Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-E5141376-8E2F-4138-8B92-6FEB0E7BB44B_3_en-US
DOI: https://doi.org/10.31003/USPNF_M35810_03_01
DOI Ref: cz57t

Chorionic Gonadotropin

CAS RN®: 9002-61-3; UNII: 6413W06WR3.

DEFINITION

Chorionic Gonadotropin is a gonad-stimulating polypeptide hormone obtained from the urine of pregnant women. Its potency is NLT 1500 USP Chorionic Gonadotropin Units in each mg, and NLT 80.0% and NMT 125.0% of the potency stated on the label.

ASSAY

• **Procedure**

Diluent: Saline TS, freshly prepared to contain 1 mg/mL of bovine serum albumin and adjusted with sodium hydroxide TS to a pH of 6.9–8.0

Standard stock solution: 10 Units/mL of USP Human Chorionic Gonadotropin RS in *Diluent*

Standard solutions: From the *Standard stock solution*, prepare three *Standard solutions* in *Diluent* such that the respective concentrations of chorionic gonadotropin constitute a geometric series such as 1:1.2:1.44 or 1:2:4 and such that the activity in each mL lies within the range of 0.1–1.0 Unit.

Sample solutions: Following the analysis outlined for the *Standard stock solution* and *Standard solutions*, prepare solutions of Chorionic Gonadotropin to obtain three *Sample solutions* corresponding to those of the *Standard solutions*.

Animals: Select 20- to 23-day-old female rats, but restrict the selection so that no rat is more than 30% heavier than the lightest. House the animals under uniform conditions of temperature, lighting, feeding, and watering. Mark the animals for identification, and divide them at random into groups of the same number but NLT 10 animals. Assign one group to each of the three *Standard solutions* and three *Sample solutions*, respectively.

Analysis: Inject each rat subcutaneously in the dorsal area with 0.20 mL of the solution to which it was assigned, at approximately the same time on each of 3 consecutive days. On the afternoon of the fifth day, sacrifice the animals, and excise the uterus from each animal by cutting through the cervix, stripping off the surrounding tissue, and severing at the utero-tubal junction. Gently press out the uterine fluid on moistened absorbent paper, and weigh the uterus to the nearest 0.2 mg, using a suitable balance.

Calculation: Tabulate the observed uterine weight for each rat, designated by the symbol *y*, for each dosage group of *f* rats. If the data from one or more rats are missing, adjust to groups of equal size by suitable means. Total the values of *y* in each group, and designate each total as *T*, subscripts 1–3 for the three successive dosage levels and subscripts *S* and *U* for the *Standard solutions* and the *Sample solutions*, respectively. Test for parallelism and linearity between the results for the *Standard solutions* compared to the *Sample solutions* by suitable statistical methods.

Determine the logarithm of potency of the sample taken:

$$\text{Result} = (4iT_a/3T_b) + \log R$$

i = interval between successive log doses of both the *Standard solution* and the *Sample solution*

$$T_a = \Sigma(T_U - T_S)$$

$$T_b = \Sigma(T_3 - T_1)$$

$$R = v_S/v_U$$

v_S = high dose of the Standard (USP Units)

v_U = high dose of the sample (mL)

Compute the log confidence interval *L* (see *Design and Analysis of Biological Assays* ⟨111⟩). If the confidence interval is more than 0.1938, which corresponds at *P* = 0.95 to confidence limits of 80% and 125% of the computed potency, repeat the *Assay* until the combined

data of two or more assays, redetermined as described under *Design and Analysis of Biological Assays ⟨111⟩, Combination of Independent Assays*, meet this limit.

Acceptance criteria: Potency is NLT 1500 USP Chorionic Gonadotropin Units/mg, and 80.0%–125.0% of the potency stated on the label.

SPECIFIC TESTS

- **Water Determination, *Method I* ⟨921⟩:** NMT 5.0%
- **Estrogenic Activity**

  Sample solution: Dissolve a suitable quantity in saline TS to obtain an equivalent of 1000 USP Chorionic Gonadotropin Units/mL.

  Analysis: Into each of five rats that have been ovariectomized NLT 2 weeks previously, inject subcutaneously 0.25 mL of the *Sample solution* in the morning and in the afternoon of 2 successive days. On each of the 3 following days, take a vaginal smear from each animal.

  Acceptance criteria: The requirements of the test are met if the cellular elements in the smears consist mainly of leukocytes and a few nucleated epithelial cells, but no cornified epithelial cells.
- **Bacterial Endotoxins Test ⟨85⟩:** Contains NMT 0.03 USP Endotoxin Unit/USP Chorionic Gonadotropin Unit
- **Sterility Tests ⟨71⟩:** Where the label states that it is sterile, it meets the requirements.
- **Acute Toxicity**

  Sample solution: Prepare by dissolving a suitable quantity in sterile, pyrogen-free saline TS to obtain a solution containing 2000 USP Chorionic Gonadotropin Units/mL.

  Analysis: Select five healthy mice, weighing 18–22 g. Inject intravenously a dose of 0.5 mL of the *Sample solution* into each of the mice. Observe the animals over the 48 h following the injection.

  Acceptance criteria: The requirements of the test are met if, at the end of 48 h, all of the animals survive and NMT 1 of the animals shows outward symptoms of a toxic reaction. If more than 1 of the animals show outward signs of a toxic reaction or if NMT 2 of the animals die, repeat the test on 10 additional, similar animals. If all of the animals of the repeat test survive for 48 h and show no symptoms of a toxic reaction, the requirements of the test are met.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers, preferably of Type I glass, in a refrigerator.
- **USP Reference Standards ⟨11⟩**

  USP Human Chorionic Gonadotropin RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
CHORIONIC GONADOTROPIN	Rebecca C. Potts Associate Scientific Liaison	BIO2 Biologics Monographs 2 - Proteins

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 39(5)

Current DocID: GUID-E5141376-8E2F-4138-8B92-6FEB0E7BB44B_3_en-US
Previous DocID: GUID-E5141376-8E2F-4138-8B92-6FEB0E7BB44B_1_en-US
DOI: https://doi.org/10.31003/USPNF_M35810_03_01
DOI ref: cz57t