

Herceptin Storage, Preparation and Administration Recommendations

This article responds to your request for information on Herceptin® (trastuzumab) and storage and compatibility recommendations.

Herceptin storage recommendations

Please refer to the locally approved storage information provided in the Herceptin package insert or prescribing information. Any deviation from this information is considered off-label and any treatment decisions based on such deviations are the full responsibility of the prescribing physician.

Storing the unopened vial

Temperature

Herceptin vials should be stored at 2°C to 8°C.¹

If Herceptin was inadvertently stored outside of this temperature range, a stability assessment can be requested through medinfo.roche.com.

Light

Herceptin was tested according to the ICH Guidance for Photostability Testing.² Results support that Herceptin is not sensitive to light in lyophilised state. While these results support that there is no impact under defined exposure to lighted conditions, Herceptin should be kept at recommended storage conditions and not exposed to light during routine or long-term storage.

Storing the reconstituted solution

Temperature

The reconstituted product is physically and chemically stable for 48 hours at 2°C to 8°C after reconstitution with sterile water for injection.¹

From a microbiological point of view, the reconstituted solution should be further diluted in infusion solution immediately.¹ If not, in-use storage times and conditions prior to use is the responsibility of the user and would normally not be longer than 24 hours at 2°C to 8°C, unless reconstitution has taken place in controlled and validated aseptic conditions.

Do not freeze the reconstituted solution.¹

Storing the infusion bag containing the diluted solution

Temperature

The infusion solution containing the reconstituted product diluted with 0.9% NaCl is physically and chemically stable up to 30 days at 2°C to 8°C and 24 hours at room temperature, or ≤30°C.¹

From a microbiological point of view, the Herceptin infusion solution should be used immediately.¹ If not used immediately, in-use storage times and conditions prior to use is the responsibility of the user and would normally not be longer than 24 hours at 2°C to 8°C, unless reconstitution and dilution have taken place in controlled and validated aseptic conditions.

Light

Infusion bags containing reconstituted and diluted Herceptin IV 2°C to 8°C for 30 days under dark conditions, followed by storage at 30°C for 24 hours in ambient light.³ Refer to the locally approved prescribing information for any additional storage recommendations.

Preparing Herceptin for IV infusion

Recommended solutions for reconstitution or dilution

Physical and chemical stability data supports the reconstitution of Herceptin lyophilised powder with

- sterile water, or
- bacteriostatic water for injection.¹

Refer to the locally approved prescribing information or contact your local medical information service for further information on reconstitution of Herceptin lyophilised powder.

The reconstituted solution should be further diluted with 0.9% NaCl.¹

Precaution against admixtures

Herceptin should not be reconstituted, diluted, or mixed with other drugs.

Precaution against using dextrose 5% solution

Roche recommends against reconstituting or diluting Herceptin with dextrose (or glucose) 5% solution as it causes aggregation of the protein.¹

Compatibility of in-line filters

Use of in-line filters made of polyethersulfone (PES) were included during in-use stability studies.⁴ It was determined that although they may be used, they are not required.

References

1. Roche Internal Regulatory Report (Herceptin CDS 21.0). Accessed 12 July 2023.
2. Roche Internal Communication. Accessed 12 July 2023.
3. Roche Internal Technical Report (TWIMC). Accessed 25 July 2023.
4. Roche Internal Technical Report (TEC-0117489). Accessed 12 July 2023.