



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Riboflavin (Ph. Eur., USP) pure, pharma grade		Issue Date	March-23
Product Code	A6279		Prepared by	Sr. Tech Lead
CAS NO.	83-88-5		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/A6279/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies Ph. Eur., USP</i>	USP 2022	EP Version 11.0	JP 18
1	Description	Not mentioned	Yellow to orange-yellow, crystalline powder having a slight odor. Melts at about 280°. Its saturated solution is neutral to litmus. When dry, it is not appreciably affected by diffused light, but when in solution, light induces quite rapid deterioration, especially in the presence of alkalis.	Yellow or orange-yellow, crystalline powder. Sample solutions deteriorate on exposure to light, especially in the presence of alkali. It shows polymorphism	Yellow to orange-yellow crystals. It has a slight odor. A saturated solution is neutral. It is decomposed by light. Melting point: about 290°C (with decomposition).
2	Solubility	Not mentioned	Soluble in dilute solutions of alkalis; very slightly soluble in water, in alcohol, and in isotonic sodium chloride solution; insoluble in ether and in chloroform.	Very slightly soluble in water, practically insoluble in ethanol (96%).	Very slightly soluble in water, practically insoluble in ethanol (95%), in acetic acid (100%), and in diethyl ether.
3	Identification 1	Should comply by fluorescence test	Should comply by fluorescence test	Should comply with specific optical rotation test	Should comply by fluorescence test
4	Identification 2	Not mentioned	Not mentioned	By TLC, 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	The chloroform layer should show a yellow-green fluorescence.
5	Identification 3	Not mentioned	Not mentioned	Should comply with fluorescence test	UV absorption spectrum of the sample and standard should exhibit maxima at the same wavelength with similar intensity
6	Absorbance	Ratio of absorbance at 373 nm to 267 nm should be between 0.31 and 0.33, at 444 nm to 267 nm should be between 0.36 and 0.39	Not mentioned	Sample should show maxima at 223 nm, 267 nm, 373 nm and 444 nm. Ratio of absorbance at 373 nm to 267 nm should be between 0.31 and 0.33, at 444 nm to 267 nm should be between 0.36 and 0.39	Not mentioned
7	Loss on drying	NMT 1.5%	NMT 1.5%	NMT 1.5%	NMT 1.5%
8	Sulfated ash	NMT 0.10%	Not mentioned	NMT 0.1%	Not mentioned
9	Residue on ignition	Not mentioned	0.3%	Not mentioned	NMT 0.2%
10	Optical rotation	Between -135° to -115°	Between -135° to -115°	Between -135° to -115°	Between -142° to -128°
11	Related substances	Impurity A: NMT 0.025% Impurity B: NMT 0.2% Impurity C: NMT 0.2% Impurity D: NMT 0.2% Maximum unknown impurity : NMT 0.10% Total impurities: NMT 0.5%	Not mentioned	Impurity A: NMT 0.025% Impurity B: NMT 0.2% Impurity C: NMT 0.2% Impurity D: NMT 0.2% Maximum unknown impurity : NMT 0.10% Total impurities: NMT 0.5%	Not mentioned
12	Lumiflavin	Should comply the test	Absorbance is NMT 0.025	Not mentioned	Sample solution should be less intensely colored than standard
13	Assay(Dried basis)	Between 98.0% and 102.0%	Between 98.0% and 102.0%	Between 97.0% and 103.0%	NLT 98.0%
	Storage condition	Store at room temperature, protected from light	Preserve in tight, light-resistant containers.	In an airtight container, protected from light.	Tight containers, Light-resistant.

Note - If you need any additional testing, you may use our Additional Testing Feature on the product page or contact your Clyzo representative.

Disclaimer - The information above is solely for your consideration. We do not recommend or affirm the suitability for any specific end use. We suggest the users should research & verify the specifications in accordance with their intended usage.