CHOOSING THE RIGHT SHELL EXCIPIENT TO MEET FUTURE CAPSULE CHALLENGES

Excipients play a key role in the formulation and performance of pharmaceutical hard and soft capsules.

THE MOST COMMON EXCIPIENTS INCLUDE:

GELATIN
Derived from natural animal sources

HPMC
HYDROXYPROPYL METHYLCELLULOSE
• Obtained from shredded trees
• Etherified with chemicals methyl chloride and propylene oxide
• Chemically modified cellulose polymer

PULLULAN
Obtained from the biotechnological fermentation of hydrolyzed starch by the action of the fungus A. pullulans

MODIFIED (HYDROXYPROPYL) STARCH
Corn crops, etherified with hydroxypropyl groups

GELATIN IS THE PREFERRED EXCIPIENT OF CHOICE, accounting for the highest revenue of the hard and soft capsule market in 2019 (estimates)

IT WAS EVEN USED IN THE FIRST EVER PRODUCTION OF CAPSULES

GELATIN 1834
HPMC 1990
PULLULAN LATE 1990'S
Gelatin is a safe ingredient of natural origin
• Does not contain additives
• Facilitates free-from claims
• Non-allergenic
• Fully digestible and compatible
• Neutral in flavor and color

DID YOU KNOW?
HPMC, pullulan, and modified starch capsules are all additives and are therefore classed as e-numbers

SUPERIOR TECHNICAL PERFORMANCE
Gelatin provides functional properties for immediate release designing and optimal formulation stability
9.25 the average time it takes for a gelatin capsule to rupture
27.25 the average time it takes for a modified starch-based capsule to rupture

OPERATIONAL EFFECTIVENESS
Gelatin has a number of manufacturing advantages over alternatives such as HPMC, pullulan and modified starch:
• High level of machinability
• Proven manufacturing technology
• Greatest cost efficiency
40% less raw material is required to manufacture gelatin capsules than HPMC alternatives

MOST RELIABLE WEIGHT STABILITY PROFILE
Average weight variation measured:

<table>
<thead>
<tr>
<th>Gelatin HC (size 1)</th>
<th>HPMC HC (size 1)</th>
<th>Pullulan HC (size 1)</th>
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<tbody>
<tr>
<td>RSD (%)</td>
<td>1.7</td>
<td>3.0</td>
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<tr>
<td></td>
<td>2.2</td>
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DID YOU KNOW?
There are 5 global gelatin manufacturers and many local players, which ensure the continued supply of consistent gelatin. This compares with only a few pharmaceutical grade HPMC, pullulan and modified starch suppliers

Rousselot is the worldwide leader in pharmaceutical gelatins

References available upon request

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