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Riboflavin Injection

» Riboflavin Injection is a sterile solution of Riboflavin in Water for Injection. It contains not less than 95.0 percent and not more than 120.0 percent of the labeled amount of $C_{17}H_{20}N_4O_6$. It may contain niacinamide or other suitable solubilizers.

Packaging and storage—Preserve in light-resistant, in single-dose or in multiple-dose containers, preferably of Type I glass.

USP REFERENCE STANDARDS (11).—
[USP Riboflavin RS](#)

Identification—It responds to the [Identification](#) test under [Riboflavin](#).

BACTERIAL ENDOTOXINS TEST (85).—It contains not more than 7.1 USP Endotoxin Units per mg of riboflavin.

pH (791): between 4.5 and 7.0.

Other requirements—It meets the requirements under [Injections and Implanted Drug Products \(1\)](#).

Assay—Dilute an accurately measured volume of not less than 1 mL of Injection to make a solution containing approximately 0.1 µg of riboflavin per mL. Using this as the Assay Preparation, proceed as directed under [Riboflavin Assay \(481\)](#), [Chemical Methods, Procedure 1](#). Calculate the quantity, in mg, of $C_{17}H_{20}N_4O_6$ in each mL of the Injection taken by the formula:

$$C(A/B)$$

in which *C* is the concentration, in mg per mL, of $C_{17}H_{20}N_4O_6$ obtained for the Assay Preparation, *A* is the test specimen dilution volume, in mL, and *B* is the volume, in mL, of Injection taken.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
RIBOFLAVIN INJECTION	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: [Chromatographic Database](#)

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