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Hyaluronidase Injection

» Hyaluronidase Injection is a sterile solution of dry, soluble enzyme product, prepared from mammalian testes and capable of hydrolyzing mucopolysaccharides of the type of hyaluronic acid, in Water for Injection. It contains not less than 90.0 percent of the labeled amount of USP Hyaluronidase Units. Hyaluronidase Injection contains not more than 0.25 µg of tyrosine for each USP Hyaluronidase Unit. It may contain suitable stabilizers.

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of Type I glass, and store in a refrigerator.

USP REFERENCE STANDARDS (11).—

[USP Hyaluronidase RS](#)
[USP L-Tyrosine RS](#)

BACTERIAL ENDOTOXINS TEST (85).—It contains not more than 2.30 USP Endotoxin Units per USP Hyaluronidase Unit.

pH (791). between 6.4 and 7.4.

Limit of tyrosine—Transfer an accurately measured volume, equivalent to about 120 USP Hyaluronidase Units, to a 15-mL centrifuge tube calibrated at 6 mL, and evaporate at 105° to dryness. Proceed as directed in *Limit of tyrosine* under [Hyaluronidase for Injection](#), beginning with “Add 200 µL of 6 N sodium hydroxide,” except to read Hyaluronidase Injection for Hyaluronidase for Injection in the second paragraph. Calculate the quantity, in µg, of tyrosine in the volume of Injection taken by the formula:

$$45(A_u/A_s)$$

in which A_u and A_s are the absorbances of the solution from the Injection and the Standard solution, respectively: not more than 0.25 µg of tyrosine is found for each USP Hyaluronidase Unit.

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

Assay—

Acetate buffer solution, Phosphate buffer solution, Hydrolyzed gelatin, Diluent for hyaluronidase solutions, Serum stock solution, Serum solution, Potassium hyaluronate stock solution, Hyaluronate solution, and Standard solution—Prepare as directed in the Assay under [Hyaluronidase for Injection](#).

Assay preparation—Quantitatively dilute an accurately measured volume of Injection with cold *Diluent for hyaluronidase solutions*, on the basis of trial or experience, so that the observed absorbances with the three dilutions of the Injection fall on the upper, linear part of the standard curve prepared as directed in the *Procedure*.

Procedure—Proceed as directed for *Procedure* in the Assay under [Hyaluronidase for Injection](#). The potency, in USP Hyaluronidase Units, of the portion of Injection taken is the average of the six activity values read from the standard curve.

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

Topic/Question	Contact	Expert Committee
HYALURONIDASE INJECTION	Mandy Alger Scientific Liaison	BIO2 Biologics Monographs 2 - Proteins
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO2 Biologics Monographs 2 - Proteins

Chromatographic Database Information: [Chromatographic Database](#)

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