

Impact of PCS #54414 on USP Resolution Calculations in Empower

PCS #54414 applies to those using Empower 2 Feature Release 5 (FR5) up to and including Empower 3 Service Release 2 (SR2) Hotfix 2. This defect has been fixed in Empower 3 FR3.

Description of defect

When selecting **US Pharmacopoeia** in the Suitability tab of the processing method (see Figure 1), Empower may incorrectly calculate USP Resolution. When incorrect, Empower uses the Width @ Tangent (USP Resolution) value from the previous peak in place of the value for the peak of interest.

This problem only occurs when using the Traditional integration algorithm.

The problem may also occur when using ApexTrack integration and performing manual integration. This is because for some manual integration cases, the individual peak may revert to traditional methods of determining peak width. Refer to [TECN134899112](#) – Resolution Values in Empower 3, for more details. The presence of the I37 processing code and the absence of the S29 Processing code may indicate an incorrect USP Resolution value for the specific manually integrated peak. Other peaks in the chromatogram may be calculated correctly.

This defect should not exist when selecting **All** as the **Pharmacopoeia** choice in the processing method. It also does not manifest if using the ApexTrack integration algorithm, provided there is no manual integration, even if you select **US Pharmacopoeia** in the processing method.

Reprocessing suspect data using **All** as the **Pharmacopoeia** choice in the processing method will calculate the USP Resolution values correctly.

NOTE: This defect has no effect on the calculation of Relative Resolution, USP Resolution (HH) or Resolution.

Figure 1 shows an example of a chromatogram with an incorrect result. This result was processed using **US Pharmacopoeia** as the Suitability selection instead of **All**.

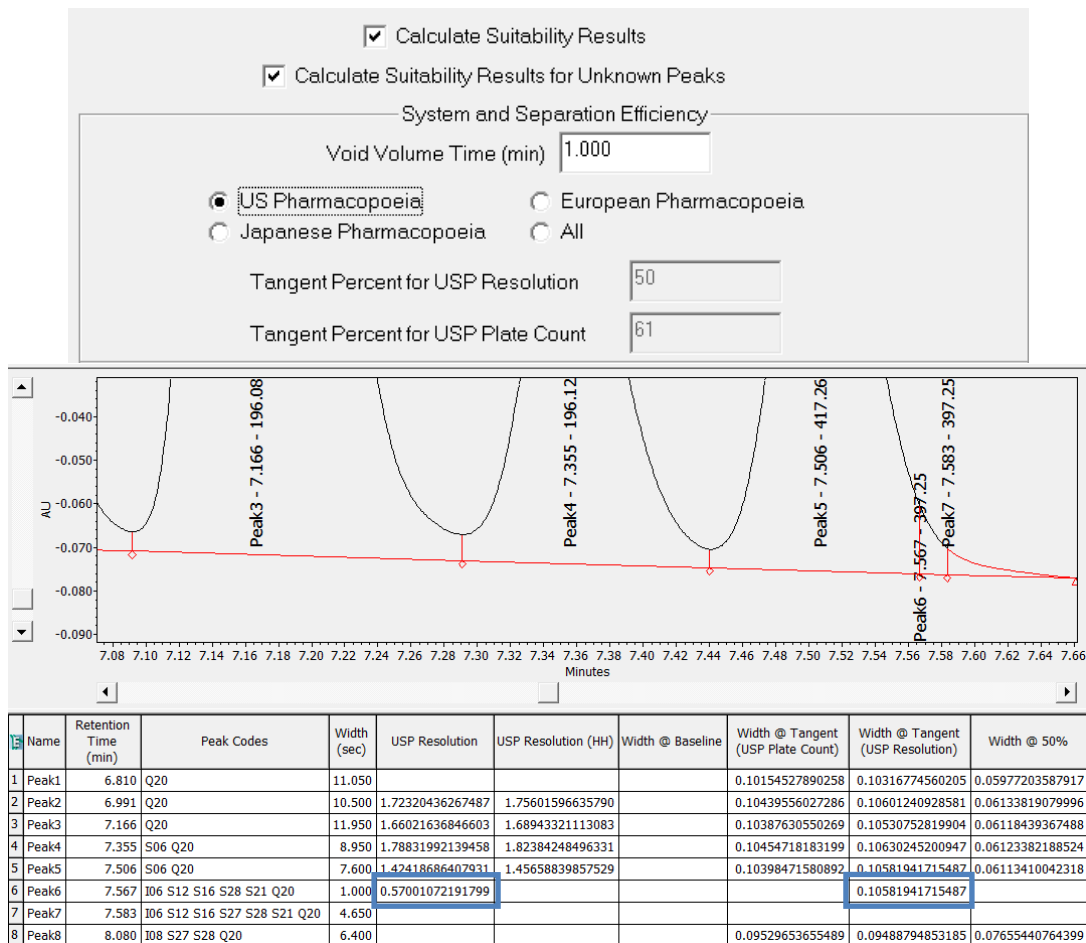


Figure 1 –US Pharmacopoeia selected with Traditional integration

In this example, Peak6 and Peak7 were inserted as manually integrated peaks. Thus, even if ApexTrack was initially used, both peaks would still be integrated using Traditional integration.

The incorrectly calculated USP Resolution value and a misrepresented calculated Width @ Tangent value are highlighted in blue.

Figure 2 shows the same chromatogram as Figure 1 but with **All** selected as the Suitability selection instead of **US Pharmacopoeia**. This created correctly-reported Suitability results.

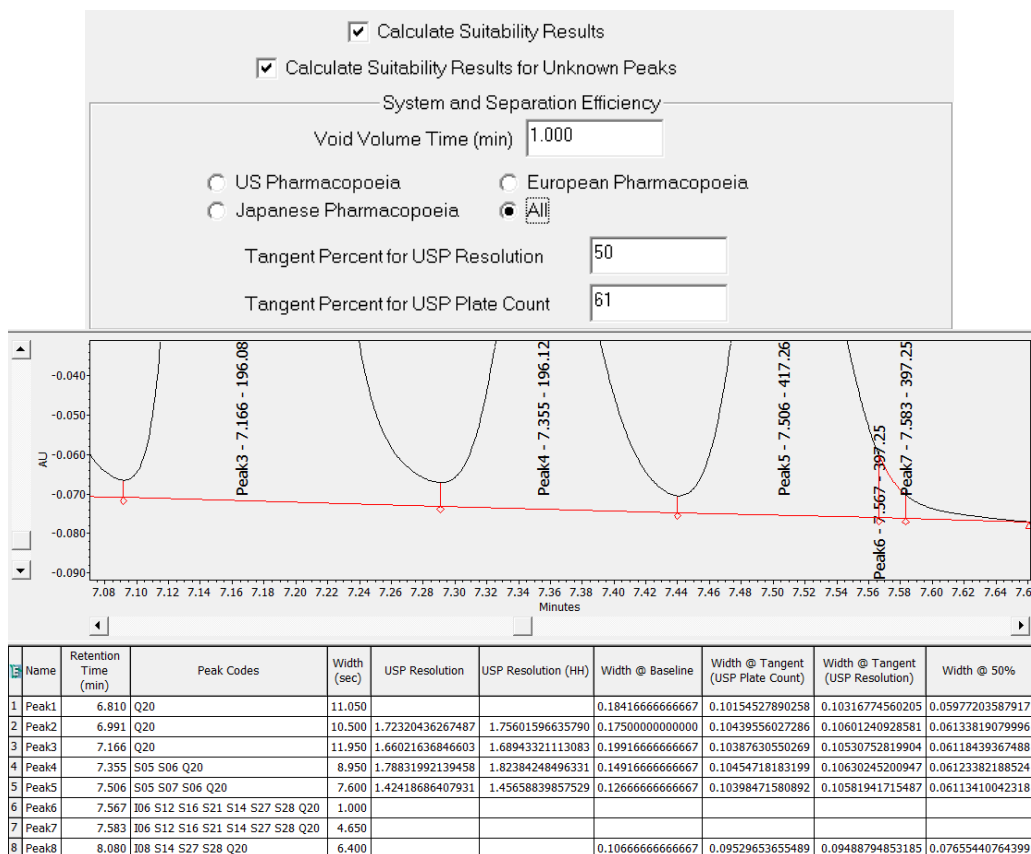


Figure 2 – All selected as the Suitability selection using Traditional integration

Note that there is no USP Resolution value reported for Peak6 in Figure 2. This is due to the fact that Peak6 does not have a way to determine the Width @ Tangent value, whether Traditional or ApexTrack integration is used.

Table 1 illustrates when USP Resolution may be incorrectly calculated for a peak when using Empower 2 FR5 through Empower 3 SR2 Hotfix 2.

Table 1 – Impact of PCS #54414 on USP Resolution Calculations for a Peak

	Traditional integration	ApexTrack integration without manual integration	ApexTrack with manual integration (presence of S29 and absence of I37 Processing Codes)	ApexTrack with manual integration (presence of I37 and absence of S29 Processing Codes)
All Selected	Correct	Correct	Correct	Correct
USP Selected	May be Incorrect	Correct	Correct	May be Incorrect

An alternative tool to determine the potential impact of the defect is seen in Figure 3 below. Potentially impacted results are highlighted in orange.

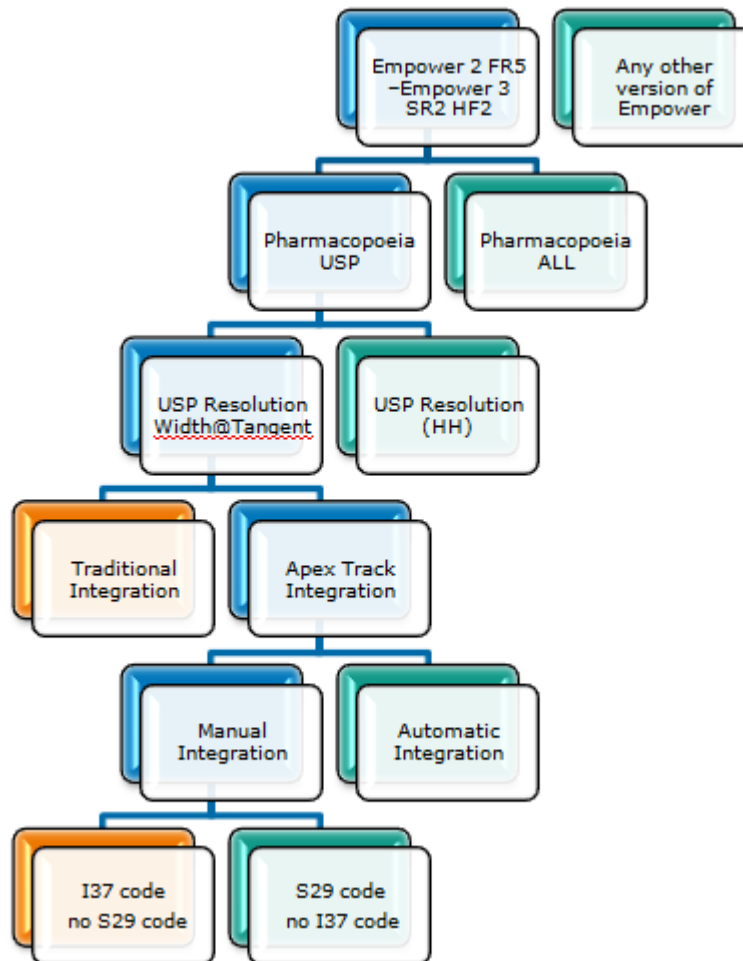


Figure 3 – Impact of PCS #54414 on USP Resolution calculations for a peak

How to fix this issue for impacted results

Results that were impacted by PCS #54414 can be reprocessed to obtain correct USP Resolution calculations, even if using Empower 2 FR5 through Empower 3 SR2 HF2.

Follow these steps to generate new results that are not impacted by this defect:

1. Modify and save the processing method. Select **All** as the Pharmacopoeia choice in the Suitability tab (Figure 4).
2. Reprocess the data (manually integrate as necessary) to have Empower calculate and report USP Resolution values correctly.
3. Review the new results.

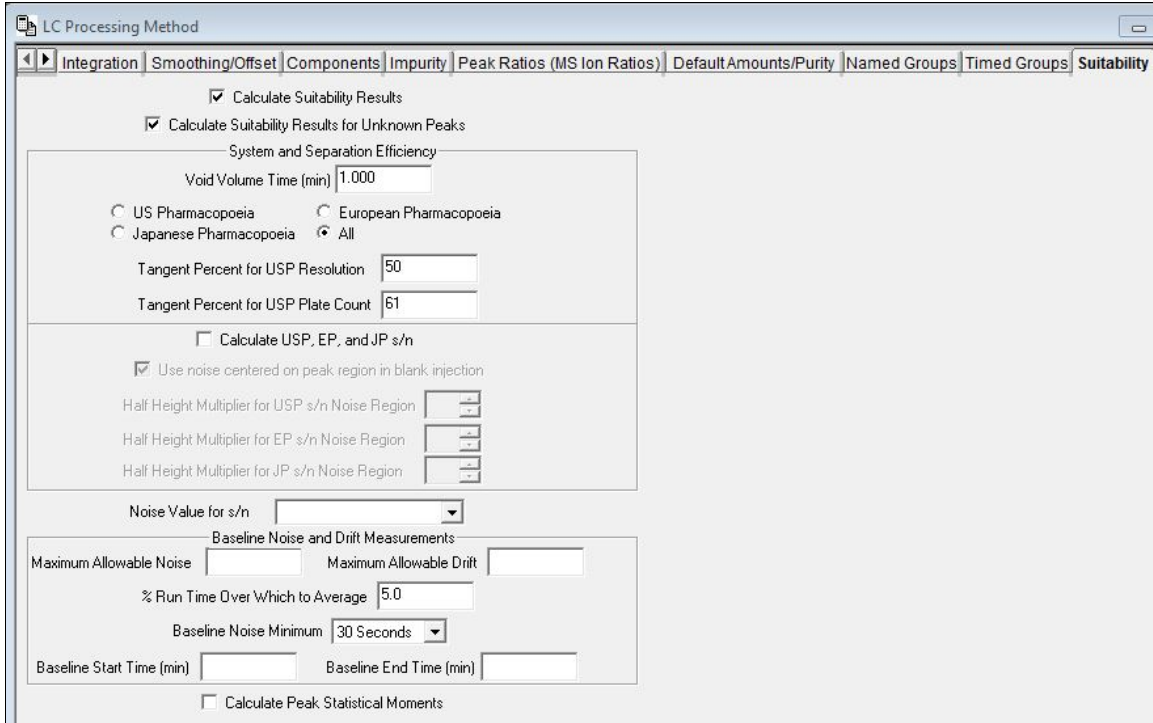


Figure 4 – Selecting All in the Suitability tab to generate correct USP Resolution values

NOTE: If the USP Resolution values in the reprocessed results match the original values then the defect did not impact your Suitability results. Therefore, the original results were valid.