DRAFT REVISIONS FOR COMMENTS

This draft amendment contains revised text of monographs for inclusion in the Indian Pharmacopoeia (IP). The content of this draft document is not final, and the text may be subject to further revisions prior to publication in the IP.This draft do not necessarily represent the decisions or the stated policy of the IP or Indian Pharmacopoeia Commission (IPC).

Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Comments received after the last date will not be considered by the IPC before finalizing the monograph.

Please send any comments you may have on this draft document to lab.ipc@gov.in/ biologics-ipc@gov.in **before the last date for comments.**

Document History and Schedule for the Adoption Process

Description	**Details**
Document version	0.0
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Monograph Revision proposed for Inclusion in	IP Addendum 2028
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Draft revision published on IPC website for public comments	NA

BIOTECHNOLOGY DERIVED THERAPEUTIC PRODUCTS

Follicle Stimulating Hormone, Pg 5106

Insert following note after para 2

Note: *This monograph is applicable to Recombinant Follicle Stimulating Hormone Alfa and Recombinant Follicle Stimulating Hormone Beta.*

Follicle Stimulating Hormone Concentrated Solution, Pg 5113

Insert following note after para 2

Note: *This monograph is applicable to Recombinant Follicle Stimulating Hormone Alfa and Recombinant Follicle Stimulating Hormone Beta.*

Follicle Stimulating Hormone Injection, Pg 5121

Insert following note after para 1

Note: *This monograph is applicable to Recombinant Follicle Stimulating Hormone Alfa and Recombinant Follicle Stimulating Hormone Beta.*

Identification

D. Immunoblotting. Determine by electrophoresis (Sodium dodecyl sulphate polyacrylamide gel electrophoresis) (SDS-PAGE) followed by immunoblotting (2.4.12).

Insert following note:

NOTE- Identification D. Immunoblotting. Determine by electrophoresis (Sodium dodecyl sulphate polyacrylamide gel electrophoresis) (SDS-PAGE) followed by immunoblotting (2.4.12)may be omitted if the recombinant Follicle Stimulating Hormone injection is prepared from recombinant Follicle Stimulating Hormone complied as per monograph in current edition of IP.

Tests
Free subunits. Determine by sodium dodecyl sulphate polyacrylamide gel electrophoresis (SDS-PAGE) (2.4.12) under non-reducing conditions

Change **from:**
In the electropherogram obtained with the test solution, the content of *free subunits* is not more than 3 per cent.

to:
In the electropherogram obtained with the test solution, the content of *free subunits* is not more than 5 per cent.

Interferon Beta-1a Injection, IP 2022 Pg. 5157

Tests

Change **from: pH** (2.4.24).4.5 to 5.1

to: pH (2.4.24).3.5 to 5.1

VACCINES AND ANTISERA FOR HUMAN USE

3-O-desacyl-4′-monophosphoryl lipid A, Pg 2315

TRIETHYLAMINE SALT OF 3-O-DESACYL-4'-MONOPHOSPHORYL LIPID A

Pyrogens (2.2.8). The triethylamine salt of 3-*O*-desacyl-4′-monophosphoryl lipid A complies with the test for pyrogens. Inject into each rabbit per kilogram of body mass 3 mL of a solution containing 2.5 µg of 3-*O*-desacyl-4′-monophosphoryl lipid A.

Insert following note at the end
"*Note:* *It is recommended to perform the monocyte-activation test during development of the production process to verify the presence of any non-endotoxin pyrogens; if any changes are made to the production process that could influence the quality of the product with regard to pyrogenicity. It is recommended to repeat the monocyte-activation test*.**"**

BCG for Immunotherapy, Pg 4825

FINAL BULK

Count of viable units

Change **from:**

Determine the number of viable units per milliliter on solidmedium using a method suitable for the product **(Using notless than 5 containers before freeze drying)** to be examinedor by a suitable biochemical method. Carry out the test inparallel on a reference preparation of the same strain.

to: Determine the number of viable units per milliliter on solidmedium using a method suitable for the product to be examinedor by a suitable biochemical method. Carry out the test in parallel on a reference preparation of the same strain.