

TECHNICAL DATA SHEET

1896-TDS-ENG-2022

VITAMINA B2 PH.EUR. (RIBOFLAVINA)		
DESCRIPTION DCI: RIBOFLAVINE		DESCRIPTION DOE: RIBOFLAVINA
CAS N°: 83-88-5	EC N°: 201-507-1	AEMPS CODE: ---
MOL. WEIGHT: 376.40	MOL. FORMULA: C ₁₇ H ₂₀ N ₄ O ₆	ARTICLE CODE: 1896

ATTRIBUTES	SHOULD BE
Appearance	Yellow or orange-yellow, crystalline powder
Solubility	Very slightly soluble in water, practically insoluble in ethanol (96 %)
Identification A	Complies
Identification B	Complies
Identification C	Complies
Specific optical rotation	-115 / -135
Absorbance	
Absorption maxima	223, 267, 373 and 444 nm
Absorbance ratio	
Abs 373/267	0.31 - 0.33
Abs 444/267	0.36 - 0.39
Related substances	
Impurity A	= < 0.025 %
Impurity B	= < 0.2 %
Impurity C	= < 0.2 %
Impurity D	= < 0.2 %
Unspecified impurities	= < 0.10 %
Total impurities	= < 0.5 %
Loss on drying	= < 1.5 %
Sulfated ash	= < 0.1 %
Assay	97.0 - 103.0 %

COMPLIES WITH

European Pharmacopoeia 10.0

STORAGE

Keep the container tightly closed in a cool, dry and well-ventilated place.

REMARKS

Riboflavine is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

Properties and uses

RIBOFLAVINE is a water-soluble vitamin essential for the utilization of food energy, participating in oxidative phosphorylation reactions.

It is present in numerous foods (milk, eggs, liver, kidney, fish, cheese, and some vegetables such as spinach, broccoli, etc ...)



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, so the deficiency occurs due to an inadequate diet. It is recommended a consumption of about 1.1 - 1.7 mg daily with food. It does not act as such a vitamin until in the intestine it is phosphorylated and bound to proteins by 60%, forming flavin mononucleotide (FMN) and subsequently flavin adenine dinucleotide (FAD), which participate as coenzymes in the oxidation-reduction metabolic reactions. It is excreted in urine partly in the form of metabolites. It crosses the placental barrier and passes into breast milk. RIBOFLAVINE is also necessary for the functioning of pyridoxine and nicotinic acid.

The deficiency produces a syndrome called arriboflavinosis, which is characterized by the appearance of cheilosis, seborrheic dermatitis, mucosal color alterations, glossitis, angular stomatitis, ocular alterations (keratitis, vascularization of the cornea, itching and inflammation of the eyes, lacrimation, and photophobia), superficial lesions of the genitals, and normocytic anemia. Some of these symptoms may be due to deficiencies of other vitamins such as pyridoxine and nicotinic acid, which do not work correctly in the absence of RIBOFLAVINE. A deficiency of RIBOFLAVINA can also occur associated with deficiencies of other B vitamins, such as in pellagra.

RIBOFLAVINE is used in deficiency states of this vitamin, preferably administered orally. If gastric intolerance can be part of multivitamin preparations intramuscularly or intravenously.

It is also used as a dye in food and medicines, due to its harmlessness. Its use as a dilution indicator in the preparation of capsules is very useful, especially if we use very active substances that are used in microdoses, and therefore we have to ensure homogeneity.

Dosage

At a dose of 1 - 2 mg for the prophylaxis of the deficit, up to 30 mg daily for the treatment of the deficit, and up to 30 - 90 mg daily for disorders of the nervous system, in one or more doses. As a dilution control for capsules, 0.25 - 0.5% of the total mixture to be encapsulated.

Side effects

You can color the bright yellow urine.

Incompatibilities

Alkalis, heavy metal salts, reducing agents, and other water-soluble vitamins.

Other observations

It is photosensitive. Solutions are altered when exposed to light, particularly if they are alkaline. Unstable in the face of heat.