

Guide to Method Modernization: USP <621>

With latest developments in allowable adjustments for both isocratic and gradient compendial methods of USP, Industries following USP guidelines, now can modernize the HPLC methods to address the organizational goals, faster methods for faster release, reduced extra work of revalidation of methods, reduce solvent consumption for better & safe lab environment and reduced per sample cost.



Save **45-75%*** more time



Save **40-70%*** more solvent



Go Green!
Reduce hazardous waste

How to **increase savings** while complying to USP <621>?

Follow these simple steps to save more:

Step 1

Selection of new column dimensions within allowed deviation:

L/dp



4.6 X 250 mm, 5 microns, C18*



2.1 X 75 mm, 1.9 microns, C18**

L/dp Ratio - 50000

L/dp Ratio - 39473

* Permissible L/dp range: -25% - + 50%
** Permissible L/dp range: 37500 - 75000

Step 2

Adjust The Flow Rate For New Column
 $F2 = F1 [(dc22 \times dp1)/(dc12 \times dp2)]$

mL/min

F1 = 1.5 ml/min*

F2 = 0.80 ml/min**

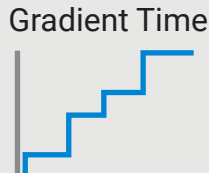
* $F2 = 1.5 \times [(2.1^2 \times 5) / (4.6^2 \times 1.9)]$
** $F2 = 1.5 \times [(22.05 / (40.20))] = 0.80 \text{ mL/min}$

Step 3

Gradient Timetable Adjustment

Original calculation:

$$tG2 = tG1 \times (F1/F2) [(L2 \times dc22)/(L1 \times dc12)]$$



Time (min)	Solution A (%)	Solution B (%)
0	100	0
10	100	0
20	0	100
25	0	100
27	100	0
35	100	0

Adjusted Time (min)	Solution A (%)	Solution B (%)
0	100	0
1.2	100	0
2.4	0	100
3.0	0	100
3.2	100	0
4.2	100	0

Tg calculation:
 $tG2 = 1 \times (1.5/0.80) [(75 \times 2.1^2)/(250 \times 4.6^2)]$
(tG1 set to '1' to determine 'gradient factor')
 $tG2 = 1 \times 1.875 [(330.75)/(5290)]$
 $tG2 = 0.12$

Step 4

Injection volume adjustment

$$V_{inj2} = V_{inj1} \times [(L2 \times dc22)/(L1 \times dc12)]$$



F1 = 1.5 ml/min



F2 = 0.80 ml/min

$V_{inj2} = 20 (75 \times 2.1^2)/(250 \times 4.6^2)$
 $V_{inj2} = 20 (331)/(5290) = 1.25 \mu\text{l}$



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Enhanced Solution for method modernization keeping backward compatibility intact:

InfinityLab Parts and Columns

1220 Infinity II Binary LP 600 bar

1260 Infinity II Quaternary 600 bar

1260 Infinity II Prime LC 800 bar (ISET enabled)

Backward Compatible - Future Upgradable

*Depending upon the column ID, flow rate & run time of modernized method