



(-)-Riboflavin

Meets USP-NF, EP, BP, JP and IP testing specifications

Product Code: TC167M

Product Description : Molecular weight: 376.36 Molecular formula: C₁₇H₂₀N₄O₆ CAS No.: 83-88-5

Quality Control:

Appearance (EP, BP)

Yellow to orange-yellow crystalline powder

Appearance (JP)

Yellow to orange-yellow crystals

Appearance (USP)

Yellow to orange-yellow crystalline powder

Appearance (IP)

Yellow to orange-yellow crystalline powder

Solubility (EP, BP)

Very slightly soluble in water, practically insoluble in ethanol (96 %)

Solubility (USP)

Soluble in dilute solution of alkalies; very slightly soluble in water, in alcohol, and in isotonic sodium chloride solution; insoluble in ether and in chloroform

Solubility (JP)

Very slightly soluble in water, practically insoluble in ethanol (95 %), in acetic acid (100), and in diethyl ether. It dissolves in sodium hydroxide TS

Solubility (IP)

Very slightly soluble in water, more soluble in saline solution than in water; practically insoluble in chloroform, in ethanol (95%) and in ether.

Identification A : Colour and fluorescence of solution (USP)

The sample solution is pale greenish yellow by transmitted light. By reflected light, it exibits an intense yellowish green fluorescence that disappears upon the addition of mineral acids and alkalies

Identification A: Specific optical rotation (EP, BP)

-135.00° to -115.00° (c = 0.50% in 0.05M NaOH, at $20 \pm 0.5^{\circ}$ C, dried substance, measure the rotation within 30 min. of dissolution)

Identification A : FTIR (IP)

Matches with the standard pattern

Identification B : TLC (EP, BP)

The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution.

Identification B (IP)

A pale greenish yellow colour by transmitted light and an intense yellowish green fluorescence by reflected light, which disappears on addition of mineral acids or alkalis Identification C (FP, PP)

Identification C (EP, BP)

The solution has, by transmitted light, a pale greenish yellow colour, and, by reflected light, an intense yellowish-green fluorescence which disappears on the addition of mineral acids or alkalis.

Identification 1 (JP)

The fluorescence disappears upon the addition of dilute hydrochloric acid or sodium hydroxide TS

Identification 2 (JP)

The chloroform layer shows a yellow-green fluorescence.

Identification 3 (JP)

Both spectra exhibit similar intensities of absorption at the same wavelengths.

Melting point (JP) about 290°C (with decompositions)

pH (Saturated aqueous solution) : (IP) 5.50 - 7.20

Specific rotation (USP, IP)

-135.00° to -115.00° (c = 0.50% in 0.05M NaOH, measure the rotation within 30 min. of dissolution, use dry substance)

Specific rotation (EP, BP)

-135.00° to -115.00° (c = 0.50% in 0.05M NaOH, at 20 \pm 0.5°C, dried substance, measure the rotation within 30 min. of dissolution)

Optical rotation (JP)

-142.00° to -128.00° (c = 0.50% at 20°C, 0.1 g of dried Riboflavin, dissolve in 4 mL of dilute NaOH TS, add 10 mL water, add 4 mL of aldehyde-free ethanol and dilute with water to make 20 mL, measure the rotation within 30 min. after preparing the solution)

Light Absorbance 1 at A373/A267 : (IP)

0.31 to 0.33

Absorbance ratio 1 at A373/A267 : (EP, BP) 0.31 to 0.33

Light Absorbance 2 at A444/A267 : (IP)

0.36 to 0.39

Absorbance ratio 2 at A444/A267 : (EP, BP) 0.36 to 0.39

Related substance, system suitability, HPLC: Resolution (EP, BP)

>= 5.0 between the peak due to impurity A and B in the chromatogram obtained with reference solution (C)

Related substances 1: Impurity A : HPLC (EP, BP) <= 0.025%

Related substances 2: Impurities B, C, D for each impurity: HPLC (EP, BP)

<= 0.20%

Related substances 3: Unspecified impurities for each impurity: HPLC (EP, BP)

<= 0.10%

Related substances 4: Total impurities: HPLC (EP, BP)

<= 0.50%

Loss on drying (at 105°C, 2h) : (USP, EP, BP, JP, IP)

<= 1.50%

Residue on ignition (USP)

<= 0.30%

Disclaimer :

Residue on ignition (JP) <= 0.20% Sulfated ash (EP, BP, IP) <= 0.10% Limit of Lumiflavin (by UV, USP) <= 0.025

Lumiflavin (JP)

The filtrate has no more color than the control solution. (Control solution: To 2.0 mL of 1/60 mol/L potassium dichromate VS add water to make 1000 mL.)

Lumiflavin (IP)

The filtrate is not more intensely colored than reference solution BYS6 **assay (UV, on dry basis) : (JP)**

min. 98.00%

assay (UV, on dry basis) : (USP)

98.00 - 102.00%

assay (UV, on dry basis) : (EP, BP)

97.00 - 103.00% assay (UV, dried basis) : (IP)

98.00 - 101.00%

Storage and Shelf Life:

Store below 30°C away from bright light. Shelf life is 36 months. Use before expiry date given on the product label.

Revision : 04/2023

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