



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

GENERAL TESTING PROCEDURE

Title: Colour of Solution

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Effective Date :		Review Date :	
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Supersede SOP No.:	Nil		

1.0 OBJECTIVE:

1.1 To lay down a procedure for Colour of Solution.

2.0 SCOPE:

2.1 It is applicable for the estimation of Raw material.

3.0 RESPONSIBILITY:

3.1 Analyst / Officer / Executive follow the procedure.

3.2 Head-QC are responsible for effective implementation of this SOP.

4.0 REFERENCE:

4.1 Ph. Eur. method

5.0 DEFINITION: NA

6.0 PROCEDURE:

The examination of the degree of coloration of liquids in the range brown-yellow-red is carried out by one of the 2 methods below, as prescribed in the monograph. A solution is colourless if it has the appearance of water or the solvent or is not more intensely coloured than reference solution B9•

6.1 Method I: Using identical tubes of colourless, transparent, neutral glass of 12 mm external diameter, compare 2.0 mL of the liquid to be examined with 2.0 mL of water or of the solvent or of the reference solution (see Tables of reference solutions) prescribed in the monograph. Compare the colours in diffused daylight, viewing horizontally against a white background.

6.2 Method II: Using identical tubes of colourless, transparent, neutral glass with a flat base and an internal diameter of 15 mm to 25 mm, compare the liquid to be examined with water or the solvent or the reference solution (see Tables of reference solutions) prescribed in the monograph,



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the depth of the layer being 40 mm. Compare the colours in diffused daylight, viewing vertically against a white background.

6.3 Reagents: Primary solution:

Yellow Solution: Dissolve 46 g of ferric chloride in about 900 mL of a mixture of 25 mL of hydrochloric acid and 975 mL of water and dilute to 1000.0 mL with the same mixture. Titrate and adjust the solution to contain 45.0 mg of $\text{FeCl}_3 \cdot 6\text{H}_2\text{O}$ per milliliter by adding the same acidic mixture. Protect the solution from light.

Titration: Place in a 250 mL conical flask fitted with a ground-glass stopper, 10.0 mL of the solution, 15 mL of water, 5 mL of hydrochloric acid and 4 g of potassium iodide R, close the flask, allow to stand in the dark for 15 min and add 100 mL of 'water. Titrate the liberated iodine with 0.1M sodium thiosulfate, using 0.5 mL of starch solution, added towards the end of the titration, as indicator. 1 mL of 0.1M sodium thiosulfate is equivalent to 27.03 mg of $\text{FeCl}_3 \cdot 6\text{H}_2\text{O}$.

Red solution: Dissolve 60 g of cobalt chloride in about Table 2.2.2.-3. - Reference solutions BY 900 mL of a mixture of 25 mL of hydrochloric acid and 975 mL of water and dilute to 1000 mL with the same mixture. Titrate and adjust the solution to contain 59.5 mg of $\text{CoCl}_2 \cdot 6\text{H}_2\text{O}$ per milliliter by adding the same acidic mixture.

Titration: Place in a 250 mL conical flask fitted with a ground-glass stopper, 5.0 mL of the solution, 5 mL of dilute hydrogen peroxide solution and 10 mL of a 300 g/l solution of sodium hydroxide. Boil gently for 10 min, allow to cool and add 60 mL of dilute sulfuric acid and 2g of potassium iodide. Close the flask and dissolve the precipitate by shaking gently, Titrate the liberated iodine with 0.1M sodium thiosulfate, using 0.5 mL of starch solution, added towards the end-point is reached when the solution turns pink.

1 mL of 0.1M sodium thiosulfate. is equivalent to 23.79 mg of $\text{CoCl}_2 \cdot 6\text{H}_2\text{O}$.

Blue primary solution: Dissolve 63 g of copper sulfate pentahydrate R in about 900 mL of a mixture of 25 mL of hydrochloric acid and 975 mL of water and dilute to 1000.0 mL with the same mixture. Titrate and adjust the solution to contain 62.4 mg of $\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$ per milliliter by adding the same acidic mixture.

Titration: Place in a 250 mL conical flask fitted with a ground-glass stopper, 10.0 mL of the solution, 50 mL of water, 12 mL of dilute acetic acid and 3 g of potassium iodide. Titrate the



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liberated iodine with 0.1 M sodium thiosulfate, using 0.5 mL of starch solution, added towards the end of the titration, as indicator. The end-point is reached when the solution shows a slight pale brown colour.

1 mL of 0.1 M sodium thiosulfate is equivalent to 24.97 mg of $\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$

Standard solutions: Using the 3 primary solutions, prepare the 5 standard solutions as follows (Table 2.2.2.-1)

Standard solution	Volume in millilitres			
	Yellow solution	Red solution	Blue solution	Hydrochloric acid (10 g/L HCl)
B (brown)	3.0	3.0	2.4	1.6
BY (brownish-yellow)	2.4	1.0	0.4	6.2
Y (yellow)	2.4	0.6	0.0	7.0
GY (greenish-yellow)	9.6	0.2	0.2	0.0
R (red)	1.0	2.0	0.0	7.0

Reference solutions for Methods I and II Using the 5 standard solutions, prepare the following reference solutions.

Table 2.2.2.-2. - Reference solutions B



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Volumes in millilitres

Reference solution	Standard solution B	Hydrochloric acid (10 g/L HCl)
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 2.2.2.-3. - Reference solutions BY

Reference solution	Volumes in millilitres	
	Standard solution BY	Hydrochloric acid (10 g/L HCl)
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 2.2.2.-4. - Reference solutions Y



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Reference solution	Volumes in millilitres	
	Standard solution Y	Hydrochloric acid (10 g/L HCl)
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 2.2.2.-5. - Reference solutions GY

Reference solution	Volumes in millilitres	
	Standard solution GY	Hydrochloric acid (10 g/L HCl)
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 2.2.2.-6. - Reference solutions R



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Volumes in millilitres

Reference solution	Standard solution R	Hydrochloric acid (10 g/L HCl)
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	95.0

6.4 Storage: For Method I, the reference solutions may be stored in sealed tubes of colourless, transparent, neutral glass of 12 mm external diameter, protected from light.

For Method II, prepare the reference solutions immediately before use from the standard solutions.

7.0 Annexures: NA

8.0 Distribution:

8.1 Display copy 1 : Quality Control Lab

9.0 Abbreviation:

GTP : General Test Procedure

QC : Quality Control laboratories

10.0 Revision History:

10.1 Revision history table:

Document Number	CC Number/Date	Brief Description of Change