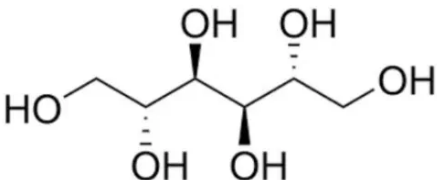
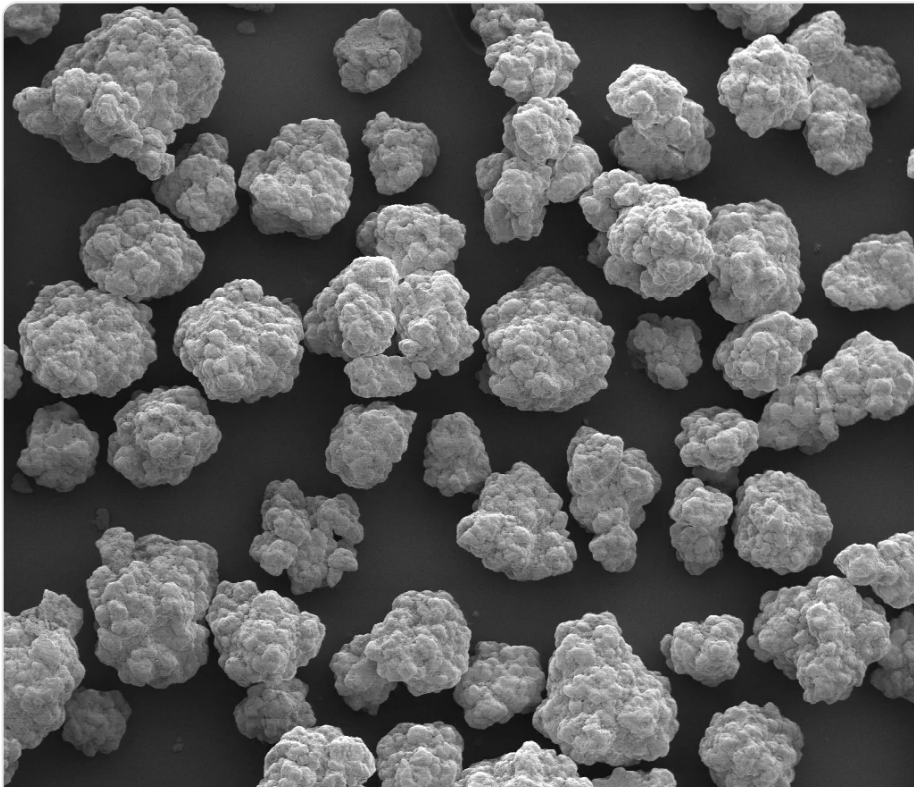
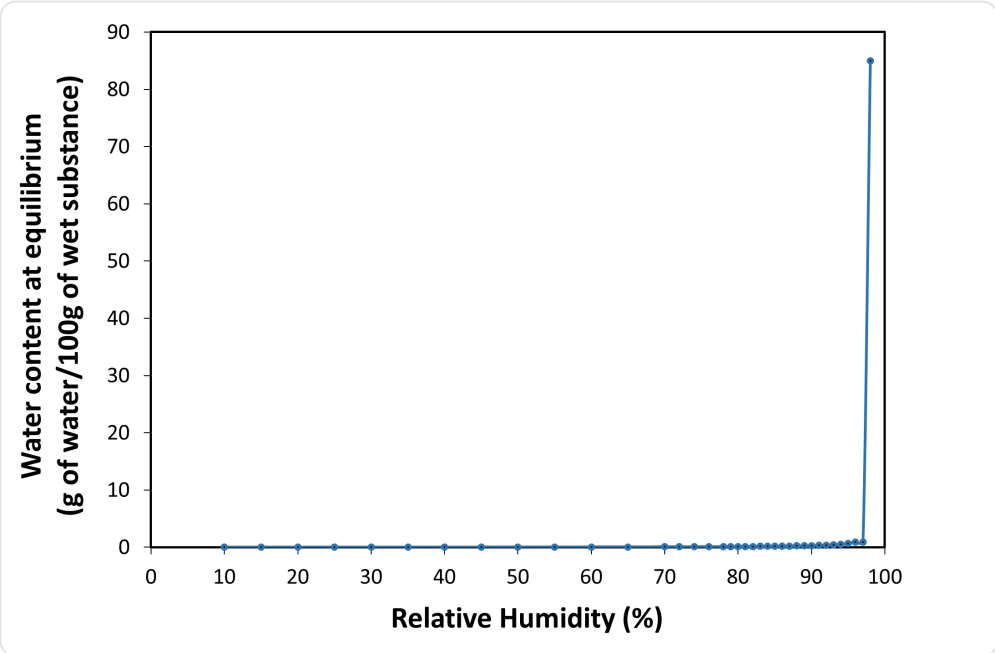
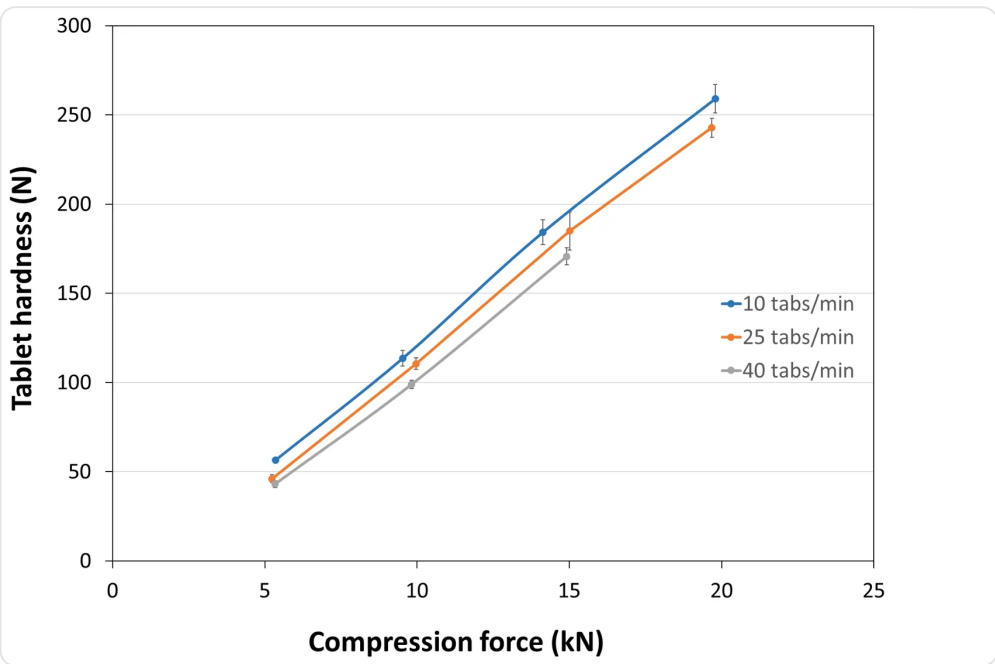


Product Name	PEARLITOL® 200 GT
Generic Name	Mannitol Directly Compressible
Physico-chemical properties	
Compliance	EP/USP-NF/JP/CHP
Synonyms	D-Mannitol
CAS Number	69-65-8
Chemical Structure	 <chem>OC[C@H](O)[C@H](O)[C@@H](O)[C@@H](O)CO</chem>
Average Molecular Weight	182.2 g/mol
Physical Form or Appearance	White or almost white crystalline powder
Application	<p>PEARLITOL® 200 GT mannitol is a direct compression excipient, specially designed to avoid capping, improve flowability and tabletability. It is a granulated form of mannitol with exceptional physical and chemical stability. It offers high API compatibility and no hygroscopicity. It is also a non-cariogenic and non-acidogenic sugar-free sweetener. It is suitable in formulations addressing all types of patient populations including pediatric and diabetic. It can be used in tablets (lozenges, swallowable tablets, orally dispersible tablets, chewable tablets, and effervescent tablets) and in powder blends (sachets, oral stick pack and hard gelatin capsules filling).</p>
Water content (LOD)	Water Content (LOD) Maximum: 0.5 %
Morphology	 <p>Det HV Spot Mag WD Pressure ETD 1.0 kV 3.0 100x 9.9 mm ---</p> <p>500.0 μm ROQUETTE - DAPF</p>
Average mean	160 μm

particle diameter	
Particle Size Distribution by Laser Diffraction	dv10: 90 µm dv50: 150 µm dv90: 260 µm
Solubility	Freely soluble in water (1 part in 5.5 part of water at 20°C), sparingly soluble in 95% ethanol (1 part in 83), practically insoluble in ether
Melting temperature	Minimum melting temperature : 165 °C Maximum melting temperature: 170 °C
Water sorption isotherm at 20°C	 <p>The graph displays the water sorption isotherm at 20°C. The y-axis represents 'Water content at equilibrium (g of water/100g of wet substance)' ranging from 0 to 90. The x-axis represents 'Relative Humidity (%)' ranging from 0 to 100. The data points show a very low water content (near 0 g/100g) for relative humidity up to approximately 95%, followed by a sharp, nearly vertical increase to about 85 g/100g at 100% relative humidity.</p>
Taste/Odor	Slightly sweet and cooling effect.
Tablet hardness	 <p>The graph shows the relationship between compression force and tablet hardness for three different production speeds. The y-axis is 'Tablet hardness (N)' from 0 to 300, and the x-axis is 'Compression force (kN)' from 0 to 25. Three data series are plotted: 10 tabs/min (blue line with circles), 25 tabs/min (orange line with circles), and 40 tabs/min (grey line with circles). All three series show a linear increase in hardness with increasing compression force. The 10 tabs/min series consistently shows the highest hardness values, followed by 25 tabs/min, and then 40 tabs/min.</p>
Experimental Conditions for Compression Behavior	<p>Tablet Press: STYLONE EVO</p> <p>Production Speed: 10, 25 and 40 tablets/min (respective linear punch velocity: 38, 96 and 152 mm/s ; respective simulated rotary press speed: 60000, 150000 and 240000 tablets/hour)</p> <p>Tooling: Diameter 10 mm R9 concave</p> <p>Formula: 98.8% PEARLITOL® 200 GT / 1.2% magnesium stearate</p> <p>Tablet Mass: 400 mg</p>
Powder Characteristics	<p>Powder Flowability (according to Ph.Eur. 2.9.16, 10mm outflow opening): 4s</p> <p>Bulk Density: 0.63 g/cm³</p>

Tapped Density: 0.75 g/cm³
True Density: 1.514 g/cm³
Specific surface area: 1.3 m²/g
Angle of Repose: 27 °

Disclaimer

These typical values are provided for information only and we believe them to be reliable. Methods available upon request.