

$$X = K \int_0^\infty f_\lambda \, \bar{x}_\lambda S_\lambda d\lambda$$

$$Y = K \int_0^\infty f_\lambda \, \bar{y}_\lambda S_\lambda d\lambda$$

$$Z = K \int_0^\infty f_\lambda \, \bar{z}_\lambda S_\lambda d\lambda$$

$$K = 100 / \int_0^\infty \bar{y}_\lambda \, S_\lambda d\lambda$$

K	=	normalising constant characterising the stimulation of one receptortype and the used illumination;
S_λ	=	relative spectral power distribution of the illuminant;
$\bar{x}_\lambda, \bar{y}_\lambda, \bar{z}_\lambda$	=	colour matching distribution coefficients for CIE 2° Standard Observer;
f_λ	=	spectral transmittance T_λ of the material;
λ	=	wavelength, in nanometres.

In practical calculations of tristimulus values, the integration is approximated by a summation, as follows:

$$X = k \sum_\lambda T_\lambda \, \bar{x}_\lambda S_\lambda \Delta\lambda$$

$$Y = k \sum_\lambda T_\lambda \, \bar{y}_\lambda S_\lambda \Delta\lambda$$

$$Z = k \sum_\lambda T_\lambda \, \bar{z}_\lambda S_\lambda \Delta\lambda$$

$$k = \frac{100}{\sum_\lambda S_\lambda \, \bar{y}_\lambda \Delta\lambda}$$

The tristimulus values can be used to calculate the CIE *Lab* colour space co-ordinates: *L*(lightness or brightness)*, *a*(red-green)* and *b*(yellow-blue)*; these are defined by:

$$L^* = 116 f(Y/Y_n) - 16$$

$$a^* = 500[f(X/X_n) - f(Y/Y_n)]$$

$$b^* = 200[f(Y/Y_n) - f(Z/Z_n)]$$

where X_n, Y_n and Z_n are the tristimulus values of *water* and

$f(X/X_n) = (X/X_n)^{1/3}$ if $X/X_n > (6/29)^3$,

Otherwise $f(X/X_n) = 841/108\,(X/X_n) + 4/29$;

$f(Y/Y_n) = (Y/Y_n)^{1/3}$ if $(Y/Y_n) > (6/29)^3$,

Otherwise $f(Y/Y_n) = 841/108\,(Y/Y_n) + 4/29$;

$f(Z/Z_n) = (Z/Z_n)^{1/3}$ if $(Z/Z_n) > (6/29)^3$,

Otherwise $f(Z/Z_n) = 841/108\,(Z/Z_n) + 4/29$;

In the spectrophotometric method, transmittance values are obtained at discrete wavelengths throughout the visible spectrum. These values are then used to calculate the tristimulus values through the use of weighting factors $\bar{X}_\lambda$ $\bar{Y}_\lambda$, and $\bar{z}_\lambda$ for a 2° Standard Observer and CIE standard illuminant C (see the current International Commission on Illumination publication, CIE).

Spectrophotometric method

Using a suitable spectrophotometer according to the manufacturer's instructions, determine the transmittance (*T*) at least over the range 400-700 nm, at intervals of not greater than 10 nm. Express the result as a percentage. Calculate the tristimulus values *X*, *Y*, and *Z* and the colour co-ordinates *L**, *a** and *b**.

Determination of coloration

Calibrate the instrument according to the manufacturer's recommendations. Carry out system performance tests prior to each measurement or at regular intervals, depending on the use of the apparatus. For this purpose, use certified reference materials within the measurement range.

Operate the apparatus according to the manufacturer's instructions and test the sample solution and reference solution(s) under the same conditions (e.g. path length of the cuvette, temperature).

For transmittance measurements, use water as the standard, assigning it a transmittance of 100.0 per cent at all wavelengths in the visible spectrum. Then the weighting factors $\bar{X}_\lambda$, $\bar{Y}_\lambda$, and $\bar{z}_\lambda$ and for CIE standard illuminant C are used to calculate the tristimulus values corresponding to colour co-ordinates $L^* = 100$, $a^* = 0$ and $b^* = 0$.

Reference measurements can be made using the colour co-ordinates of water or freshly prepared pharmacopoeial reference solutions, or using the respective colour co-ordinates stored in the instrument manufacturer's database, provided the latter have been obtained under the same testing conditions.

If the test solution is turbid or hazy, it is filtered or centrifuged. If the test solution is not filtered or centrifuged, any haziness or turbidity is reported with the results. Air bubbles are to be avoided or, where applicable, removed.

The instrumental method is used to compare 2 solutions in terms of their colour or colour difference, or a deviation from a defined colour. Calculate the colour difference (ΔE^*_{tr}) between the test solution (*t*) and a reference solution (*r*) using the following equation:

$$\Delta E^*_{tr} = \sqrt{(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2}$$

where ΔL^*, Δa^* and Δb^* are the differences in colour co-ordinates.

The CIE *LCh* colour co-ordinates may be used instead of the CIE *Lab* colour co-ordinates.

Assessment of location within the *L*a*b** **colour space**. Instruments may provide information on the actual location of the test solution within the *L*a*b** colour space. Using appropriate algorithms, correspondence to pharmacopoeial reference solutions (such as ‘test solution equals reference solution XY′, ‘test solution close to reference solution XY′ or ‘test solution between reference solutions XY and XZ′) can be obtained.