

Excipient Analysis & Quality Control



Why excipient analysis?

Common excipient-related challenges include batch-to-batch variability, reactivity with other compounds in the formulation, and limited information on the CoA. Together, these factors can make it difficult to control product performance, stability, quality, and safety.

We use our experience, proprietary expertise, and facilities to help customers address these challenges, solve development issues, and reduce risk during development.

Excipient testing services

Understanding the following product characteristics helps control and improve product performance:

- Molecular weight distribution before and after hydrolysis
- Monomer ratio
- Substituent distribution and reactivity
- Degree of substitution
- Impurities, residual monomer, and sugars
- Reducing power/reactivity
- End-group quantity



Experts in Excipient Analysis

Using our proprietary methods and 25+ years of expertise, we can quantify, qualify, and grade the following excipients:

- Monosaccharides (glucose, galactose, mannitol, sorbitol, fructose, etc.)
- Disaccharides (sucrose, lactose, maltose, etc.)
- Polysaccharides (cellulose, hemicellulose, starch, chitosan, etc.)
- Cellulose and starch derivatives (CMC, HPC, HPMC, MC, HPMC-AS, EC, SSG, etc.)
- Polymers (PEO, PEG, PVP, poloxamers, carbomers, gelatine, xanthan gum, polyvinyl alcohol, etc.)
- Polysorbates and other surfactants, fatty acids, glycerides, organic acids, alcohols, glycols, oils, etc.

When to use excipient analysis:

- **Change control and risk reduction:** Understand composition and risks when materials, processes, sites, or suppliers change.
- **Troubleshooting:** Investigate performance or stability issues, variability, or manufacturability constraints
- **Product improvement:** Improve product stability, reduce variability, and improve manufacturability constraints.

Our excipient services go beyond simple identification!

We do not just provide analytical results; we provide context and interpretation to support decision-making during development.