

### 2.3.46. Assay of Insulins. Page 160

Insert after title

Use Method A or Method B, as appropriate.

#### Method A

Insert at the end

#### Method B

Determination by liquid chromatography (2.4.14) as described under Assay of Insulins (2.3.46) Method A, following the conditions as described below:

Time (min)	Mobile phase (a) (percent v/v)	Mobile phase (b) (percent v/v)	Comments
0-30	42	58	Isocratic
30-44	42-11	58-89	Linear gradient
44-50	11	89	Isocratic
50-55	42	58	Isocratic

---

### Filgrastim Concentrated Solution. Page 3977

#### Identification. E.

*Test solution.* Line 5

Change **from** : ....dilute to 1ml with *water*....

**to**: ....dilute to 100 µl with *water*....

---

### Follicle Stimulating Hormone Concentrated Solution. Page 3991

Para 2, lines 4 and 5

Change **from**: .....contains not less than 0.4 mg and not more than 0.8 mg of protein content per ml of the solution ..... per of protein

**to**: .....contains not less than 0.1 mg and not more than 0.8 mg of protein content per ml of the solution ..... per of protein

### Pegfilgrastim. Page 4038

#### Identification. B

Change **from** : Determine by isoelectric focusing (2.4.33) capillary electrophoresis.

**to**: Determine by isoelectric focusing (2.4.33).

E. .Line1

Change **from**: Equilibrate a PD-10 column....

**to**: Equilibrate any desalting column....

#### Tests

**Impurities with charges differing from that of pegfilgrastim.**

Determine by isoelectric focusing(2.4.33).

*Reference solution (a).*

Change **from:** A solution of *filgrastim RS* containing 0.3 mg per ml.

**to:** A solution of *pegfilgrastim RS* containing 0.3 mg per ml.

*Reference solution (b).*

Change **from:** A solution of *filgrastim RS* containing 0.3 mg per ml.

**To:** A solution of *pegfilgrastim RS* containing 0.3 mg per ml.

*Detection.* Para2, Line 4

Change **from:** ..... the pI of the principal band is 7.4 – 7.8.

**to:** .....the pI of the principal band is 5.7- 6.3.