

TECHNICAL NOTE

Properties of WorkBeads IEX resins with focus on buffer compatibilities and operational temperatures (based on RSF data)

The regulatory support files (RSF) provide an invaluable starting point for process development and validation. It is also critical for preparation of standard operating procedures (SOPs), quality control, and as support to clinical and marketing applications to regulatory agencies. Thus, these documents are of utmost importance. However, since they contain large data set including e.g. extractables, an overview of important storage and operational conditions for the IEX resins are presented in this short technical note.

The data presented here are divided into two main sections: buffer compatibilities and operational temperatures.

Buffer compatibilities

The buffer compatibilities were tested for all resins incubated in selected process solutions for one week at 25°C. The analyses performed were the following: dynamic binding capacity (DBC), selectivity, and ionic capacity.

All WorkBeads™ IEX resins are fully compatible with the following conditions:

- pH 2–14
- 70% ethanol
- 1 M NaOH
- 1 M acetic acid
- 0.1% TFA
- 8 M urea
- 1 M NaCl
- 30 % acetonitrile

See more specific solution compatibilities below.

Process solutions	WB 40S	WB 100S	WB 40Q	WB 100Q	WB 40 DEAE	WB 40 TREN
40% ethanol, 0.5 M NaOH	✓	✓	✓	✓	✓	✓
25 mM Tris-HCl, 100 mM thioglycerol, pH 8.5	✓	✓	✓	✓	✓	nd
8 M urea, 100 mM citric acid, pH 2.5	✓ ¹	✓	✓	✓ ²	✓	✓
8 M urea, 100 mM citric acid, 1 M NaCl, pH 2.5	✓	✓	✓	✓	✓	nd
30% isopropanol	✓	✓	✓	✓ ²	✓	✓
1M NaCl	nd	nd	nd	nd	nd	✓
6 M guanidine hydrochloride	✓	✓ ³	✓	✓	✓	nd

¹ Slight change in selectivity

² Slightly reduced DBC

✓ No difference in performance

WB WorkBeads

nd Not determined

Storage and operational temperatures

The temperature tolerances were further tested, where selected resins were incubated at specified solutions at elevated temperatures, such as 60°C, 80°C for one week and at 121°C under high pressure for 20 minutes (autoclave condition). Oligonucleotide purifications using anion exchange resins are commonly performed at elevated temperatures, to maximize capacity values and yields due to denaturation of intramolecular structures. Therefore, WorkBeads 40Q (AIEX) was incubated in common process solutions used in oligonucleotide purifications for one week at elevated temperatures. **For all tested solutions and temperatures, $\geq 94\%$ of DBC remained, $\geq 99\%$ ionic capacity remained, and no significant selectivity change was seen.**

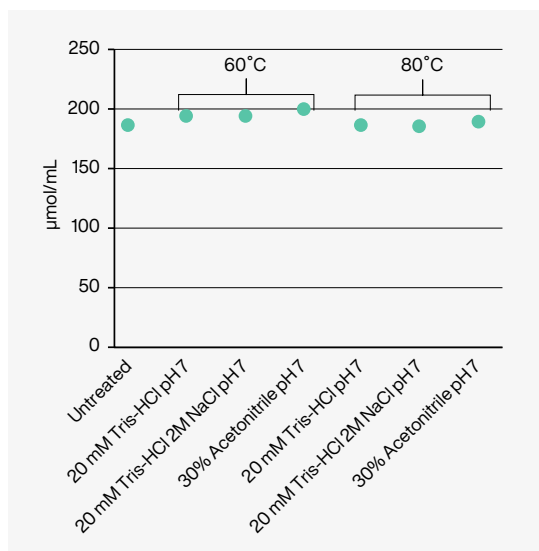


Figure 1. Temperature tolerance in different process solutions at a neutral pH for WorkBeads 40Q. Incubation of resin for 7 days at 60°C and 80°C.

Autoclavation

Autoclavation is an important parameter if sterilization is needed in the process. WorkBeads 40S, WorkBeads 40Q and WorkBeads 40 TREN were autoclaved using a standard autoclavation program (121°C at 1 bar for 20 minutes). The resins were autoclaved in a neutral buffer; WorkBeads 40S in 100 mM MES, pH 7 and WorkBeads 40Q and WorkBeads 40 TREN in 100 mM Tris-HCl, pH 7. **There was no change in performance regarding rigidity and selectivity post autoclavation indicating an extreme tolerance against high temperatures.**

- Compatible with commonly used buffers
- Tolerant to elevated temperatures
- Autoclavable

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