Coni-Snap®
capsules

Reliable and
consistent
two-piece capsules

CAPSUGEL®
Quality
People and Products Working Together™

About Coni-Snap® capsules

With more than a century of world-leading capsule manufacturing expertise, it is not surprising that Capsugel produces over 50% of all two-piece capsules sold globally. Capsugel hard capsules, known as Coni-Snap, perfectly match the stringent regulations and standards of major pharmaceutical companies as well as dietary supplement manufacturers and marketers.

Dedication to innovation extends beyond the Coni-Snap capsule itself and well into the production cycle. The latest high-capacity filling machines require a precise capsule design to work at maximum capacity. To meet this requirement, the Coni-Snap capsule features a body with a tapered rim that allows more play between the two parts, reducing the risk of the two rims meeting and therefore eliminating the splitting phenomenon. Furthermore, the new pre-lock design with six dimple-like notches reduces the chance of premature opening during both transportation and filling.

Constant technical improvement is just one of the reasons why customers around the world have been counting on Coni-Snap two-piece capsules for over fifty years. For pharmaceutical and dietary supplement manufacturing customers, Coni-Snap capsules offer a wide range of advantages. The hard gelatin capsules can be produced using a simpler manufacturing process with fewer production steps while maintaining high quality standards. On the formulation side, hard gelatin capsules are a versatile container, offering numerous filling possibilities including granules, powders, liquids, semi-solids and mini-tablets. Coni-Snap capsules are ideal for controlled release formulation as well. Consumers tend to prefer hard gelatin capsules since they are easy to swallow and mask tastes and odours.

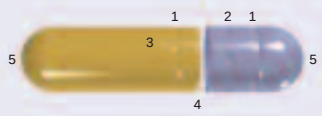
With a vast range of colours, sizes and imprinting possibilities, Coni-Snap capsules provide an ideal way to enhance product identity as well as overall brand image.

The Coni-Snap capsule

Design features

1 Closely matched locked rings provide full-circumference leak-free closure

2 Six elongated dimples maintain precise round capsule diameter, improving filling machine performance



3 Two aero-dynamic air vents allow air to escape from the cap; critical when operating high speed filling machines

4 Tapered rim of the body engages easily with the cap for problem-free closure

5 Rounded, hemispherical ends are mechanically stronger and more resistant to deformation

Manufacturing process

Gelatin, the primary raw material

Every single Capsugel hard gelatin capsule originates from high-quality gelatin derived from collagen, a fibrillar protein composed of eighteen different amino acids found in connective tissues and bones. Natural bovine or porcine collagen is macerated and purified using either acids or alkalis, depending on the production process. The collagen splits hydrolytically into an unbranched amino acid chain with a molecular weight ranging from 40,000 to 100,000. This results in a high-grade, consistent granular gelatin.

The high-grade gelatin used to produce Capsugel hard gelatin capsules meets all standards and regulations imposed by both the food and pharmaceutical industries. Every Capsugel gelatin supplier must adhere to strict Capsugel regulations and quality requirements. Delivered high-grade gelatin undergoes stringent preliminary physical, chemical and microbiological tests before it is released into production by the Capsugel quality control department. Testing methods are applied with equal thoroughness at all Capsugel factories world-wide, guaranteeing a primary raw material of the highest consistency and quality.

> “Capsugel hard capsules are produced from high-grade gelatin.”

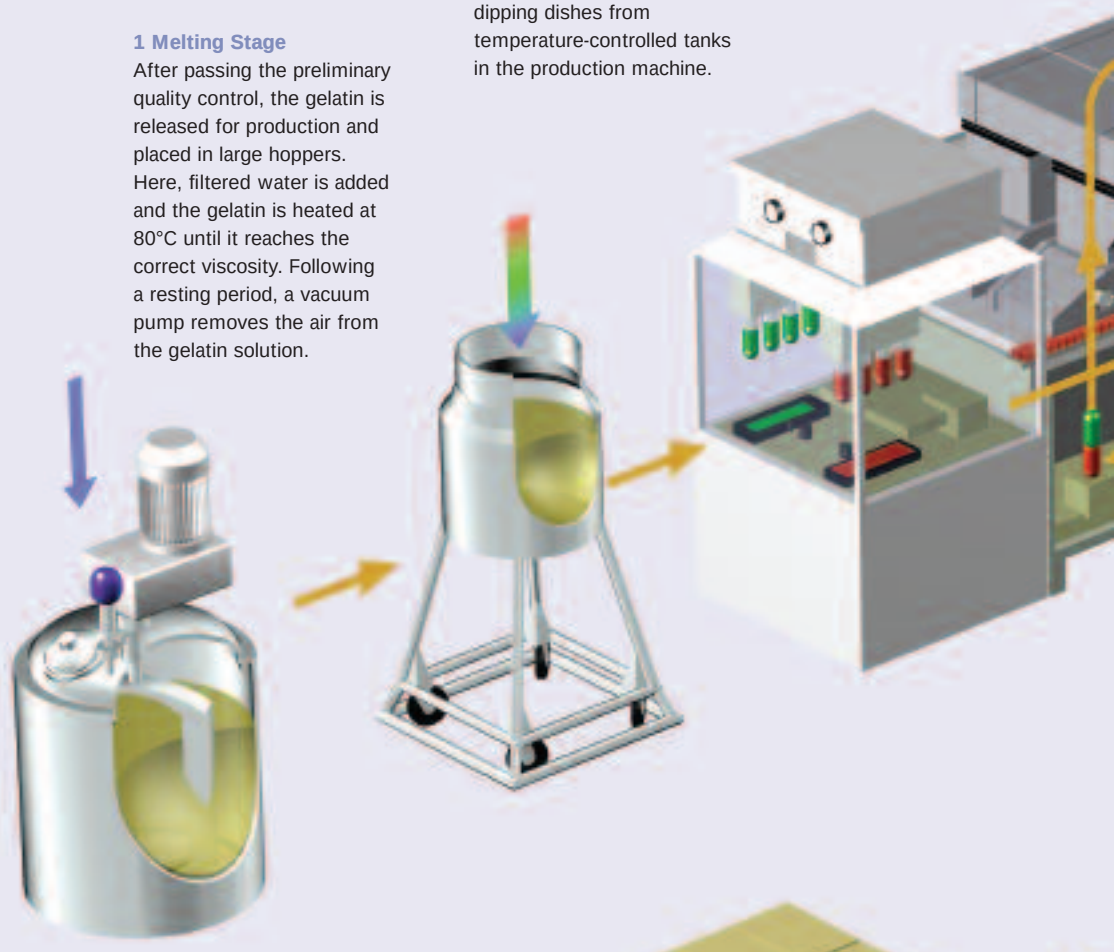
The manufacturing process

The underlying principles of capsule manufacturing have remained practically unchanged since its invention in 1833. Over the years, modern technology and automation have significantly increased production levels and product quality. Today, Capsugel counts on a specialised R&D team that constantly improves automation processes and technology, resulting in a highly effective production process centred on integrated high-capacity automatic machines.

1 Melting Stage
After passing the preliminary quality control, the gelatin is released for production and placed in large hoppers. Here, filtered water is added and the gelatin is heated at 80°C until it reaches the correct viscosity. Following a resting period, a vacuum pump removes the air from the gelatin solution.

2 Colour
At this point, the gelatin solution is moved to transfer tanks, or 'melters', where titanium oxide is added to create an opaque base. Specialists blend in the necessary colouring agents or pigments to create one of eighty possible colours. Following a colour management step to confirm colour accuracy, the transfer tank with the colour-correct gelatin solution is moved to the production area where the gelatin is fed into dipping dishes from temperature-controlled tanks in the production machine.

3 Capsule manufacturing
The process itself is an engineering feat. Standardised steel pins arranged in rows on metal bars are precision-dipped into the dishes containing the coloured solution. After dipping, the bars are removed and rotated to distribute the gelatin as uniformly as possible around the pins. The gelatin is then



7 Packaging
Arriving directly from imprinting or quality control, each individual package must pass a final shipping confirmation inspection before it is dispatched to the client.

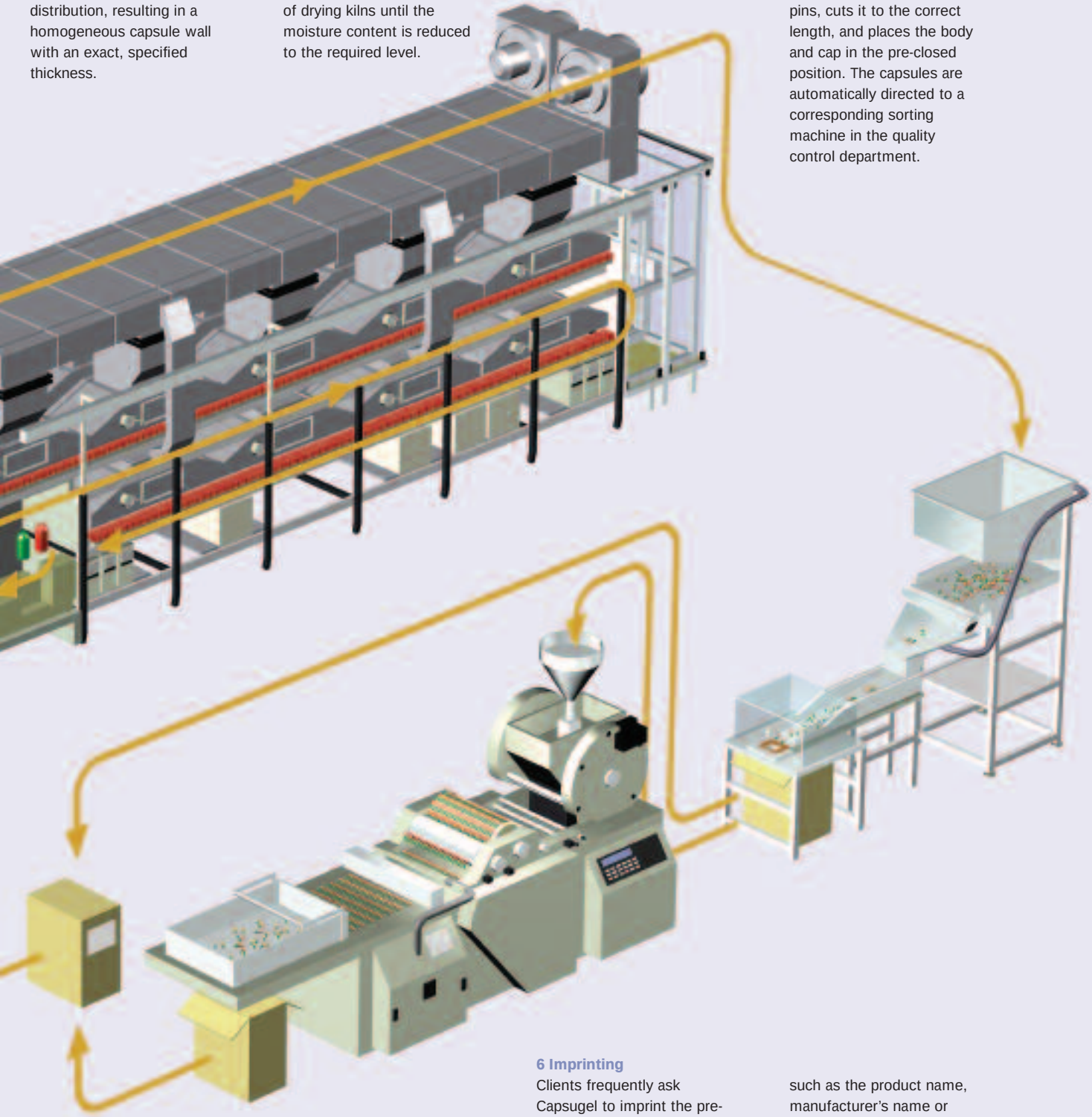
allowed to set. Precise bar rotation, gelatin viscosity and dipping rate all contribute to correct gelatin distribution, resulting in a homogeneous capsule wall with an exact, specified thickness.

4 Drying

Travelling along a conveyor belt, the bars carrying the pins coated with solidified gelatin pass through a series of drying kilns until the moisture content is reduced to the required level.

5 Automatic Finishing

During the final production stage, the machine automatically strips the formed gelatin from the pins, cuts it to the correct length, and places the body and cap in the pre-closed position. The capsules are automatically directed to a corresponding sorting machine in the quality control department.



6 Imprinting

Clients frequently ask Capsugel to imprint the pre-closed capsule. All Capsugel hard gelatin capsules can display useful information such as the product name, manufacturer's name or logo, and dosage details in either one or two contrasting ink colours.

Quality control

Quality is highly apparent and consistent throughout the entire world-wide Capsugel production process. Every Coni-Snap® capsule conforms to strict requirements found in pharmacopoeia references. To obtain increased production levels and product quality, Capsugel counts on a highly effective process centred on integrated high-capacity automatic machines. The European production process is ISO 9002 and ISO 14001 certified. Drug master files have been registered with the U.S. FDA and the Canadian Health Authority.

Another aspect of Capsugel world-wide quality, the production process features numerous quality controls. As the capsules pass through the sorting machine, they are controlled according to standard uniformity criteria using a Computer Aided Quality (CAQ) system. Additionally, the quality control operator checks the visual quality and quality status of each batch on the CAQ system. If warranted, a complete manual inspection will occur. Every hour, a sample is taken manually and processed in the Capsize, a high-tech sensorised measuring unit that gathers uniformity data like wall thickness, length, and other statistical quality control elements. This continuous quality control system guarantees the highest level of product uniformity.

When the capsules meet the strict quality standards, a random sample is taken before the entire shipment is packaged and bar-coded. This pre-sample is individually packaged and sent to the customer as an objective, representative product sample. This means that the delivered capsule boxes can remain hygienically stored and sealed until they are filled. Along with every order, customers also receive a certificate. Coni-Snap capsules meet all relevant specifications as described in the Capsugel 'Multistate File'.

Quality control

Steps in capsule manufacturing and quality control

Production step	Corresponding quality control
1 Preparation of raw material	
→ Gelatin	appearance, odour, colour, grain size, solubility, gelling, (bloom), viscosity, pH value, isoelectric point, bacteriology, chemical purity
→ Water	electrolyte content, pH value, bacteriology
→ Colouring agents and pigments	identity, solubility, bacteriology, chemical purity
→ Gelatin solution	viscosity, temperature, colour shade, colour composition
2 Production machine	
→ 1 Dipping, 2 Rotation, 3 Gelling, 4 Drying, 5 Stripping, 6 Cutting, 7 Joining, 8 Ejection	temperature, relative humidity, viscosity, dimensions, colour shade, laboratory check
3 Inspection	defects
4 Imprinting	laboratory checks on ink, statistical control
5 Counting, packaging	final release by Quality Control
6 Batch release	certificate

Properties and specifications

Colouring agents and pigments

According to international studies, one of the most reliable means of identifying drugs is colour. Although to avoid confusion, colour must not become over-complicated, creating a risk factor in itself. When defining the colour palette for hard gelatin capsules, Capsugel opted to use only approved colouring agents and pigments cited in most pharmacopoeias and other official regulations. As an opacifying agent, Capsugel exclusively uses the approved standard, titanium dioxide.

Prior to production, every particular order is individually checked for regulation conformity. During production, in-house colour experts confirm colour accuracy using a state-of-the-art colour management system. Since permitted colouring agents differ from country to country, Capsugel advises customers regarding colorant selection per specific country or region according to the appropriate regulatory agencies. The Capsugel 'List of Colorants' is a highly informative reference document to help clients select the proper colour combinations per country.*

> "One of the most reliable means of identifying drugs is colour."

* Please ask your Capsugel Representative for a copy of 'List of Colorants' (BAS 141).

Imprinting

Clear, easy-to-read text certainly assists all types of people, from medical staff and patients to consumers, correctly identify each capsule. That is why Capsugel hard gelatin capsules can be clearly imprinted in one or two colours with useful information like a logo, product name, company or even dosage details.

Capsugel's specialised imprinting team is readily available to offer technical advice and expertise.

Axial-Print

Using an offset printing process, hard gelatin capsules can be printed length-wise using the Axial-Print process. It is a simple solution suitable for several lines of text such as a company and product name.

Radial-Print

For circumferential printed capsules, Capsugel suggests the Radial-Print process. Introduced by Capsugel in 1978 to meet customer demand, the innovative Radial-Print technique enables circular printing and axial printing for several lines. A specially designed conveyor belt runs the capsules under the offset cylinder. The cylinder rotation rate is somewhat higher than the capsule transport rate. This means that the capsules rotate while being printed and the design is printed around the capsule. Up to 320° of the capsule circumference is printable, including additional room for legibility. The advantage of the Radial-Print technique is space: the printable area is five times larger than the area available using the Axial-Print technique. For example, with larger capsules in the 0 to 000 range, several lines of text can easily be printed on both the cap and the body.

For both Axial-Print and Radial-Print techniques, Capsugel offers rectified and non-rectified imprinting.

Ink colours

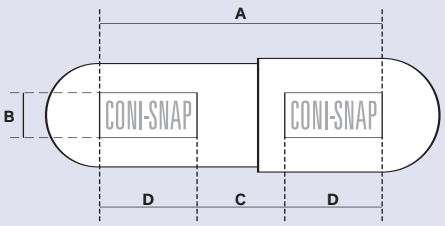
Capsugel capsules can be imprinted with a variety of standard-approved inks that easily contrast with the many capsule colour combinations. To meet specific marketing and labelling needs, special ink colours can be developed on demand.

Coni-Snap® capsules about to be imprinted in one or two colours with useful information like a logo, product name, company or even dosage details.

Please note that ink colours shown here may differ from the original. This should be considered a guideline only.

black | white | grey | red | medium blue | light blue | green | orange | yellow

Axial-Print

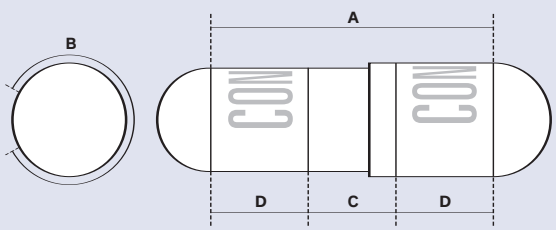


A = Overall length of total imprinting in mm
B = Height of imprinting in mm
C = Distance between cap and body imprintings in mm
D = Maximum length of cap or body imprinting in mm
I = Minimum distance between letters in mm

Imprinting Coni-Snap: dimensions

Size	A	B	C	D	I
00	16.40	3.00	4.60	5.90	0.20
0 EL	18.00	2.80	4.60	6.70	0.20
0	15.70	2.80	4.40	5.65	0.20
1	13.90	2.50	4.40	4.75	0.20
2	12.70	2.30	4.40	4.15	0.20
3	11.50	2.10	4.00	3.75	0.20
4	10.40	1.90	4.00	3.20	0.20

Radial-Print



A = Overall height of total imprinting in mm
B = Maximum overall length of cap or body imprinting in mm
C = Distance between cap and body imprintings in mm
D = Maximum length of cap or body imprinting in mm
I = Minimum distance between letters in mm

Imprinting Coni-Snap: dimensions

Size	A	B	C	D	I
0	15.70	17.00	4.40	5.65	0.20
1	13.90	15.50	4.40	4.75	0.20
2	12.70	14.20	4.40	4.15	0.20
3	11.90	13.00	4.40	3.75	0.20
4	10.80	11.80	4.40	3.20	0.20

Axial and Radial-Print combined

For specific marketing and identification needs, it is also possible to combine both methods to maximise the capsule presentation.

Specifications

Below is a table covering a wide variety of Coni-Snap® capsule specifications in regards to size, weight and filling capacity. The various dimensions are listed in metric and standard. Consult the chart to select the optimal Coni-Snap capsule.

Coni-Snap capsules

Size	000	00el	00	0el	0el*	0	1el	1	2el	2	3	4	5
1. Weight													
Mg	163	130	118	107	110	96	81	76	66	61	48	38	28
Tolerance mg	±10	±10	±7	±7	±7	±6	±5	±5	±5	±4	±3	±3	±2
2. Capacity													
Capsule volume ml	1.37	1.02	0.95	0.78	0.78	0.68	0.54	0.50	0.41	0.37	0.30	0.21	0.13
Powder density / Capsule capacity mg													
0.6 g/ml	822	612	546	468	468	408	324	300	246	222	180	126	78
0.8 g/ml	1096	816	728	624	624	544	432	400	328	296	240	168	104
1g/ml	1370	1020	910	780	780	680	540	500	410	370	300	210	130
1.2 g/ml	1644	1224	1092	936	936	816	648	600	492	444	360	252	156
3. Length of the capsule parts (body and cap)													
Body inches	0.874	0.874	0.796	0.795	0.826	0.726	0.697	0.654	0.656	0.601	0.535	0.480	0.366
Tolerance inches	±0.018	±0.018	±0.018	±0.018	±0.018	±0.018	±0.018	±0.018	±0.018	±0.018	±0.018	±0.018	±0.016
Body mm	22.20	22.20	20.22	20.19	20.98	18.44	17.7	16.61	16.66	15.27	13.59	12.19	9.30
Tolerance mm	±0.46	±0.46	±0.46	±0.46	±0.46	±0.46	±0.46	±0.46	±0.46	±0.46	±0.46	±0.46	±0.46
Cap inches	0.510	0.510	0.462	0.460	0.472	0.422	0.413	0.385	0.382	0.352	0.318	0.284	0.244
Tolerance inches	±0.018	±0.018	±0.018	±0.018	±0.018	±0.018	±0.018	±0.018	±0.018	±0.018	±0.018	±0.018	±0.016
Cap mm	12.95	12.95	11.74	11.68	11.99	10.72	10.49	9.78	9.7	8.94	8.08	7.21	6.20
Tolerance mm	±0.46	±0.46	±0.46	±0.46	±0.46	±0.46	±0.46	±0.46	±0.46	±0.46	±0.46	±0.46	±0.40
4. External diameter**													
Body inches	0.376	0.322	0.322	0.289	0.290	0.289	0.261	0.261	0.240	0.239	0.219	0.199	0.184
Body mm	9.55	8.18	8.18	7.34	7.36	7.34	6.63	6.63	6.09	6.07	5.57	5.05	4.68
Cap inches	0.390	0.336	0.336	0.301	0.301	0.300	0.272	0.272	0.250	0.250	0.229	0.209	0.193
Cap mm	9.91	8.53	8.53	7.65	7.66	7.64	6.91	6.91	6.36	6.35	5.82	5.32	4.91
5. Overall closed length													
Inches	1029	0.995	0.917	0.909	0.953	0.854	0.804	0.765	0.760	0.709	0.626	0.563	0.437
Tolerance inches	±0.012	±0.012	±0.012	±0.012	±0.012	±0.012	±0.012	±0.012	±0.012	±0.012	±0.012	±0.012	±0.016
Mm	26.1	25.3	23.3	23.1	24.2	21.7	20.42	19.4	19.3	18.0	15.9	14.3	11.1
Tolerance mm	±0.3	±0.3	±0.3	±0.3	±0.3	±0.3	±0.3	±0.3	±0.4	±0.3	±0.3	±0.3	±0.4

* Europe only. ** All tolerances ±0.002 inches or ±0.06 mm.

Please note that Capsugel Coni-Snap capsule specifications are subject to change without notice.

Please consult your Capsugel representative for updated information.

Fill material for capsules

Formulation advantages

Hard gelatin capsules continue to succeed on the market. Clearly, this is due to the numerous advantages for all key players in the sector, from scientists and R&D experts to manufacturers and marketers and finally, of course, the consumer. A hard gelatin capsule is a highly functional and versatile container suitable for numerous market segments including traditional medicines and dietary supplements. Either separately or combined, a variety of materials can be enclosed in the capsules, ranging from granules, powders, liquids and even semi-solid formulations. Opting for granules, pellets and spherical micro-capsules reduces the volume compared to powder. Another practical solution for taking two incompatible substances together is to make film-coated pellets and place them in hard gelatin capsules. Delayed release products are much easier with hard gelatin capsules. For example, polymer-coated pellets or granules that dissolve in different pH values can extend the half-life of a drug substance, creating a once-a-day dosage.

A wide selection of colour possibilities and imprinting options means hard gelatin capsules are widely identifiable. From a marketing point of view, hard gelatin capsules are easy to differentiate and highly attractive. With high formulation versatility, hard gelatin capsules are an excellent choice for a speedy market introduction.

> “A hard gelatin capsule is a highly functional and versatile container suitable for numerous market segments.”

Filling possibilities

Logically speaking, hard gelatin capsules are a minor yet vitally important part of the final product. In order for the final product to take effect, it must be released from the capsule. Even under very extreme conditions, Capsugel hard gelatin capsules dissolve in vivo without difficulty. This makes them a popular medical choice. Active substance mixtures filling hard gelatin capsules must have guaranteed content uniformity to be used in automatic filling machines. In most cases, the hard gelatin capsule is filled with a powder or granule. However, pellets, micro-capsules, tablets, dragées, small gelatin capsules, pastes, semi-solids and liquids can also be placed without difficulty.

When determining the viability of a filling, scientists and experts must consider numerous factors. This includes substance size and shape, uniformity, mixture homogeneity, consistency, moisture content and compression ability. The filling must be able to withstand extremely high speeds. Because of the absolute need for constant and accurate quantities not all substances are suitable for automatic dosage machines. These speciality cases are best addressed using other Capsugel products.

Clearly, Capsugel hard gelatin capsules offer almost unlimited possibilities. It is probably why Capsugel's Coni-Snap capsules are one of the world's most popular brands of two-piece gelatin capsules.

The Coni-Snap® capsule can be filled with a variety of substances.

powder | granules | pellets | liquid | tablets | capsule

pellets and powder | two different pellets | two different pellets and powder | powder and tablets | two different pellets and tablet | two different pellets and capsules

Automatic hard capsule filling machines

Capsugel products are suitable for use with a selection of brand name filling machines. Below there is information regarding capsule characteristics, and machine production rates and compatibility.

Automatic hard capsule filling machines

Machine	Dosing principle	Output caps/h	Products to be filled
Bosch further information: www.bosch.de			
GKF 400	Dosing disk	24,000	Powder, pellets
GKF 700	Dosing disk	42,000	Powder, pellets, tablets, liquids
GKF 2000	Dosing disk	150,000	Powder, pellets, microtablets, tablets
Dott. Bonapace further information: www.dottbonapace.com			
In-Cap	Auger	3,000	Powder, pellets, tablets
Harro Höfliger further information: www.hoefliger.de			
KFM III-C	Dosator or dosing disk	25,000	Powder, pellets, tablets, liquids
IMA further information: www.ima.it			
Zanasi 6/12 : 25/40	Dosator	6,000–40,000	Powder, pellets, tablets, liquids
Zanasi Plus 8/16/32/48/70/85	Dosator	8,000–85,000	Powder, pellets, tablets, liquids
Matic 60	Dosator	60,000	Powder, pellets
Matic 90	Dosator	90,000	Powder, pellets
Matic 120	Dosator	120,000	Powder, pellets
Imatic 100	Dosator	100,000	Powder, pellets
Imatic 150	Dosator	150,000	Powder, pellets
Imatic 200	Dosator	200,000	Powder, pellets
Impressa 130	Dosing disk	130,000	Powder
MG2 further information: www.mg2.it			
Suprema	Dosator	48,000	Powder, pellets
MG Compact	Dosator	6,000–96,000	Powder, pellets, tablets, capsules, liquids
MG Futura	Dosator	6,000–96,000	Powder, pellets, tablets, capsules, liquids
Planeta 100	Dosator	100,000	Powder, pellets, tablets, liquids
G 37/N	Dosator	100,000	Powder, pellets, tablets
G 70	Dosator	70,000	Powder, pellets, tablets
G 100	Dosator	100,000	Powder, pellets, tablets
G 140	Dosator	140,000	Powder, pellets, tablets
G 250	Dosator	250,000	Powder, pellets, tablets
Romaco-Macofar further information: www.romaco.com			
CD 5 and 20	Dosator	6,000–20,000	Powder, pellets, tablets
CD 40	Dosator	40,000	Powder, pellets, tablets
CD 60	Dosator	66,000	Powder, pellets, tablets

Blister packaging recommendations

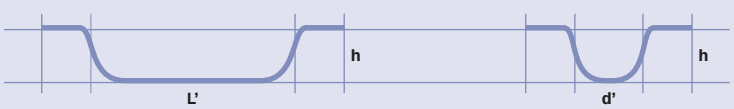
A highly popular packaging solution, especially in the over-the-counter pharmaceutical sector, blister packaging is becoming more and more common.

To ensure rapid and trouble-free blister packaging of the capsules, the overall length of the filled and closed capsules must be as precise as possible.

The following minimum die-roll cavity dimensions for blister packaging machines are recommended.

Capsugel capsules are frequently packaged in blister packaging. This is the ideal solution for both marketers and customers.

Blister packaging



h = depth of cavity of blister die-roll (mm)
L' = length of cavity of blister die-roll measured at h/2 and along the axis to the capsule (mm)
d' = width of cavity of blister die-roll measured at h/2 and along the perpendicular axis of the capsule (mm)

Minimum die-roll cavity dimensions for blister packaging

	000	00	0 el	0	1	2	3	4	5
depth (h)	10.4	9.1	8.2	8.1	7.4	6.9	6.3	5.8	5.4
length (L')	27.2	24.8	25.3	22.6	20.4	18.9	16.9	15.3	12.4
width (d')	11.1	9.8	8.9	8.8	8.1	7.6	7.0	6.5	6.1

Conclusion

As one of the industry leaders, Capsugel goes above and beyond a conventional client relationship. A true partner, Capsugel is involved in every step of the product cycle, from formulation and production to colour selection and design. Centred on a philosophy of constant and consistent innovation, Capsugel aims to improve capsule technology to satisfy all age groups and lifestyles. The Capsugel product range is immense, covering traditional two-piece capsules to highly innovative vegetal-based, liquid-filled and soft capsules.

Capsugel is equally committed to service. Complete customer service includes scientific support and formulation assistance to bring products to market faster, technical assistance to optimise customer production and dedicated customer service representatives to smoothly handle any further requirements. The right mixture of technology, products and service allows Capsugel to support every aspect of a client's business. Located in various markets around the globe, Capsugel clients enjoy access to a world-wide network of scientific and technical experts who can easily translate Capsugel's highly advanced technical formulation, manufacturing expertise and documentation support to specific market requirements.

Thanks to real expertise applied throughout the capsule life cycle, Capsugel is more than ready to explore each and every option required to meet any customer request. This way we are sure that our experts help your experts achieve their goals and objectives.

→ **If you require further information about Coni-Snap® capsules, please refer to 'Hard Capsules – Today and Tomorrow' (BAS 192). Your Capsugel Representative can provide you with more information about the Capsugel Library or any other Capsugel publication mentioned in this document.**