

## **Instructions for Visual Inspection: Herceptin Vials 150 mg**

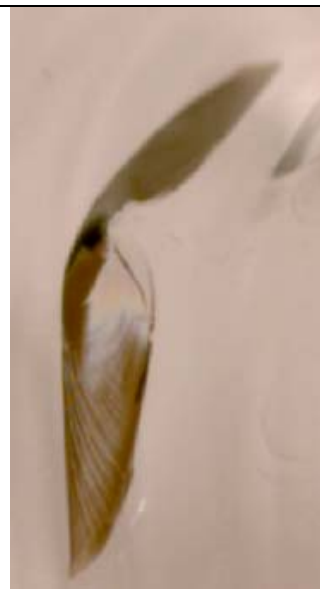
Please refer to the following instructions in order to conduct immediate inspections of all of your existing supplies of affected Herceptin vials 150 mg batches:

- Wear gloves to protect you from any risk of injury in case of a broken vial
- Unpack the vials from the folding box
- Hold each vial towards a bright white light, e.g. neon light, and if possible, use a magnifying glass
- Examine each vial shoulder carefully by continuously tilting the vial back and forth, looking especially at the transition between neck and shoulder
- Look for the presence of a crack in the neck region, identifiable as a small fissure (mostly "butterfly-like" shaped; see pictures 1 and 2 below)
- Check whether the content of each vial has a dry, white appearance and does not show any traces of humidity (e.g. a slushy appearance of the content)
- Store vials that have been inspected, and are in appropriate state, in their original box between 2 to 8 °C until use by the expiry date
- For individually identified vials with cracks, do not use them, but send them back to your local Roche organisation for replacement
- Inform your local Roche organisation of completed inspections, by using the attached "Visual Inspection Reporting Form: Herceptin Vials 150 mg."

**Picture 1**



**Picture 2**



Furthermore, at the time of reconstitution of inspected Herceptin lyophilisate, check for signs of loss of negative pressure in the vial, e.g. syringe plunger not depressing automatically upon piercing the rubber stopper.

As a preventive measure, do not use any Herceptin vials 150 mg with suspicious content, identifiable cracks, and/or loss of negative pressure. Instead, immediately contact your local Roche organisation to replace individually affected vials.