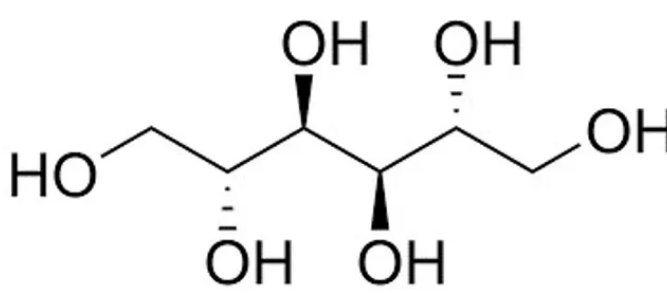
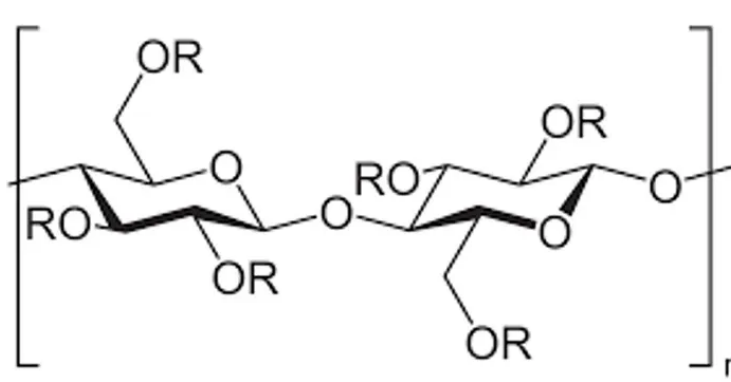
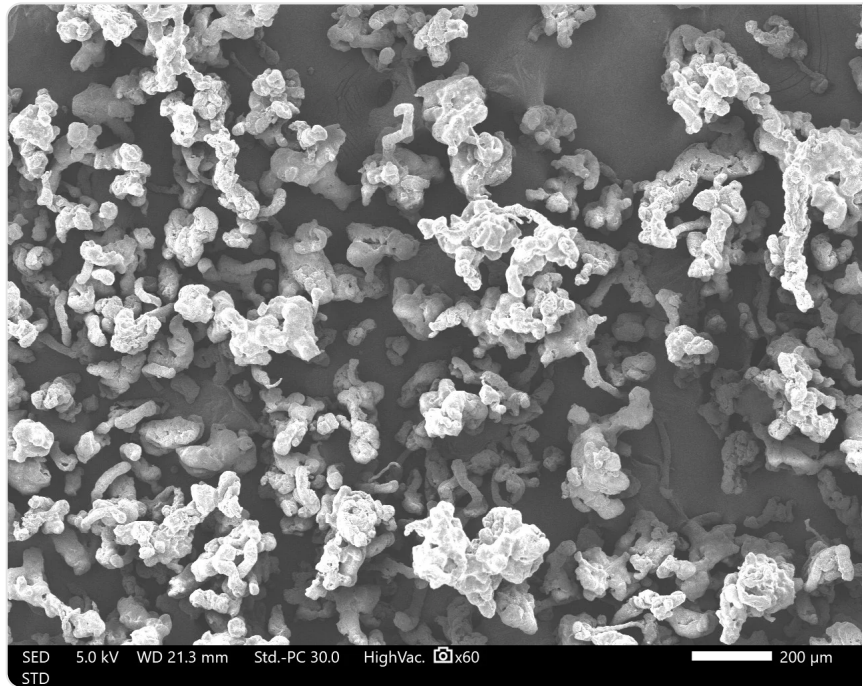


Product Name	PEARLITOL® CR-H
Generic Name	Co-processed Mannitol HPMC
Physico-chemical properties	
Compliance	EP/USP-NF/JP/CHP
Synonyms	D-Mannitol-Hydroxypropyl methylcellulose, HPMC
Composition	D-Mannitol 30%-HPMC K4M 70%
CAS Number	D-Mannitol 69-65-8 Hypromellose 9004-65-3
Chemical Structure	<div style="text-align: center;"> <p>Mannitol</p>  <p>Hydroxypropyl methylcellulose</p>  <p>$R = -H, -CH_3, -CH_2-CHOH-CH_3$</p> </div>
Average Molecular Weight	Mannitol: 182.2 g/mol
Physical Form or Appearance	White to yellowish-white, powder or granules
Application	PEARLITOL® CR-H co-processed mannitol HPMC is a direct compression excipient providing functional properties of binder as well as controlled release to your tablet. PEARLITOL® CR-H can be used in both pharmaceutical and nutraceutical oral dosage forms.
Water content (LOD)	Water Content (LOD) Maximum: 4 %

Morphology



Average mean particle diameter

150 µm

Particle Size Distribution by Laser Diffraction

dv10: 60 µm
dv50: 140 µm
dv90: 290 µm

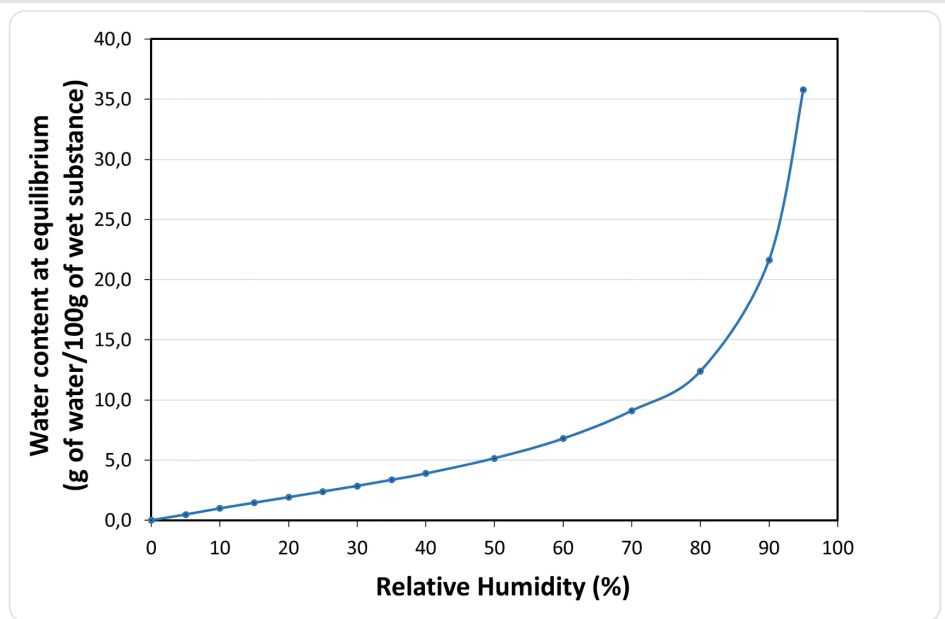
Solubility

Partially soluble in cold water.

Melting temperature

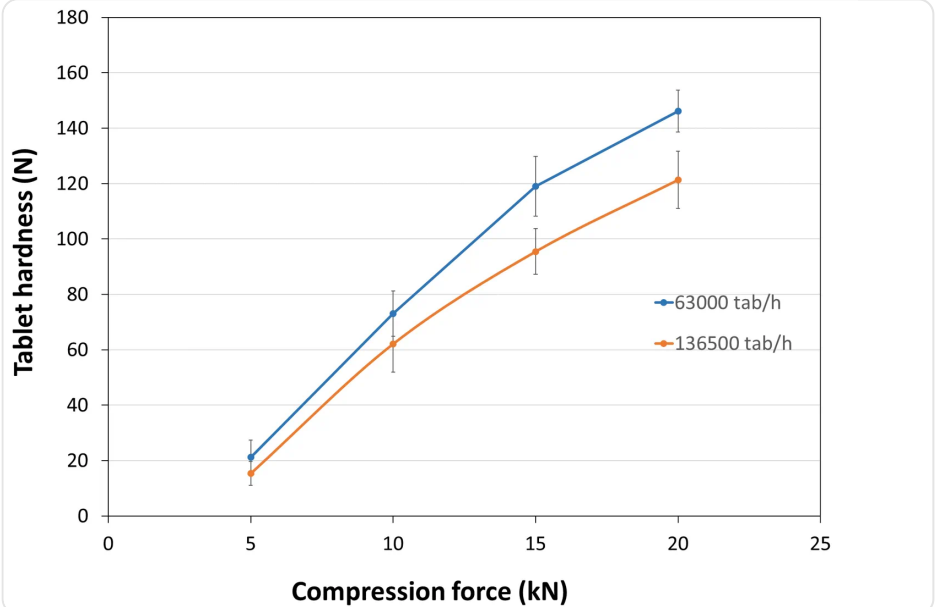
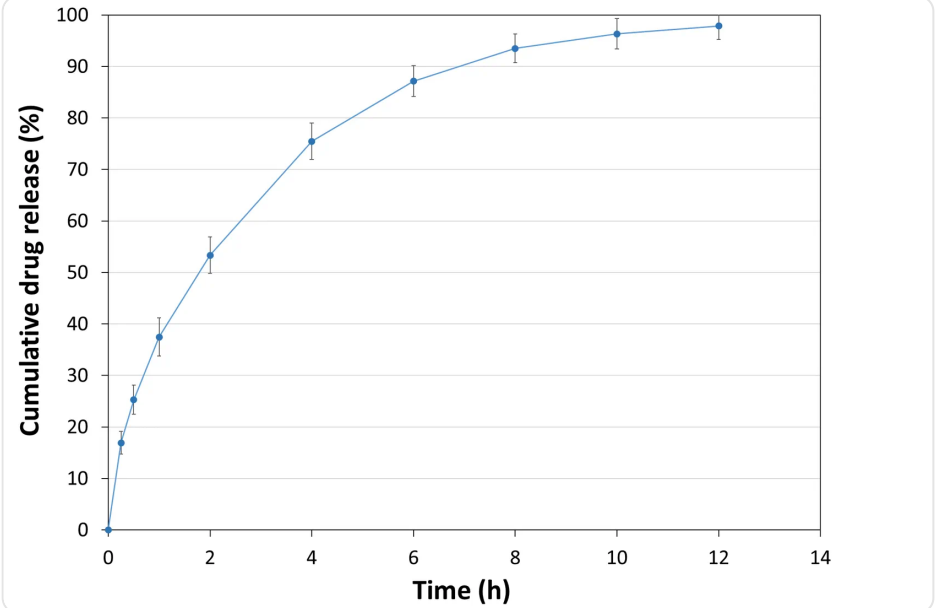
Minimum melting temperature : Mannitol: 165 °C
Maximum melting temperature: Mannitol: 170 °C

Water sorption isotherm at 20°C



Taste/Odor

Neutral taste, slightly sweet

<p>Tablet hardness</p>	 <table border="1"> <caption>Tablet Hardness Data</caption> <thead> <tr> <th>Compression force (kN)</th> <th>63000 tab/h (N)</th> <th>136500 tab/h (N)</th> </tr> </thead> <tbody> <tr> <td>5</td> <td>~22</td> <td>~18</td> </tr> <tr> <td>10</td> <td>~75</td> <td>~62</td> </tr> <tr> <td>15</td> <td>~118</td> <td>~95</td> </tr> <tr> <td>20</td> <td>~148</td> <td>~122</td> </tr> </tbody> </table>	Compression force (kN)	63000 tab/h (N)	136500 tab/h (N)	5	~22	~18	10	~75	~62	15	~118	~95	20	~148	~122							
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<p>Experimental Conditions for Compression Behavior</p>	<p>Tablet Press: STYL'ONE EVO Production Speed: 30 and 65 RPM (linear punch velocity: 49 and 91 mm/s; simulated KORSCH XL-400 rotary press speed: 63,000 and 13,6500 tablets/hour) Tooling: Diameter 13 mm flat Formula: PEARLITOL® CR-H / external lubrication with magnesium stearate Tablet Mass: 400 mg</p>																						
<p>Powder Characteristics</p>	<p>Powder Flowability (according to Ph.Eur. 2.9.16, 10mm outflow opening): 12 s Bulk Density: 0.34 g/cm³ Tapped Density: 0.43 g/cm³ True Density: 1.456 g/cm³ Specific surface area: 0.8 m²/g</p>																						
<p>API release kinetics</p>	 <table border="1"> <caption>API Release Kinetics Data</caption> <thead> <tr> <th>Time (h)</th> <th>Cumulative drug release (%)</th> </tr> </thead> <tbody> <tr> <td>0</td> <td>0</td> </tr> <tr> <td>0.5</td> <td>~18</td> </tr> <tr> <td>1</td> <td>~28</td> </tr> <tr> <td>1.5</td> <td>~38</td> </tr> <tr> <td>2</td> <td>~53</td> </tr> <tr> <td>4</td> <td>~75</td> </tr> <tr> <td>6</td> <td>~88</td> </tr> <tr> <td>8</td> <td>~94</td> </tr> <tr> <td>10</td> <td>~96</td> </tr> <tr> <td>12</td> <td>~98</td> </tr> </tbody> </table>	Time (h)	Cumulative drug release (%)	0	0	0.5	~18	1	~28	1.5	~38	2	~53	4	~75	6	~88	8	~94	10	~96	12	~98
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12	~98																						
<p>Experimental conditions for sustained release behaviour</p>	<p>Tablet press: STYL'ONE EVO Production speed: 30 RPM (linear punch velocity: 49 mm/s; simulated KORSCH XL-400 rotary press speed: 63,000 tablets/hour) Tooling: Diameter 13 mm flat Formula: 50% Metformin / 49% PEARLITOL® CR-H / 1% magnesium stearate Tablet mass: 1,000 mg Tablet hardness: 109 N Tablet thickness: 6.8 mm Dissolution bath: USP II with helical sinker</p>																						

Disclaimer

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