

GATTEFOSSÉ

• PHARMACEUTICALS

**New insights into
rectal drug delivery**



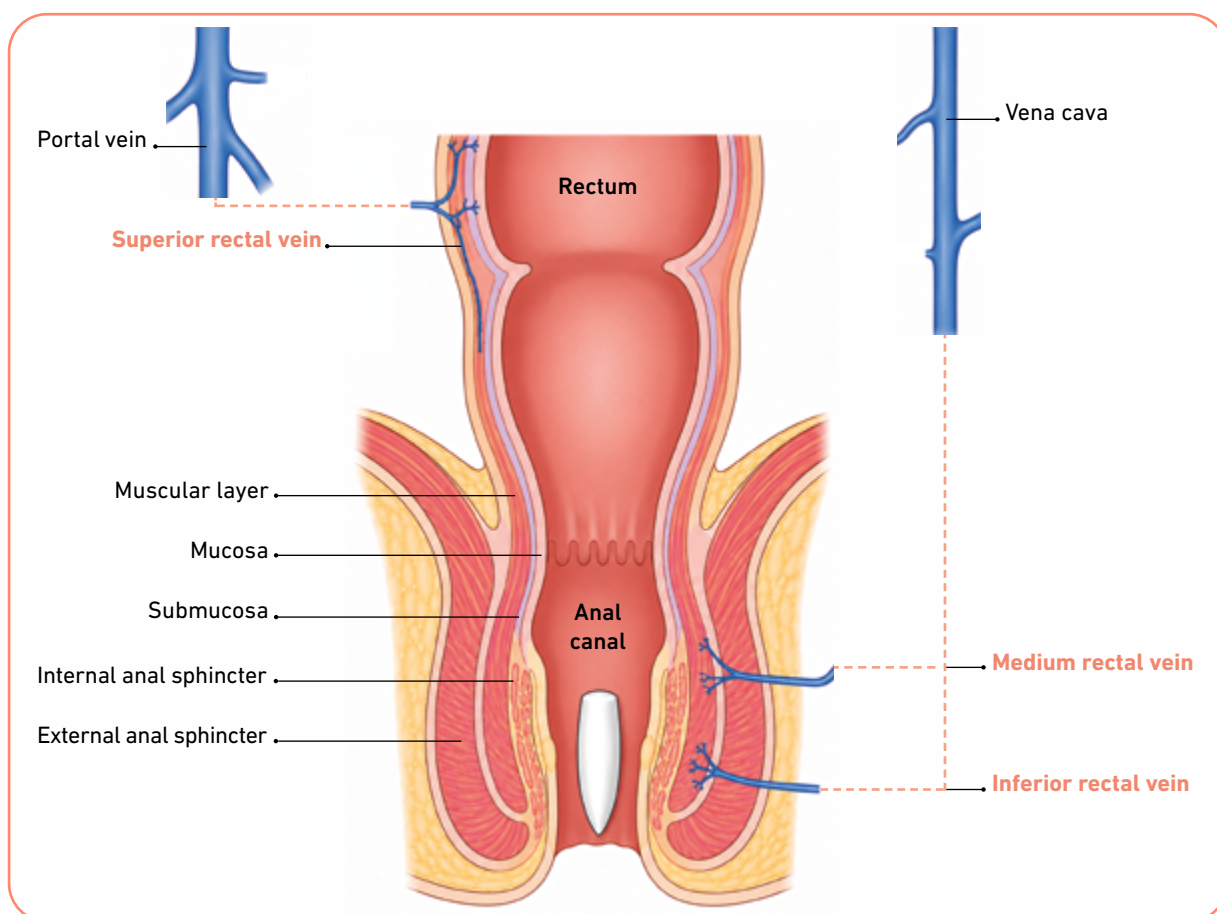
Rectal route: an effective alternative

The rectal route of administration has been used for ages and is being revisited nowadays due to its benefits. It is highly effective and enables to achieve high bioavailability. It is also very convenient for specific populations or indications.

The rectal route enables local and systemic delivery of drugs, as inferior and medium rectal veins lead to vena cava by-passing the liver, while the superior rectal vein leads to hepatic portal vein. The possibility of increasing bioavailability through the rectal route provides attractive alternatives for drugs which undergo high first-pass metabolism, such as for example ergotamine, diclofenac or morphine.

Rectal drug delivery is also the best option for some populations, when there are difficulties to swallow oral dosage forms or to avoid injections. This is the case for pediatric patients, whatever their age: preterm newborn, term born infants (0 - 28 d), infants and toddlers (1m - 24m), preschool children (2y - 5y). It is also convenient for geriatric population or psychiatric patients.

The main indications/drugs for which the rectal drug delivery are used are inflammation: mesalazine and diclofenac; gastro-intestinal diseases: zinc oxide and metopimazine; pain management: acetaminophen, ibuprofen, lidocaine. Rectal drug delivery can also be the only solution for some indications, such as for instance, emesis or epilepsy when oral route is excluded.



The rectal medicinal products should be formulated with safe and non-irritant excipients bearable by the highly sensitive rectal mucosae. Gattefossé supplies safe and functional excipients suitable for all rectal dosage forms.

Our manufacturing sites are ISO certified by SGS (9001 version 2015) and follow IPEC Good Manufacturing Practices (GMP) guidelines. Production processes comply to international standards and follow a rigorous Quality Management System. We have obtained the GMP certificate of inspection from ANSM (Agence nationale de sécurité du médicament et des produits de Santé - the French health authority).

Functional excipients for all rectal dosage forms

Gattefossé range of functional excipients enable the formulations of all rectal dosage forms:

- Solid dosage forms, mainly as suppositories, although tablets and capsules exist marginally
- Semi-solid dosage forms, such as creams, gels, ointments and foams
- Liquid dosage forms, namely solutions and suspensions.

Excipients for solid dosage forms:

- Lubricants
- Sustained-release agents
- Solubilizers



Excipients for suppositories:

- Hard fats



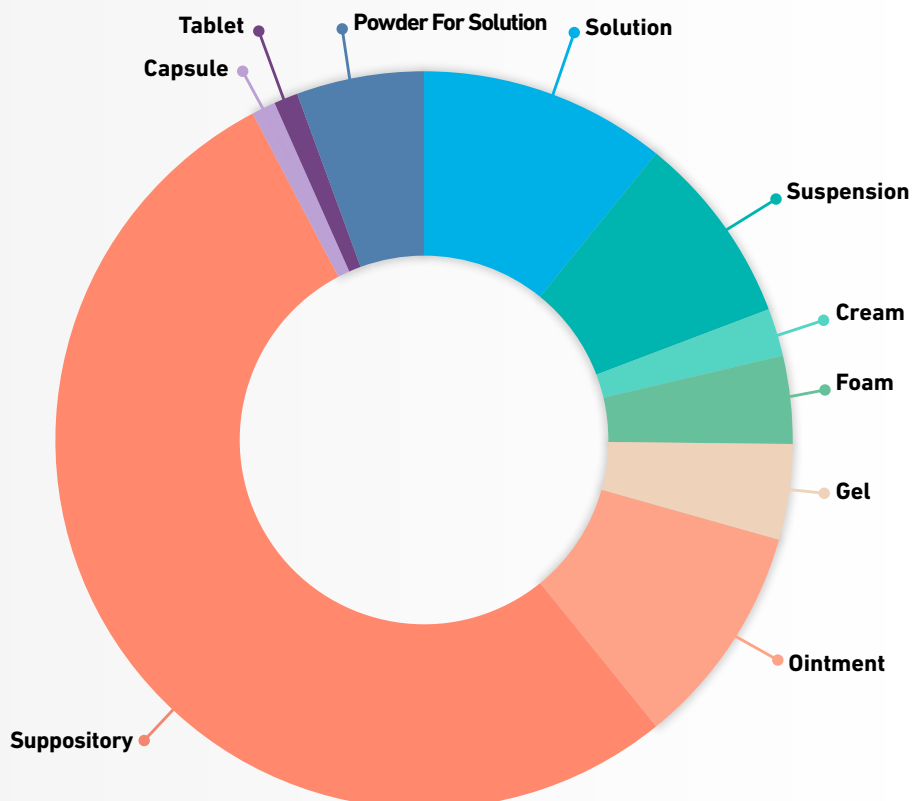
Excipients for liquid dosage forms:

- Solubilizers
- Suspending agents and thickeners
- Oily vehicles and emollients



Excipients for semi-solid dosage forms:

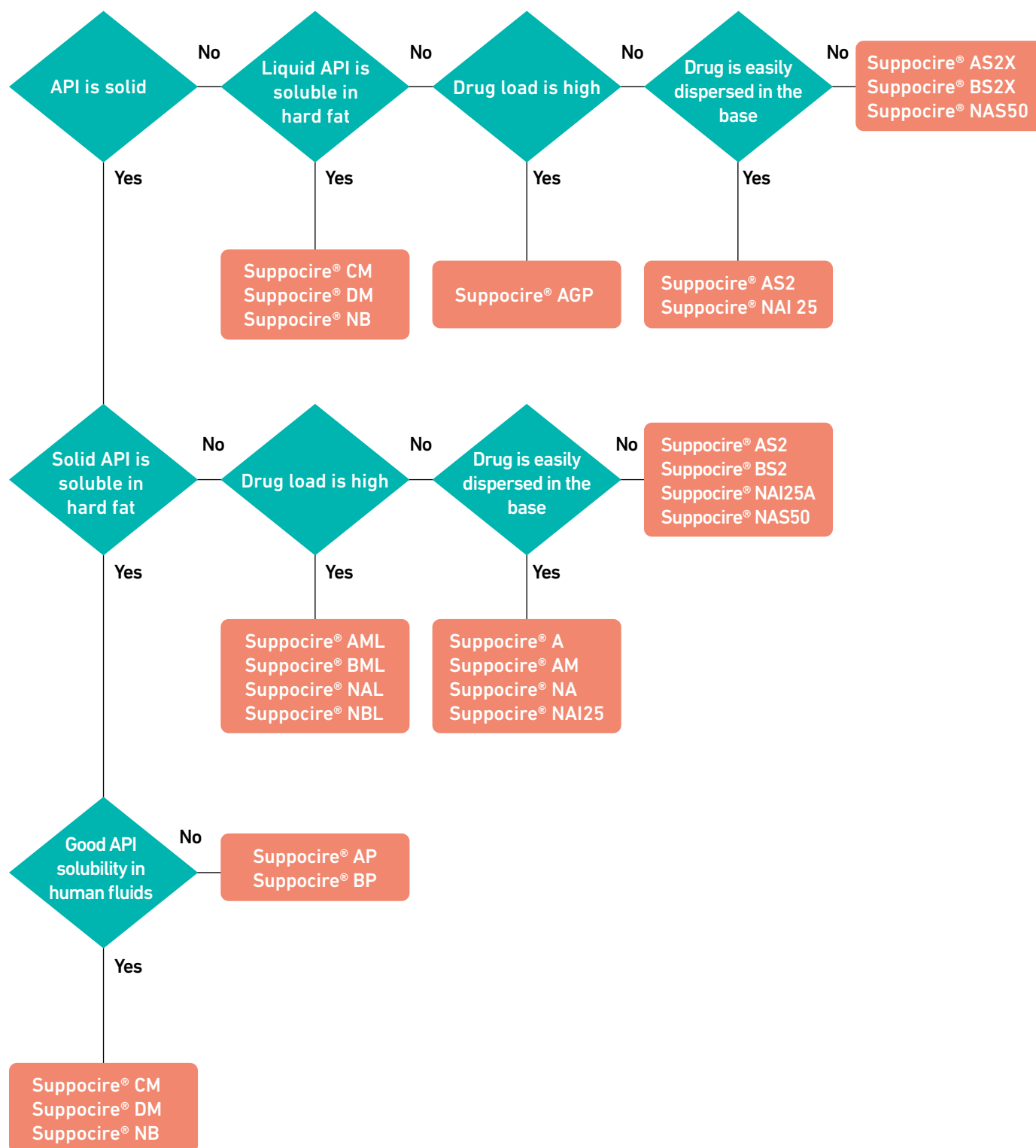
- Solubilizers
- Penetration enhancers
- Emulsifiers/co-emulsifiers
- Thickeners
- Oily vehicles and emollients



Lubricants	Thickeners	Oily vehicles and emollients	Solubilizers and Penetration enhancers	Emulsifiers
Compritol® 888 ATO Precirol® ATO 5 Labrafac™ Lipophile WL 1349	Compritol® 888 Pellets Geleol™ Mono and Diglycerides NF Gelucire® 43/01 Monosteol™ Precifac™ 95-3 Precirol® ATO 5		Capryol® 90 Capryol® PGMC Labrafac™ MC60 Labrafil® M 1944 CS Labrasol® Lauroglycol™ 90 Lauroglycol™ FCC Maisine® CC Peceol™ Plurol® Oleique CC 497 Transcutol® P	Apifil® Gelot™ 64 Sedefos™ 75 Tefose® 1500 Tefose® 63 Plurol® Diisostearique
Sustained release agents	Suspending agents	Gelucire® 43/01 Labrafac™ PG Labrafac™ Lipophile WL 1349 Peceol™ Ovucire® range Suppacire® range		Co-emulsifiers
Compritol® 888 ATO Precirol® ATO 5 Geleol™ Mono and Diglycerides NF	Labrafil® M 1944 CS Plurol® Oleique CC 497			Capryol® 90 Capryol® PGMC Emulcire™ 61 WL 2659 Labrafil® M 1944 CS Labrafil® M 2125 CS Labrafil® M 2130 CS Lauroglycol™ 90 Lauroglycol™ FCC Plurol® Oleique CC 497

Hart fat base, the basis for suppository success

Gattefossé range of Suppocire® enables the formulation of any drug. The choice of hard fat base is critical to ensure appropriate drug release. The following scheme provides an overview of hard fat selection based on API properties.





Supporting your product development

With a worldwide network of technical representatives and more than 20 high-level scientists and technicians in our Technical Centers of Excellence in China, France, India and the USA, we continuously work to deepen our understanding of excipients and drug behavior in the formulation and how it interacts with the mucosae.

Our laboratories are equipped with all material necessary for in-depth product characterization.

For suppository characterization, content uniformity, liquefaction time, disintegration time, slip melting temperature, mechanical resistance or drug release from suppository unit are routine tests.

We provide our customers with comprehensive documentation to support their product development, including generic dossiers, formulations, regulatory datasheets and precedence of use information.

Apifil®, Capryol®, Compritol®, Gelucire®, Labrafil®, Labrasol®, Maisine®, Ovucire®, Plurol®, Precirol®, Tefose®, Transcutol® and Suppocire® are registered trademarks of Gattefossé.

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GATTEFOSSÉ ● CORPORATE HEADQUARTERS

36 chemin de Genas - CS 70070 - 69804 Saint-Priest Cedex - France
+(33) 4 72 22 98 00

www.gattefosse.com



People make our name