

IBSA Satellite Symposium



“Unique quality features of Fostimon and Merional manufacturing and purification processes”

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The manufacturing process for the purification of FSH drug substance present in the IBSA's products has been designed in order to obtain a high level of purity of the protein preparation and a high percentage of acidic isoforms of FSH.

A comparative analysis of the main quality characteristics of the marketed products in which FSH is the active compound (either recombinant or human-derived) has been performed. Despite the differences in the manufacturing processes of the FSH-based products presently on the market, all these products show a comparable high level of purity when analysed either using RP-HPLC and SDS-PAGE.

On the contrary, significant differences were observed in the glycosylation status and in the isoelectric point distribution of the different FSH-based drugs present on the market when these products were comparatively analysed using a series of biochemical techniques. In particular, FSH in the IBSA products shows a higher percentage of acidic isoforms when compared to the other products containing gonadotrophins either recombinant or human-derived.

Thus, the purification process of the FSH designed by IBSA is able to provide a high level of purity of the therapeutic protein and a product enriched in its highly-glycosylated and acidic isoforms.