

RayBiotech, Inc.

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Certificate of Analysis and Data Sheet

Human Follicle Stimulating Hormone

Catalog No. 228-10497

Source

Urine of post-menopausal women

Synonyms

Follitropin subunit beta, Follicle-stimulating hormone beta subunit, FSH-beta, FSH-B, Follitropin beta chain, FSH.

Introduction

Follicle stimulating hormone (FSH) is a hormone synthesized and secreted by gonadotropes in the anterior pituitary gland. FSH and LH act synergistically in reproduction. In women, in the ovary FSH stimulates the growth of immature Graafian follicles to maturation. As the follicle grows it releases inhibin, which shuts off the FSH production. In men, FSH enhances the production of androgen-binding protein by the Sertoli cells of the testes and is critical for spermatogenesis.

In both males and females, FSH stimulates the maturation of germ cells. In females, FSH initiates follicular growth, specifically affecting granulosa cells. With the concomitant rise in inhibin B FSH levels then decline in the late follicular phase. This seems to be critical in selecting only the most advanced follicle to proceed to ovulation. At the end of the luteal phase, there is a slight rise in FSH that seems to be of importance to start the next ovulatory cycle.

Like its partner, LH, FSH release at the pituitary gland is controlled by pulses of gonadotropin-releasing hormone(GnRH). Those pulses, in turn, are subject to the estrogen feed-back from the gonads.

Description

FSH Human is a glycoprotein produced from urine of post-menopausal women and having a total molecular mass of 30,000 Dalton.

FSH is a heterodimeric hormone consisting of 92 amino acids a chain and 111 amino acids b chain. The FSH is purified by proprietary chromatographic techniques.

Physical Appearance

Sterile Filtered White lyophilized (freeze-dried) powder.

Formulation

The FSH was lyophilized from a concentrated (1 mg/ml) solution with no additives.



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Solubility

It is recommended to reconstitute the lyophilized Follicle Stimulating Hormone in sterile $18M\Omega$ -cm H2O not less than $100 \mu g/ml$, which can then be further diluted to other aqueous solutions.

Purity

Greater than 98.0% as determined by:

- (a) Analysis by RP-HPLC.
- (b) Analysis by SDS-PAGE.

Biological Activity

The specific activity was found to be 10,000 IU/mg protein (IRP reference preparation 68/140).

Contaminants

Less than: 0.1% hCG, 0.5%TSH, 0.5% LH, 0.5%GH and 0.5%Prl. Free of HbsAg, antibodies to HIV and HCV.

Stability

Lyophilized FSH although stable at room temperature for 3 weeks, should be stored desiccated below - 18°C. Upon reconstitution FSH-beta should be stored at 4°C between 2-7 days and for future use below -18°C. For long term storage it is recommended to add a carrier protein (0.1% HSA or BSA). **Please prevent freeze-thaw cycles.**