

Non-Conformance Initiation Form — NC-ATO-2026-0892

AMGEN — TRACKWISE QMS

Non-Conformance Initiation Form

NC Number: NC-ATO-2026-0892

Site: Thousand Oaks (ATO)

Date Filed: 2026-02-17

Classification: Minor

Product: Repatha (erenumab-aooe)

Equipment: FLT-030-007 (0.22um Sterilizing Filter, Filling Line 3, Building 30)

Shift: Night Shift A

Operator: EMP-3847

Event Description:

Post-use integrity test on 0.22um Millipore Durapore CVGL filter (hydrophilic PVDF membrane) showed diffusive flow of 14.2 mL/min vs acceptance limit of 12.0 mL/min. Filter was used for sterile filtration of Repatha drug substance batch RPT-2026-0447. Test performed per SOP-FLT-003 Rev 7. Filling Line 3 placed on hold pending investigation. No product released.

Immediate Actions:

1. Filling Line 3 placed on hold
2. Retained filter sample collected for lab analysis
3. Batch RPT-2026-0447 quarantined pending investigation
4. Backup filter from same lot tested — also failed (13.8 mL/min)

Attachments:

- Filter integrity test printout
- Batch record page 47 (filtration step)
- Equipment logbook entry