
Liquid coloration degree

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Supersedes Rus.Ph. X monograph

Supersedes Rus.Ph. XI, ver.1 monograph

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Determine the liquid coloration visually using on the below methods comparing with respective reference standards. The monograph includes control methods for medicinal products under “color” and “solution color” parameters. Color is a conditional quantitative characteristics for liquids with insignificant color.

Color is a perception or subjective reaction of observer to objective irritant in the form of energy emitted in the visible spectrum area and covering the range of wavelengths between 400 and 700 nm. The color of two solutions coincides (in particular light source) if their absorption spectra and reflections are identical and the observer does not notice any difference between them.

Achromatism or the lack of color means the absence of visible absorption in test solution.

For visual evaluation of liquids coloration subject to the intensity in the area of brown, yellow and red colors, use one of two methods described in the monograph.

The liquid is colorless when its color does not differ from that of water (in case of solutions – from respective solvent) or it is colored not more intensively then reference standard B₉.

The degree of liquid coloration is usually compared with reference standards (B, BY, Y, GY, R)₁₋₃ using method 1; if reference standards B₄₋₉, (BY, Y, GY, R)₄₋₇ are used, apply method 2.

Method 1

Perform the test in the similar transparent neutral glass test tubes with about 12 mm inner diameter using equal volumes (2.0 mL) of test liquid and water or solvent or reference standard described in the monograph. Compare the color in scatted daylight, horizontally (perpendicularly to test tubes axis) against matte white background.

Method 2

Perform test in similar transparent neutral glass test tubes with about 15 to 25 mm inner diameter using equal layers of test liquid and water or solvent or reference standard 40 mm high as described in the monograph. Compare the color in scatted daylight downward along the vertical axis of test tubes against matte white background.

Preparation of baseline solutions

Yellow solution. Accurately weigh 46.0 g of iron(III) chloride ($\text{FeCl}_3 \cdot 6 \text{H}_2\text{O}$; Mr 270.30) into 1000 mL volumetric flask, dissolve in 900 mL of mixture prepared from 25 mL of concentrated hydrochloric acid and 975 mL of water, dilute to volume with the same mixture and mix. Perform the assay of iron(III) chloride in 1 mL of solution. Dilute iron(III) chloride solution with the same mixture so that the content of iron(III) chloride per 1 mL to be 45.0 mg.

Store the solution in place protected from light.

Assay: Place 10.0 mL of iron(III) chloride into 250 mL conical flask with a ground stopper, add 15 mL of water, 5 mL of concentrated hydrochloric acid and 4 g of potassium iodide, mix, close with a stopper and allow to stand for 15 min in the dark place, then add 100 mL of water. Titrate the released iodine with 0.1 M sodium thiosulphate solution addition 0.5 mL of 1% starch solution as an indicator at the end of titration.

Simultaneously perform control experiment.

1 mL of 0.1 M sodium thiosulphate solution corresponds to 27.03 mg iron(III) chloride ($\text{FeCl}_3 \cdot 6 \text{H}_2\text{O}$).

Red solution. Accurately weigh 60.0 g of grinded cobalt chloride ($\text{CoCl}_2 \cdot 6 \text{H}_2\text{O}$; Mr 237,93) into 100 mL volumetric flask, dissolve in 900 mL of mixture prepared from 25 mL of concentrated hydrochloric acid and 975 mL of water, dilute to volume with the same mixture and

mix. Perform the assay of cobalt chloride in 1 mL of solution. Dilute cobalt chloride solution with the same mixture so that the content of cobalt chloride per 1 mL to be 59.5 mg.

Assay. Place 5.0 mL of cobalt chloride into 250 mL conical flask with a ground stopper, add 5 mL of 3% hydrogen peroxide solution and 30 mL of 10% sodium hydroxide solution. Reflux the mixture for 10 min, then cool down to room temperature and add 60 mL of 1 M sulphuric acid solution and 2 g of potassium iodide. Close the flask and dissolve the sediment mixing carefully. Titrate the released iodine with 0.1 M sodium thiosulphate solution until light pink color develops using 0.5 mL of 1% starch solution as an indicator at the end of titration.

Simultaneously perform control experiment.

1 mL of 0.1 M sodium thiosulphate corresponds to 23.79 mg of cobalt chloride ($\text{CoCl}_2 \cdot 6 \text{H}_2\text{O}$).

Blue solution. Accurately weigh 63.0 g of copper(II) sulphate ($\text{CuSO}_4 \cdot 5 \text{H}_2\text{O}$; Mr 249.68) into 1000 mL volumetric flask, dissolve in 900 mL of mixture prepared from 25 mL of concentrated hydrochloric acid and 975 mL of water, dilute to volume with the same mixture and mix. Perform the assay of copper(II) sulphate in 1 mL of solution. Dilute copper(II) sulphate solution with the same mixture so that the content of copper(II) sulphate per 1 mL to be 62.4 mg.

Assay. Place 10.0 mL of copper(II) sulphate solution into 250 mL conical flask with a ground stopper, add 50 mL of water, 12 mL of 2 M acetic acid solution, 3 g of potassium iodide and mix. Titrate the released iodine with 0.1 M sodium thiosulphate solution until light brown color develops using 0.5 mL of 1% starch solution as an indicator at the end of titration.

Simultaneously perform control experiment.

1 mL of 0.1 M sodium thiosulphate corresponds to 24.97 mg of copper(II) sulphate ($\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$).

Preparation of standard solutions

Obtain standard solutions by mixing baseline solutions of iron(III) chloride, cobalt chloride, copper(II) sulphate with 1% hydrochloric acid solution measuring them using a calibrated pipette or burette with the accuracy up to 0.02 mL (table 1).

Table 1 - Standard solutions

Standard solutions	Yellow baseline solution, mL	Red baseline solution, mL	Blue baseline solution, mL	1% hydrochloric acid solution, mL
B (brown)	30.0	30.0	24.0	16.0
BY (brownish-yellow)	24.0	10.0	4.0	62.0
Y (yellow)	24.0	6.0	0	70.0
GY (greenish-yellow)	96.0	2.0	2.0	0
R (red)	10.0	20.0	0	70.0

Place prepared baseline and standard solutions into dry flasks with ground stoppers and store at $(20 \pm 3)^\circ\text{C}$ in place protected from direct sun light.

Shelf life of baseline and standard solutions is 1 year.

When storing baseline and standard solutions assure the absence of turbidity, sediment and flakes before use. If any present, substitute the solutions with freshly prepared ones.

Preparation of reference standards

Prepare reference standards from five standard solutions by diluting with 1% hydrochloric acid solution.

Measure baseline and standard solutions to prepare scales using calibrated pipette or burette with accuracy up to 0.02 mL.

Store reference standards for determination of liquid coloration using method I in colorless transparent neutral glass ampules with 12 mm outer diameter in place protected from light for

1 year.

Prepare reference standards for determination of liquid coloration using method II from respective standard solutions immediately before use.

The amounts of components to prepare color reference standards are given in tables 2-6.

Table 2 - Reference standards for brown shades (scale B)

Reference standards for scale B	Standard solution B, mL	1% hydrochloric acid solution, mL
B ₁	75.0	25.0
B ₂	50.0	50.0
B ₃	37.5	62.5
B ₄	25.0	75.0
B ₅	12.5	87.5
B ₆	5.0	95.0
B ₇	2.5	97.5
B ₈	1.5	98.5
B ₉	1.0	99.0

Table 3 - Reference standards for brownish-yellow shades (scale BY)

Reference standards for scale BY	Standard solution BY, mL	1% hydrochloric acid solution, mL
BY ₁	100.0	0.0
BY ₂	75.0	25.0
BY ₃	50.0	50.0
BY ₄	25.0	75.0
BY ₅	12.5	87.5
BY ₆	5.0	95.0
BY ₇	2.5	97.5

Table 4 - Reference standards for yellow shades (scale Y)

Reference standards for scale Y	Standard solution Y, mL	1% hydrochloric acid solution, mL
Y ₁	100.0	0.0
Y ₂	75.0	25.0
Y ₃	50.0	50.0
Y ₄	25.0	75.0
Y ₅	12.5	87.5
Y ₆	5.0	95.0
Y ₇	2.5	97.5

Table 5 - Reference standards for greenish-yellow shades (scale GY)

Reference standards for scale GY	Standard solution GY, mL	1% hydrochloric acid solution, mL
GY ₁	25.0	75.0
GY ₂	15.0	85.0
GY ₃	8.5	91.5
GY ₄	5.0	95.0
GY ₅	3.0	97.0
GY ₆	1.5	98.5
GY ₇	0.75	99.25

Table 6 - Reference standards for red shades (scale R)

Reference standards for scale R	Standard solution R, mL	1% hydrochloric acid solution, mL
R ₁	100.0	0.0
R ₂	75.0	25.0
R ₃	50.0	50.0
R ₄	37.5	62.5
R ₅	25.0	75.0
R ₆	12.5	87.5
R ₇	5.0	95.00

The coloration degree of test solution should not be more than the coloration degree of respective reference standard. The color of test sample should be maximally close to the color of respective reference standard.

When comparing the color of test solution with reference standards, specify the number of reference standard and the letter of scale. For example, the color should not exceed reference standard B₇.

If necessary, other reference standards can be used prepared by mixing standard solutions of different color scales with precise indication of their volumes necessary to achieve the required color close to the color of test solution, if specified in the pharmacopoeial monograph.

Spectrophotometric method can be used to evaluate liquids coloration, if specified in the pharmacopoeial monograph, at that, the following should be specified: wavelength at which visible absorption maximum is observed, cuvette thickness and optical density with acceptable tolerance.