Agilent Dissolution Systems

Frequently Asked Questions

Dissolution Applications:
Filters

Q: How do I choose an appropriate dissolution filter?

A: When choosing a dissolution filter, screen and validate one or more filters for the following three parameters to make sure that they are fit for use. Filters need to be validated for each new dosage form test, and there is not one filter which works for all dosage forms.

- Efficiency
- Leachability
- Adsorbance

Q: How do I choose an appropriate dissolution filter?

Filter Efficiency – the ability of the filter to remove all undissolved drug from a sample.

- If a filter is not efficient, undissolved drug can pass through the filter and dissolve in the collected sample leading to higher and more variable results.
- A good way to check efficiency is to take a sample with the filter and separate that sample into three separate aliquots.
  - First aliquot - analyze immediately
  - Second aliquot - can be shaken or mixed for 5 minutes
  - Third aliquot – shaken or mixed for 10 minutes

If <1% difference is seen among the three aliquots then the filter can be considered to be efficient.

Q: How do I choose an appropriate dissolution filter?

Leachability - a check to ensure the filter does not leach or release a compound that could interfere with the analysis of the active drug sample.

- Tested by filtering a sample of the blank dissolution media and analyzing it. If no peak is observed or a peak of <1% of the standard absorbance, then the filter is acceptable.
- If leaching >1% is seen, the filter may still be acceptable, but a pre-rinse or purge of the first few mL may be needed to get the peak below the 1% threshold. If a wash or discarded amount is needed to achieve this, it must be validated and documented in the SOP.

Q: How do I choose an appropriate dissolution filter?

Adsorbance – Adsorbance is a property of filters where some of the dissolved drug will bind to the filter rather than pass through into the sample. A filter should be checked to ensure it does not bind more than 1-2% of the drug to allow for representative results. Filtered standard should be compared to unfiltered standard to determine the level of adsorbance

Adsorbance:

- Reduces the drug in the solution
- Artificially lowers results

Q: How do I choose an appropriate dissolution filter?

Adsorbance

- As the sample is pushed through the filter and discarded, the drug will bind onto the active sites in the filter and eventually the majority of these sites will be bound, making a representative sample possible.
- To verify, take a 10 mL sample, dispense in 1 mL increments into different vials, and then analyze them.
- Once 98-99% recovery as compared to the unfiltered standard is reached, the acceptable adsorbance is reached.
- The amount which needs to be purged in order to reach acceptable adsorbance must be recorded into the SOP.

Aliquot	% Recovery
1st mL	94%
2nd mL	96%
3rd mL	98%
4th mL	99%
5th mL	99%