

Viral Clearance Strategy for POROS Hydrophobic Interaction Chromatography

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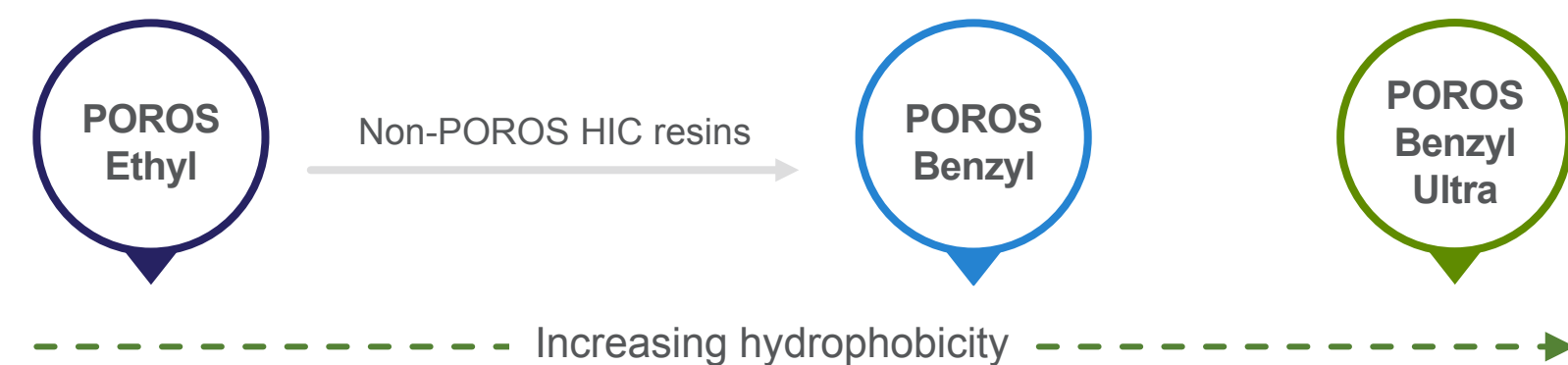
INTRODUCTION

In this study, we examined viral clearance on POROS hydrophobic interaction chromatography (HIC) resins using two designed polish steps for a clinical stage mAb. We evaluated the predictive power of a mock virus particle (MVP) that mimics Mouse Minute Virus (MMV), and also the potential of utilizing a cocktail (MMV/XmuLV) spike strategy during early phase feasibility viral clearance studies.

GOAL OF THE STUDY

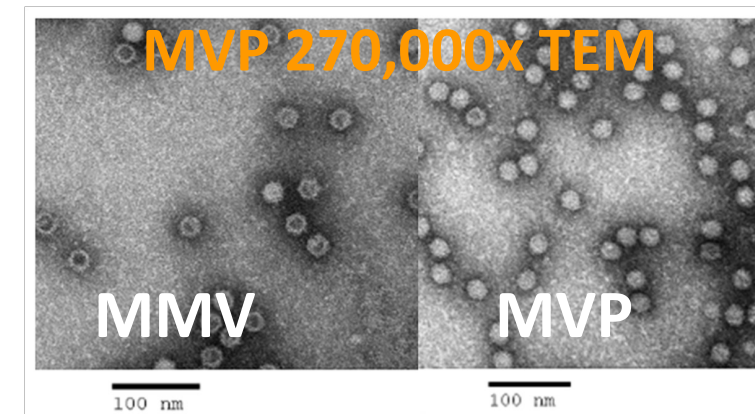
Explore viral clearance strategies for rapid and predictive process development on POROS HIC resins

POROS HIC RESINS



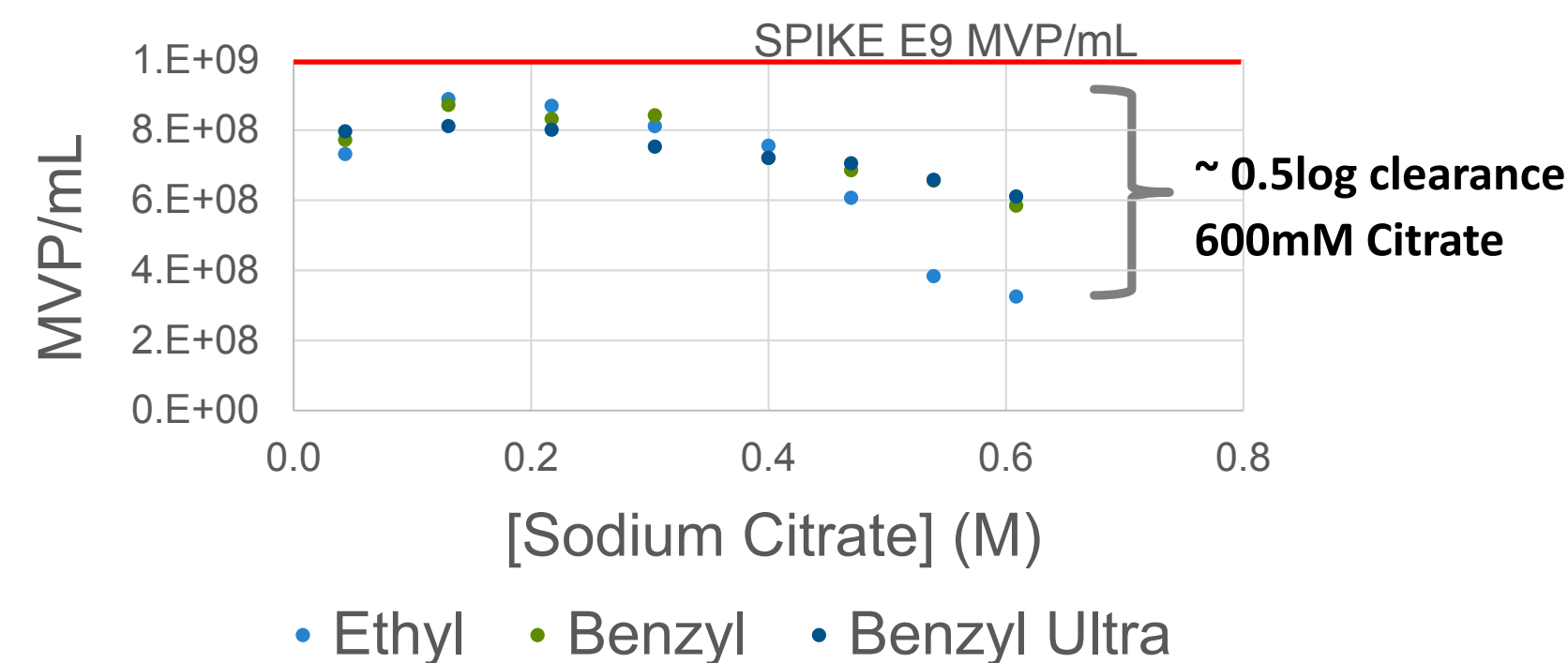
- ✓ Designed for use with lower salt concentrations
- ✓ Differentiated selectivity and ligand chemistry
- ✓ Novel 50 µm base bead
- ✓ Improved recovery, resolution and capacity
- ✓ Superior pressure-flow characteristics
- ✓ Consistent lot-to-lot performance
- ✓ Robust chemical and base stability

POROS HIC HTS Viral Clearance Study



- MVP biochemically and physically resemble MMV
- Assay: Immuno-qPCR Readout
- MVP are BSL-1 safe (Empty)

MVP binding on POROS HIC resins

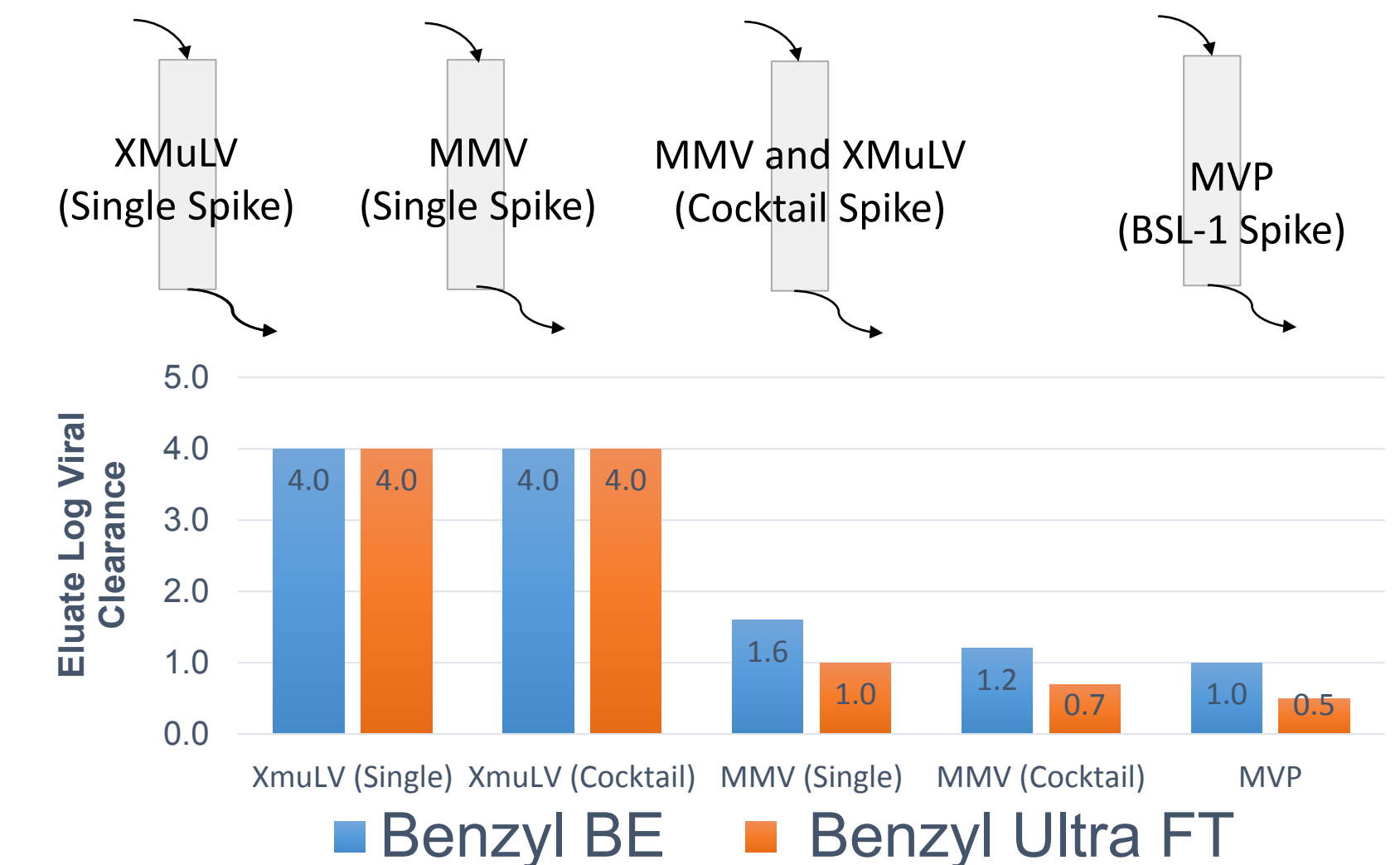


POROS HIC resins are not predicted to bind MMV even at high salt

POROS HIC Polish Design for Viral Clearance

Process Summary	POROS Benzyl Bind-Elute Mode	POROS Benzyl Ultra Flow-through Mode
Load Monomer Purity (%)	89	89
Eluate Monomer Purity (%)	>99	>99
Load Density (mg/mL resin)	32	120
Monomer Recovery (%)	>99	98
HCP (ppm)	120 to 12ppm	100 to 35 ppm
Residence time (min)	2	2
Buffers	Bind-600mM Elute-265mM Citrate	Tris pH7.0, 3mS

Cocktail MMV and XmuLV Spiking Strategy



Conclusion

- ✓ POROS HIC resins showed complete XmuLV and partial MMV viral clearance
- ✓ MVP clearance (BSL-1) could predict MMV clearance (BSL-2)
- ✓ Cocktail (MMV/XmuLV) viral spike strategy is viable and can reduce run number for viral clearance studies
- ✓ POROS HIC resins do not significantly bind MVP by HTS
- ✓ Mock-V MVP can be used in early process development to predict MMV clearance