

# PDG General chapters

## Pilot Phase

Tablet Friability  
Optical Microscopy

Implementation  
1<sup>st</sup> December 2022

## Phase I

Particulate Contamination  
Analytical Sieving  
Laser Diffraction Measurement of Particle Size  
X-Ray Powder Diffraction  
Chromatography  
Peptide Mapping

Implementation  
December 2024

## Phase II

Dissolution  
Disintegration  
Uniformity of Uniformity of Content/Mass  
Color (Instrumental method)  
Residue on Ignition  
Bulk Density and Tapped Density  
Conductivity  
Powder Fineness  
Water-solid Interaction  
Amino Acid determination  
Capillary Electrophoresis

Implementation  
December 2026

## Phase III

Tests for Specified Microorganism  
Microbial Enumeration  
Limits for Non-sterile Products  
Bacterial Endotoxins  
Extractable Volume  
Sterility Test  
Gas Pycnometric Density of Solids  
Powder Flow  
Specific Surface Area  
Thermal Analysis  
Isoelectric Focusing  
Polyacrylamide Gel Electrophoresis

Implementation  
December 2028



# PDG Excipient Monographs

## Phase I

Alcohol  
Dehydrated Alcohol  
Benzyl Alcohol  
Croscarmellose Sodium  
Lactose, Anhydrous  
Ethyl Paraben  
Propyl Paraben

Implementation  
December 2024

## Phase II

Calcium Disodium Edetate  
Calcium Phosphate Dibasic  
Calcium Phosphate Dibasic Anhydrous  
Carmellose Calcium  
Cellulose, Microcrystalline  
Crospovidone  
Ethylcellulose  
Hydroxyethylcellulose  
Hydroxypropylcellulose  
Hydroxypropylcellulose, Low Substituted  
Lactose, Monohydrate  
Magnesium Stearate  
Methyl Paraben

Implementation  
December 2026

## Phase III

Cellulose, Powdered  
Cellulose Acetate Phthalate  
Citric Acid, Anhydrous  
Citric Acid, Monohydrate  
**Hypromellose**  
**Hypromellose Phthalate**  
Methylcellulose  
Methyl Paraben  
Petrolatum  
White Petrolatum  
Polysorbate 80  
Povidone

Implementation  
December 2028

