

MabThera and Use of In-Line Filters

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

Adminstration requirement

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

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

Use of a 0.2 µm in-line filter was assessed in internal in-use stability studies.² MabThera IV solution diluted to concentrations between 0.5 mg/mL and 4 mg/mL remained stable with or without the use an of in-line filter. MabThera met the USP specifications for particulates for single dose, large volume infusion without the use of an in-line filter.

Use of in-line filter from published literature

Two studies in the literature report the use of a 0.22 µm in-line filter to administer MabThera infusions diluted to a maximum concentration of 1 mg/mL.^{3,4} Study results suggest that the use of an in-line filter would not anticipate any issues.

Yamanouchi et al. evaluated the drug adsorption of pediatric doses of rituximab with 0.2 µm endotoxin-retentive in-line filter use.⁵ Study results showed the usefulness of one point masurement method of pediatric dose and UV spectrophotometry for filterability test of in-line filters.

References

1. Roche Internal Regulatory Document (Accessed on 24Jul23).
2. Roche Internal Clinical Study Report (Accessed on 29 Jun 2023).
3. Piro L, White C, Grillo-López A, et al. Extended Rituximab (anti-CD20 monoclonal antibody) therapy for relapsed or refractory low-grade or follicular non-Hodgkin's lymphoma. *Ann Oncol* 1999;10:655-61. <https://www.ncbi.nlm.nih.gov/pubmed/10442187>
4. McLaughlin P, Grillo-López A, Link B, et al. Rituximab chimeric anti-CD20 monoclonal antibody therapy for relapsed indolent lymphoma: half of patients respond to a four-dose treatment program. *J Clin Oncol* 1998;16:2825-33. <https://www.ncbi.nlm.nih.gov/pubmed/9704735>
5. Yamanouchi T, Horiuchi K, Ishii K, et al. [Usefulness of one point measurement method of pediatric dose and UV spectrophotometry for filterability test of in-line filter]. *Yakugaku Zasshi* 2014;134:671-7. <https://www.ncbi.nlm.nih.gov/pubmed/24790051>