

## Calcitonin Salmon Nasal Solution

### Change to read:

» Calcitonin Salmon Nasal Solution is a solution of Calcitonin Salmon in a suitable diluent. It contains suitable preservatives, and is packaged in a form suitable for nasal administration so that the required dosage can be controlled as required. Each mL of Calcitonin Salmon Nasal Solution possesses an activity of not less than 80 percent and not more than 115 percent of that stated on the label. (RB 1-Mar-2010)

**Packaging and storage**—Preserve in containers suitable for spraying the contents into the nasal cavities in a controlled individualized dosage. Store unopened containers in a refrigerator, and opened containers at room temperature.

**Labeling**—Label it to indicate that it is for intranasal administration only. The labeling also states that it has been prepared either with Calcitonin Salmon of synthetic origin or Calcitonin Salmon of rDNA origin. Label it to state that it is to be stored in a refrigerator and that freezing is to be avoided. Label it to indicate the activity in USP Calcitonin Salmon Units per mL.

**USP Reference standards** (11)—USP Calcitonin Salmon RS. USP Calcitonin Salmon Related Compound A RS.

**Identification**—The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay.

**Microbial enumeration tests** (61) and **Tests for specified microorganisms** (62)—The total aerobic microbial count does not exceed 100 cfu per g, and the total combined molds and yeasts count does not exceed 50 cfu per g. It meets the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

**pH** (791): between 3.5 and 4.5.

### Assay—

*Solution A, Solution B, Mobile phase, and Chromatographic system*—Proceed as directed in the Assay under Calcitonin Salmon.

*Standard stock preparation and Standard preparation*—Prepare as directed in the Assay under Calcitonin Salmon Injection.

*System suitability solution*—Prepare as directed for Resolution solution under Calcitonin Salmon Injection.

*Diluent*—Dissolve 0.75 g of sodium chloride, 0.2 g of sodium acetate, and 0.2 g of glacial acetic acid in 100 mL of water, and mix.

*Assay preparation*—Transfer 1 mL of Nasal Solution to a 10-mL volumetric flask, dilute with Diluent to volume, and mix.

*Procedure*—Separately inject equal volumes (about 200 µL) of the Standard preparation and the Assay preparation into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the potency, in USP Calcitonin Salmon Units per mL, in the Nasal Solution taken by the formula:

$$10C(r_U / r_S)$$

in which *C* is the concentration of the Standard preparation, in USP Calcitonin Salmon Units per mL; and *r<sub>U</sub>* and *r<sub>S</sub>* are the main peak areas from the Assay preparation and Standard preparation, respectively.