

Excipients used in Monoclonal Antibody (mAb) manufacturing

USP offers the following reference standards for excipients used in the mAb manufacturing process or present in mAb formulations. Pharmaceutical excipients are substances other than the active pharmaceutical ingredient (API) that have been appropriately evaluated for safety and are intentionally included in a drug delivery system.

Citric acid	<u>Mannitol</u>
Dextrose	Monosodium glutamate
Glacial acetic acid	Pentetic acid
Glutamic Acid	Polysorbate 20
Glycine	Polysorbate 80
<u>L-Histidine</u>	Sodium acetate trihydrate
L-Histidine monohydrochloride monohydrate	Sodium chloride
L-Lysine hydrochloride	Sodium citrate
L-Methionine	<u>Sorbitol</u>
L-Phenylalanine	Sucrose
<u>L-Threonine</u>	<u>Trehalose</u>

Effective: 03 AUG 2023

Please visit our site for all available excipients.