

A large circular image of a smiling woman with brown hair, looking down at a small yellow pill she is holding between her fingers. The background is a soft-focus indoor setting.

# Rousselot® Pharmaceutical Gelatines



Improvement  
by nature



# Rousselot®

Strengthening our capability to offer you excellence

Rousselot, world leader in manufacturing gelatine, draws on 120 years of experience and success and sets new standards in pharmaceutical gelatine with the introduction of the Rousselot® Pharmaceutical Gelatine product offer.

Excellent and constant product quality and process integrity are the pillars of Rousselot's offer to the pharmaceutical industry, while our long-standing expertise allows us to apply our know-how to provide a world-class range of gelatines compliant with international pharmacopeia and food standards. Catering to the specific needs of the pharmaceutical industry, we offer gelatine that satisfies all the relevant regulatory requirements and is specifically developed and manufactured to meet customer constraints.

Rousselot has carved out a position as the leading provider of high quality gelatine to the pharmaceutical market. We began establishing GMP plants in the 1990's and have since made



The right gelatine, whatever your application

notable acquisitions to achieve an outstanding network of pharmaceutical facilities. This structure is the backbone of our high-quality product and service offering and our reputation for expertise and regulatory excellence.

Leveraging our key product functionalities and extensive technical know-how, Rousselot® Pharmaceutical Gelatines and services offer the perfect solution for all your major developments.



# Rousselot® Pharmaceutical Gelatine

Reliable and consistent ingredients for pharmaceutical with almost unlimited possibilities

Rousselot® Gelatines meet all the stringent regulations and standards of both major pharmaceuticals companies and dietary supplements manufacturers.

We consider these applications equally demanding and carefully select our gelatines to provide unbeatable repeatability.

Rousselot adheres to strict quality requirements and undergoes stringent quality control, physical, chemical and microbiological tests before releasing products to customers. Test methods are applied with equal thoroughness at all Rousselot plants worldwide, guaranteeing a gelatine of the highest consistency and quality.

Our expertise allows us to bring you an almost limitless range of pharmaceutical gelatines and our experience helps deliver consistent and on-time deliveries. On-going technical improvement is just one of the reasons why customers around the world have been counting on Rousselot for over 100 years.

## Fit-for-use offer

### Developing your customized solution together

Dedicated to innovation, we combine our scientific, regulatory, production and commercial resources to offer a customized approach to all your requirements.

At Rousselot, we are able to specify additional parameters according to individual customer constraints and produce fit-for-use pharmaceutical gelatines. From standard to specific gelatine, the Rousselot range is immense. No company offers you more gelatine options and solutions for the pharmaceutical industry than Rousselot.

## Rousselot® Pharmaceutical Gelatine range

Commercial name	Process				Application				
	Alkaline	Acid	Type	Raw material	Soft Capsule	Hard Capsule	Plasma	Tableting	Ostomy
Rousselot® 150 LB	•		B	Bovine bones	•				
Rousselot® 160 LB	•		B	Bovine bones	•				
Rousselot® 160 B			A	Bovine bones	•				
Rousselot® 160 LP	•		B	Porcine bones	•				
Rousselot® 160 SH	•		B	Bovine hides	•				
Rousselot® 180 H				Bovine hides	•				
Rousselot® 180 PS		•	A	Pig skin	•				
Rousselot® 200 AH		•	A	Bovine hides	•				
Rousselot® 200 PS		•	A	Pig skin	•			•	•
Rousselot® 200 FG		•	A	Fish skin	•				
Rousselot® 200 LB	•		B	Bovine bones		•			
Rousselot® 220 LB	•		B	Bovine bones		•			
Rousselot® 220 SH	•		B	Bovine hides		•			
Rousselot® 275 FG		•	A	Fish skin	•	•			
Rousselot® 280 PS		•	A	Pig skin		•			
Rousselot® 250 LB	•		B	Bovine bones			•		
Rousselot® Hydrolyzed gelatine		•	A	Fish, bovine or pig				•	

Centered on continuous improvement, Rousselot aims to improve its gelatine offer to fit all applications.

They can be used "as is" or adapted to meet specific customer's requirements.

# Rousselot® Gelatine for pharmaceutical applications

## Rousselot® Gelatine in hard capsules

Capsule attribute	Gelatine key characteristics	Rationale
Film forming	Melting/setting	Ensure a uniform and repeatable gelation
	Viscosity/Viscosity loss	Ensure uniform thickness of capsule walls
	Transparency/clarity	Capsule appearance
	Compatibility with pigments and dyes	
Protection of active ingredients	Gel strength	Provide mechanical resistance: balance brittleness and tamper evidence
	Elasticity	
	Gliding	Facilitate capsule filling step
Release of active ingredient	Melting	Melt at body temperature

### Hard gelatine capsules

*Flexibility to adapt to customer's specific request and regulatory evolution.*

Highly functional, hard gelatine capsules are a versatile container suitable for numerous market segments. In hard capsules, Rousselot® Gelatine provides a strong and flexible film for tamper-evident dosage form. These gelatines have been developed to meet the most stringent parameters. Along with excellent disintegration and gliding properties, Rousselot understands well that beyond their drug-carrier role, hard capsules need to be filled quickly and to disintegrate in the body for optimal delivery of the active principle. Rousselot is able to adjust the gliding properties of the gelatine it delivers so that finished capsules can meet the speed of filling machines.

### Soft capsules

*Collaborative partnerships to exceed your aspirations.*

The Rousselot range of Pharmaceutical gelatines for soft gelatine capsules makes it possible to adjust encapsulation conditions to the encapsulated formula and active compound.. This helps, in particular, to prevent interactions between the shell and the active ingredients contained in the fill and thus optimizing its bio-availability. Our application laboratories are able to provide critical information, such as the setting temperature.

### Micro-encapsulation

In micro-encapsulation, Rousselot® Gelatines' emulsifying and filming properties allow the preparation of a coating that will prevent the active ingredient (vitamins, unsaturated fatty acids, carotenoids) from reacting with oxygen or water. Encapsulation has the added benefit of masking the unpleasant taste and odor of the encapsulated preparation.

## Rousselot® Gelatine in soft capsules

Capsule attribute	Gelatine key characteristics	Rationale
Film forming	Setting temperature	Film casting
	Viscosity / viscosity loss	Standardize the thickness of film Impact gel-mass maturation
	Transparency/clarity	Capsule appearance
	Compatibility with plasticizers, pigments and dyes	
Encapsulation	Elasticity	Proper shell formation
	Melting/Setting	Improve capsule sealing
Protection of active ingredients	Gel strength	Provide mechanical resistance: balance brittleness and tamper evidence
	Elasticity	
Release of active ingredient	Melting	Melt at body temperature

## Tablets

Tablet has become one of the most popular solid dosage forms for medicines, OTC drugs and dietary supplements. Tablets are divided into several categories, the best known being:

- the compressed tablets to be swallowed,
- the effervescent tablets
- the chewable tablets

Rousselot® Gelatines and hydrolyzed gelatines are suitable for both wet granulation and direct compression as tablet binders and fair disintegrants thanks to their key features:

- flexibility of use (wettability and cold solubility)
- appropriate binding power (adhesive and cohesive properties)
- excellent powder flowability and compression properties
- suitable disintegration (<10 seconds) ensuring good drug availability.

Due to the dust-free powder form, Rousselot® Gelatines are easy to use, generate no dust and help to maintain clean workshops.

Rousselot® Gelatines are natural binding and disintegration agent that meets the requirements of tablets manufacturers.

## Ostomy

Rousselot® Gelatine offer for ostomy devices is especially granulated to absorb water more rapidly than larger granulated particles. It is specifically designed to work with other fine-mesh substances synergistically, and provide the safety and protection your product warrants.

## Blood plasma substitute

The quality and purity of Rousselot® Gelatines has made it the material of choice for the preparation of blood plasma substitute, which mimic the viscosity and molecular properties of blood. Our very specific process enables us to provide a pharmaceutical gelatine that complies with your most stringent requirements in term of microbiological and endotoxin content. The acceptance of Rousselot® Gelatines in this end use endorses our technical and production capabilities.



# Rousselot® Pharmaceutical Services and commitments

Let our experts help your experts achieve their goals and objectives

Dedicated to the success of its customers, Rousselot is a dependable worldwide leader in gelatine manufacturing. Rousselot brands are widely recognized not only for their consummate quality but also always the on-going innovation we bring our customers.

Rousselot's multi-national diversity, linked by outstanding communication and coordination, results in synergistic teams and task forces. This is made possible by our double-edge organization comprising centralized headquarters in Son, Netherlands, and our decentralized local networks of branch offices and commercial partners.

Located in various markets, Rousselot customers enjoy access to a worldwide network of scientific and technical experts who can easily translate our expertise to specific market requirements.

To address regulatory and market changes, Rousselot pharmaceutical expertise is shared with our customers through:

- Regulatory assistance
- Technical support
- Customer service

## **Regulatory compliance**

*One of our fundamentals.*

Compliance, regulatory understanding and foresight are part of Rousselot's core foundations..

Rousselot provides regulatory and support services helping to meet the needs of the most complex local or global regulatory environment.

Our regulatory service encompasses all necessary documentation preparation, submission and review with a proactive approach.

As changing regulations significantly impacts the gelatine business, Rousselot is constantly in contact with the main regulatory bodies throughout the world, either directly or through the gelatine manufacturers associations, such as the GME, GMIA, GMJ, SAGMA and GMAP.

Rousselot keeps a constant watch on all major regulatory changes (EU: DGSANCO, EMEA; USA: USDA, FDA; Japan: MHWL) and adapts its offering to ensure full compliance and maximize the availability of products on a global basis, increasing our capability to deliver the solution customers need.

Rousselot also integrated cultural differences and diverse needs around the globe to provide gelatines that are Kosher or Halal approved by the competent authorities.

Throughout our organization, we pursue a committed, proactive strategy focusing on customer satisfaction.



### Technical Support

*Whether you need a single solution or have a complex set of challenges, Rousselot's experts can meet your expectations.*

As the leader in gelatine manufacturing, Rousselot goes above and beyond a conventional customer relationship. Rousselot leverages its long-standing expertise through a worldwide network of scientific and technical experts. Continually trained in pharmaceutical applications, our experts constantly upgrade their knowledge and understanding of both gelatine and our customers' applications and requirements. Our technical support team has access to extensive resources:

- A network of application laboratories
- An R&D laboratory as well as collaboration with leading universities or faculties.

A full-fledged partner to the industry, Rousselot's technical support team is readily available to offer technical advice and expertise. At Rousselot, we recognize the complexity and varied approaches needed to solve these issues and offer custom solutions to meet your particular needs. With our state-of-the-art development and application centers we offer a complete array of services for pharmaceutical applications.

### Customer service

*A reliable partner you can trust.*

Rousselot is committed to service. Complete customer service includes scientific and formulation assistance, technical support to optimise your production, and dedicated customer service to smoothly handle any further requirements. The right mix of technology, products and service allows Rousselot to support every aspect of a customer's business.

All Rousselot teams work on customer-defined projects. When it comes to attaining or achieving their goals, customers benefit from Rousselot's operational expertise, coupled with extensive knowledge of local and global markets. We are committed to delivering value-added solutions and to bringing customers only the best. Our organization is designed to reach that goal. Our sales teams offer you personalized contact with open and fluid communication in order to find the best commercial solutions. In these challenges, they are supported by technical support and marketing departments.

Shipment is made directly by Rousselot or through an approved distributor. This ensures that we fulfill our own stringent safety specifications, from raw materials and packaging through storage, logistics and delivery.

Obviously, this comes in addition to the traditional services we provide to ensure that our products reach our customers on time. Our worldwide supply chain and transportation specialists work in hand with our sales network to answer all customer queries.

Bringing ingenuity to each partnership, and backed by our expertise in high-quality gelatine manufacturing and regulatory compliance, every Rousselot pharmaceutical product conforms to the strictest food and pharmacopoeia standards. We leverage this organization to deliver excellence in both pharmaceutical products and services.

Worldwide  
presence yet  
close proximity





## Total Quality Excellence

*Guaranteeing the highest level of product uniformity.*

Rousselot counts on a specialized production team that constantly strives to improve processes and technology. We have been widely recognized for our manufacturing expertise based on over one hundred years of production successes. Globally positioned, our pharmaceutical plants employ harmonized methods. We offer complete quality assurance and in-house validation at all our production sites.

Woven into our culture, quality is highly apparent and consistent throughout the entire Rousselot network. Quality excellence provides our customers with fit-for-use products and the assurance of on-time delivery, security of supply and confidence in optimized process improvement. Rousselot's stringent quality methodology is implemented across all our sites as expected from a global manufacturer. We practice comprehensive quality management to consistently achieve high standards. All production methods and processes are documented, and finished products are subject to intensive testing. Through our resources and our highly trained, safety-conscious employees, we comply with relevant regulations and offer you pharmacopoeia-relevant analytics.

The highest quality raw materials are chosen to go through Rousselot's strictly controlled and fully traceable process.

We maintain our high standards through integrated and global quality management to ISO 9001, ISO 14001 and IPEC-GMP. Our quality system describes in detail the production procedures for our gelatines and monitors compliance with the relevant guidelines.

Committed to customer satisfaction, all Rousselot manufacturing facilities are ISO certified. Alongside this backbone of our quality system, Rousselot has also implemented:

- A Food Safety system regarding work environment, equipment, hygiene, GMP, HACCP..
- Sophisticated production management systems based on SPC and SIX SIGMA and providing continuous improvement.

This allows Rousselot to meet and exceed quality norms in force and particularly:

- International food standards, as defined by FAO/WHO,
- Pharmaceutical requirements such as those defined by the USP, EP or JP.
- IPEC-GMP conformity, setting strict benchmark in the areas of training and hygiene, cleaning of production equipment, documentation of individual process steps, traceability of intermediate products and raw materials, and supplier audits

We produce the most repeatable product on the market thanks to a quality system which has been designed to respect our natural environment.

Hygiene, selection and control are our watchwords for repeatable Rousselot® Pharmaceutical Gelatines.

### Rousselot®

Rousselot is the leading manufacturer of gelatine and hydrolyzed collagen to the food, pharmaceutical and technical industries. With a staff of 2,400 people, the company benefits from a global sales and production network of 13 plants and 10 sales offices located in Europe, North America, South America and Asia. Rousselot is part of VION N.V., an international food company with production and sales facilities on all continents.

### VION

With two international divisions Food and Ingredients, the company is active in the field of high quality foodstuffs and health products for humans and animals. Rousselot is part of the Ingredients division. VION has annual sales of EUR 9.0 billion and provides employment for 27,000 people worldwide. VION's head office is in Eindhoven, The Netherlands.  
[www.vionfood.com](http://www.vionfood.com)

### Rousselot® Headquarters:

Visiting address: Kanaaldijk Noord 20-21

5691 NM SON The Netherlands

Phone: +31 (0)499 364100

Fax: +31 (0)499 364972

[gelatin@rousselot.com](mailto:gelatin@rousselot.com)

[www.rousselot.com](http://www.rousselot.com)

