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

HYDROXYPROPYL METHYLCELLULOSE (HPMC)

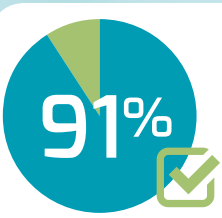
- Obtained from shredded trees
- Etherified with chemicals methyl chloride and propylene oxide
- Chemically modified cellulose polymer

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[1] (estimates)

IT WAS EVEN USED IN THE FIRST EVER PRODUCTION OF CAPSULES

GELATIN	HPMC	PULLULAN
1834	1990	LATE 1990'S

Reaching Further Together

Rousselot

DARLING INGREDIENTS

1 CLEAR LABEL

1

Number one trend in 2017 by Innova Market Insights

- 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**

2 SUPERIOR TECHNICAL PERFORMANCE

Gelatin provides functional properties for immediate release dosing and optimal formulation stability

- Optimal API release[2]
- Low oxygen permeability
- Good restricted water permeability
- Good mechanical resistance[3]

9.25 the average time it takes for a gelatin capsule to rupture[5]

27.25 the average time it takes for a modified starch-based capsule to rupture[6]

MINUTES

50x SLOWER

OXYGEN TRANSFER IN GELATIN CAPSULES COMPARED WITH HPMC SHELLS[4]

3 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

MOST RELIABLE WEIGHT STABILITY PROFILE

Average weight variation measured[7]

	Gelatin HC (size 1)	HPMC HC (size 1)	Pullulan HC (size 1)
RSD (%)	1,7	3,0	2,2

40% less raw material is required to manufacture gelatin capsules than HPMC alternatives[8]

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[9]

- Global expertise
- Dedicated local teams
- World class products
- Highest quality & safety standards
- Full responsibility
- Product integrity

>25% of capsules are sourced with Rousselot gelatin[10]

References available upon request

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DARLING INGREDIENTS