

Identification

Change **from:**

A. Bioassay

to:

A. It complies with the biological activity as described under Assay.

E. Determine by isoelectric focussing (2.4.33) Capillary Electrophoresis

Last Para

Delete following:

It complies with the biological activity as described under Assay.

Tests

Charged variants. Determine by ion-exchange liquid chromatography (2.4.14) using method A or method B

Method B.

Last Para

Change **from:**

Integrate all rituximab.....and basic peak 1 should not less than 1.0.

Acidic variants. Acidic variants ≤ 30 per cent

Main peak. Main peak ≥ 40 per cent

to:

Integrate all rituximab.....and basic peak should not be less than 1.0.

Acidic variants ≤ 30 per cent

Main peak ≥ 40 per cent

Tests

Glycan Distribution. Determine by capillary electrophoresis with fluorescence detection (2.4.32). Determine by method A or method B.

Method A.

Last Para

Change **from:**

The percent area of the peaks corresponding to galactosylatedglycan is not more than 35.0 per cent.

to:

The percent area of the peaks corresponding to galactosylatedglycan should be between 35 and 65 per cent.

Method B.

Last Para

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Rituximab Injection. IP 2022 Pg. 4676

Tests

Glycan Distribution. Determine by capillary electrophoresis with fluorescence detection (2.4.32). Determine by method A or method B.

Method A.

Last Para

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Method B.

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