

# COMMERCIAL PRODUCTS LIST

## **Product Categories:**

- Bulk, GMP Biological Buffers & Denaturants
- GMP Process Chemicals & Solutions
- Excipients & Key Ingredients
- GMP Custom Products
- Active Substances



**Exclusively Manufactured in the USA** 

#### **Product Grade**

Commercial Products	Bio Pharma	Bio Excipient	Bio Active	LBLE* Active/Excipient
Galactose				Х
Guanidine HCl (also 6M Solution)	X	Х		Х
Guanidine Thiocyanate	X	Х		Х
HEPES Free Acid	X	Х		
L-Cystine Dihydrochloride		Х		
MES Monohydrate	X	Х		
MOPS Free Acid	X	Х		
Potassium Bromide (KBr)			Х	
Sodium Hydroxide 10N <5 ppm Cl	X			
Sucrose				Х
Trehalose				Х
TRIS HCI	X	Х		X
TRIS/Tromethamine	X	Х	Х	Х
Uracil	X			
Urea	X	Х	Х	Х

LBLE\* = Low Bioburden Low Endotoxin, non-sterile products for further use in parenteral manufacturing

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#### **Custom Products & Services:**

- GMP Compounded Solvents & Solutions
- API Development & Manufacturing
- Small Molecule Custom Synthesis
- Full GMP Product Development
- Purification of Key Ingredients

### **Custom Capabilities**

- State-of-the-art Instrumentation & Laboratories
- Global GMP Requirements US, IPEC, ICH Q7
- FDA & ICH Q7 Guidance for Drug Substances
- Document Support DMF Submissions
- FDA Registered and Inspected



