PROTOCOL FOR INITIAL LRA® EVALUATION

LRA (lipid removal agent) is a patented synthetic mineral that has a unique affinity for lipid, lipoprotein and endotoxin. It is a filterable alternative to fumed silica.

The efficiency with respect to time that it takes for the LRA™ to interact with lipid or other molecules is dependent on the characteristics of the particular starting material. As a result, it is generally recommended that an initial sample test be performed after 1 to 2 hours of contact time and another sample be allowed overnight contact. This will give an indication of how long the LRA™ needs to be in contact with the fluid and whether additional contact time results in greater binding or, conversely, that lesser contact time results in increased process throughput.

Objective: To determine from an initial screening test, if LRA™ can remove lipid or other impurities from a biological fluid.

Test Method:

1. Prepare two 10-mL aliquots of the test fluid into a centrifuge tube.

2. Add 0.4-g of LRA to each sample.

3. Gently agitate both samples at process temperature.

4. After 1 to 2 hours, centrifuge one of the samples.

5. Test the supernatant for lipid depletion* and retention of product of interest.

6. Allow the other sample to agitate overnight.

7. Centrifuge the overnight sample, and test the supernatant for lipid depletion* and retention of product of interest.

* If you do not have a standard test method to detect a specific lipid or other impurity, several indirect methods for evaluation are suggested. A simple procedure involves challenging the centrifuged liquid through a 0.2-µm syringe filter. If liquid passes though the filter with little resistance, lipid has been potentially depleted. A second method involves comparing the absorbance (e.g. OD600 nm) of the starting material to the supernatant. A significant reduction in absorbance should correlate with removal of haze (lipid or other impurity).