

Gazyva and Use of In-Line Filter

This response corresponds to your request for information on use of in-line filters with Gazyva® (obinutuzumab).

Adminstration requirement

There is no requirement to use an in-line filter during Gazyva administration.¹ Use of an in-line filter is optional.

Use of in-line filter in in-use stability studies

In-line filter size

In an in-use stability study, Gazyva IV solution diluted in 0.9% sodium chloride was compatible with use of a 0.22µm in-line filter made from polyethersulfon (PES).²

Material compatibilities of in-line filter

Gazyva IV solution diluted in 0.9% sodium chloride to concentrations between 0.4 mg/mL to 20.0 mg/mL was compatible with the following product contact surfaces

- PES
 - Polycarbonate (PC) 3-way stockcock infusion aid, and
 - Polyethereurethane (PEU) cathether.¹
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References

1. Roche Internal Regulatory Document (Accessed on 30 Jun 2023).
2. Roche Internal Technical Report (Accessed on 24 Jul 2023).