

Boost your drug bioavailability with Labrafac™ MC60, glycerol monocaprylocaprate

For a better experience, download our brochure



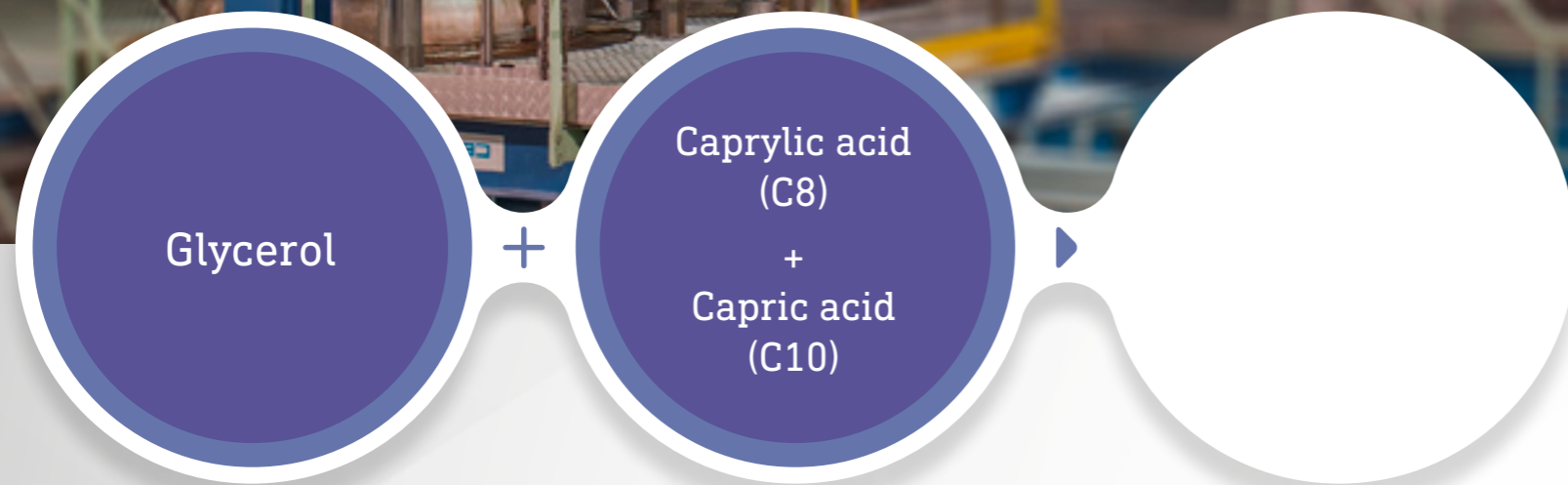


Product
description

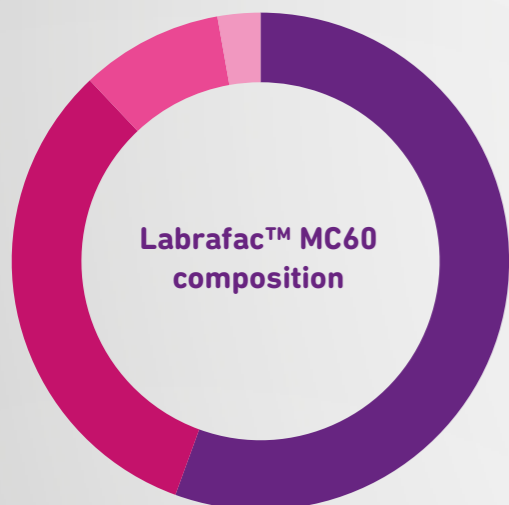




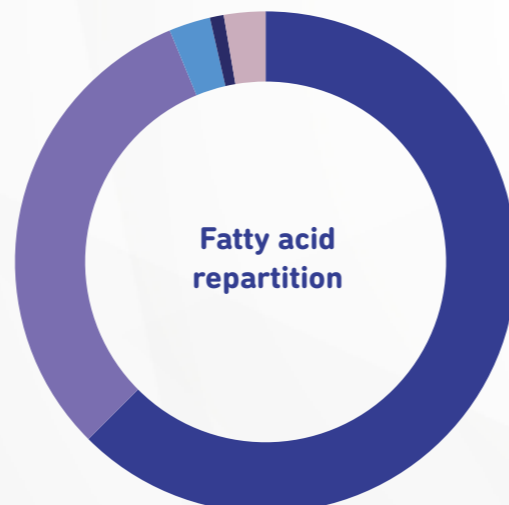
A well-defined multi-constituent excipient



A controlled esterification process

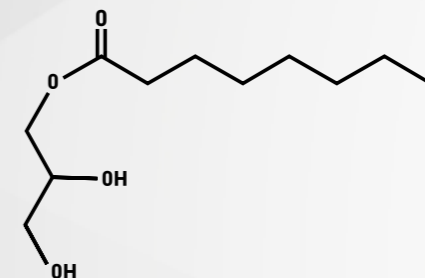


- Monoglycerides 45-75%
- Diglycerides 20-50%
- Triglycerides ≤10%
- Free glycerol ≤3%

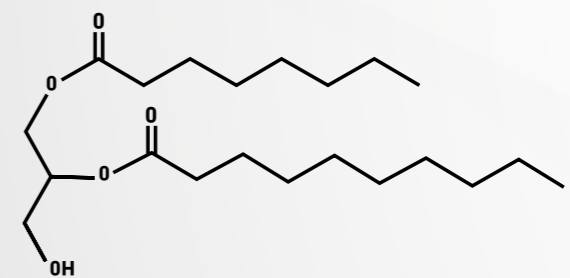


- C6 ≤3%
- C8 50-90%
- C10 10-50%
- C12 ≤3%
- C14 ≤1%

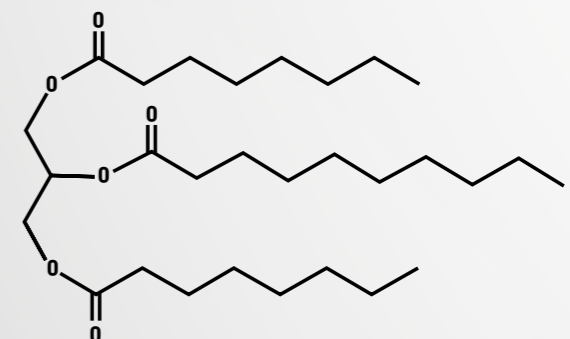
Monoglycerides



Diglycerides

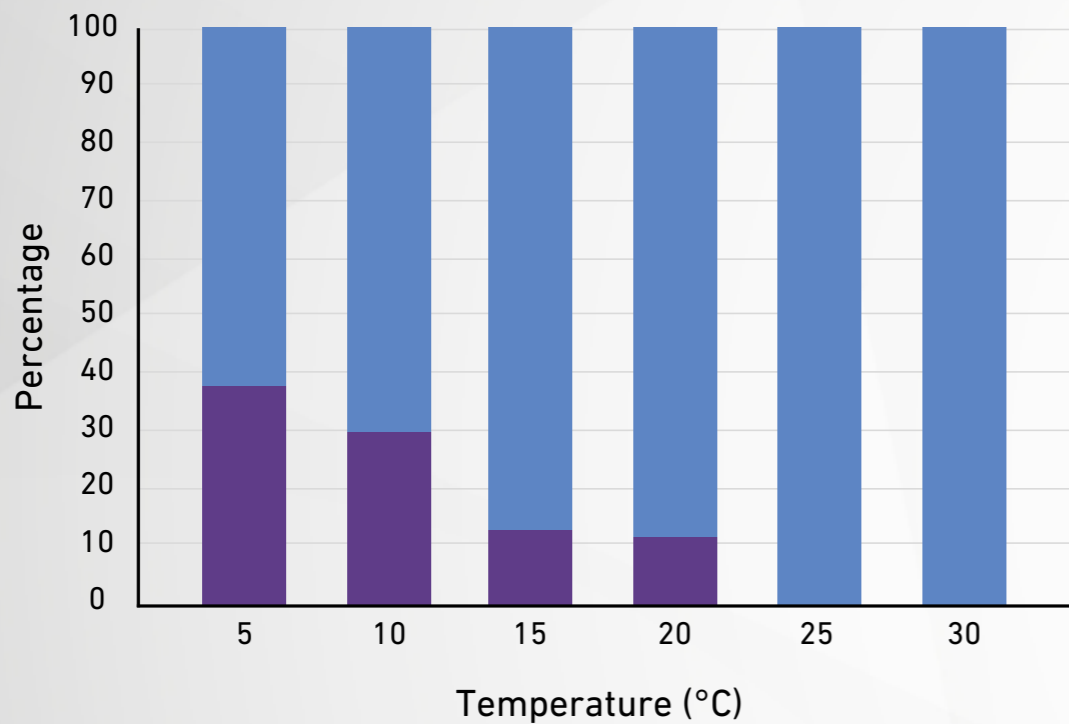


Triglycerides





A liquid excipient at 25°C



■ Liquid fat content
■ Solid fat content

**Labrafac™ MC60
solid and liquid fat
content repartition
vs temperature**

(NMR conditions: sample stored 1h at 0°C, then 12h at measurement temperature)

At 25°C, Labrafac™ MC60 is fully liquid. At 20°C, approximately 90% of Labrafac™ MC60 is liquid with the remaining fraction being crystallized. Therefore, partial crystallization may occur at 20°C.

Product handling



Heat (>40°C) before use to eliminate crystals if any



Flush the container with nitrogen after use



Physico-chemical properties



• Labrafac™ MC60 has co-surfactant properties due to its HLB_{PIT} of 6 ± 1 .

HLB_{PIT} (Nollet M., 2019)	6 ± 1
Viscosity (mPa.s)	120 at 20°C; 40 at 40°C
Relative density	1.006 at 20°C
Miscibility (25°C)	
Acetonitrile	Miscible
Ethanol 96°	Miscible
Methanol	Miscible
Water	$\geq 90\%$

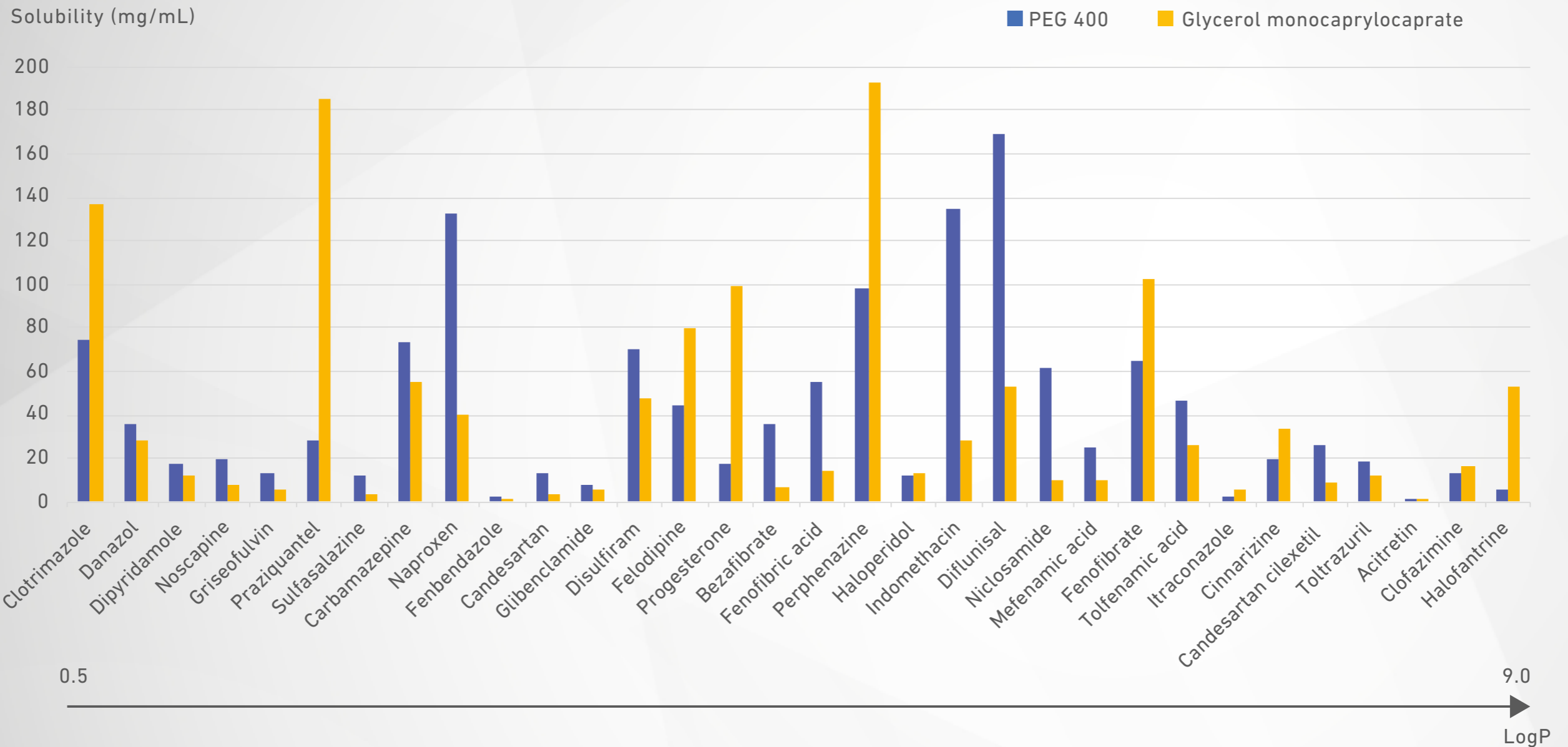


Product functionality





Good solubilizer for a wide range of molecules





Intestinal permeation enhancer

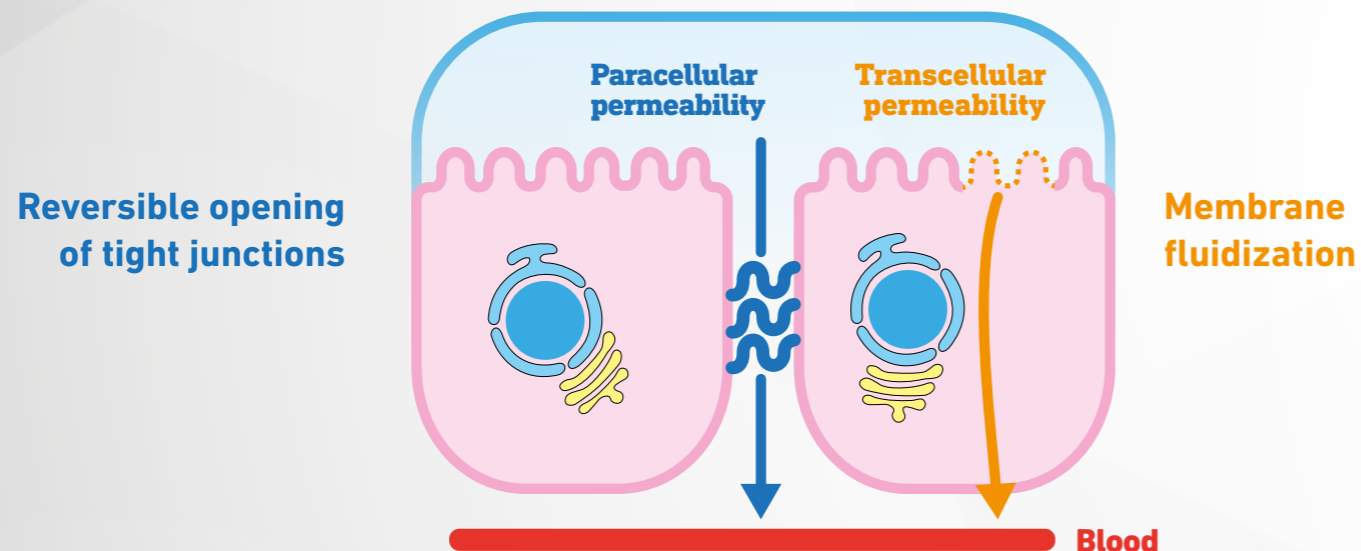
This excipient is reported to have permeation enhancing properties due to its high content of medium chain fatty acids.

The proposed mechanism of action of C8/C10 fatty acids is a combination of:

> Paracellular transport with the reversible opening of enterocytic tight junctions

> Transcellular transport due to membrane fluidization

Reported examples





Oral bioavailability enhancer

API	Increase in oral bioavailability	Reference
Atorvastatin calcium	3.45-fold for the SEDDS vs drug suspension	Yeom et al., 2015
Nisoldipine	2.4-fold for SMEDDS vs pure drug suspension	Nekkanti et al., 2016
Ticagrelor	6.4-fold for SMEDDS vs pure drug	Na et al., 2019
Valsartan	1.8-fold for SMEDDS vs capsule suspension	Dixit et al., 2010



More information on SEDDS development



Use in
lipid-based
formulations





Lipid-based formulation development

Solubilization of the entire therapeutic dose

in a **single excipient**

Oily formulation

> Dutasteride

in **several excipients**

SEDDS formulation

> Cinnarizine
> Terfenadine

Lipid-based formulations are designed for poorly water-soluble drugs with the aim to:

Solubilize the therapeutic dose

Maintain solubilization throughout the digestion process

Increase oral bioavailability

More information on how to develop lipid-based formulations



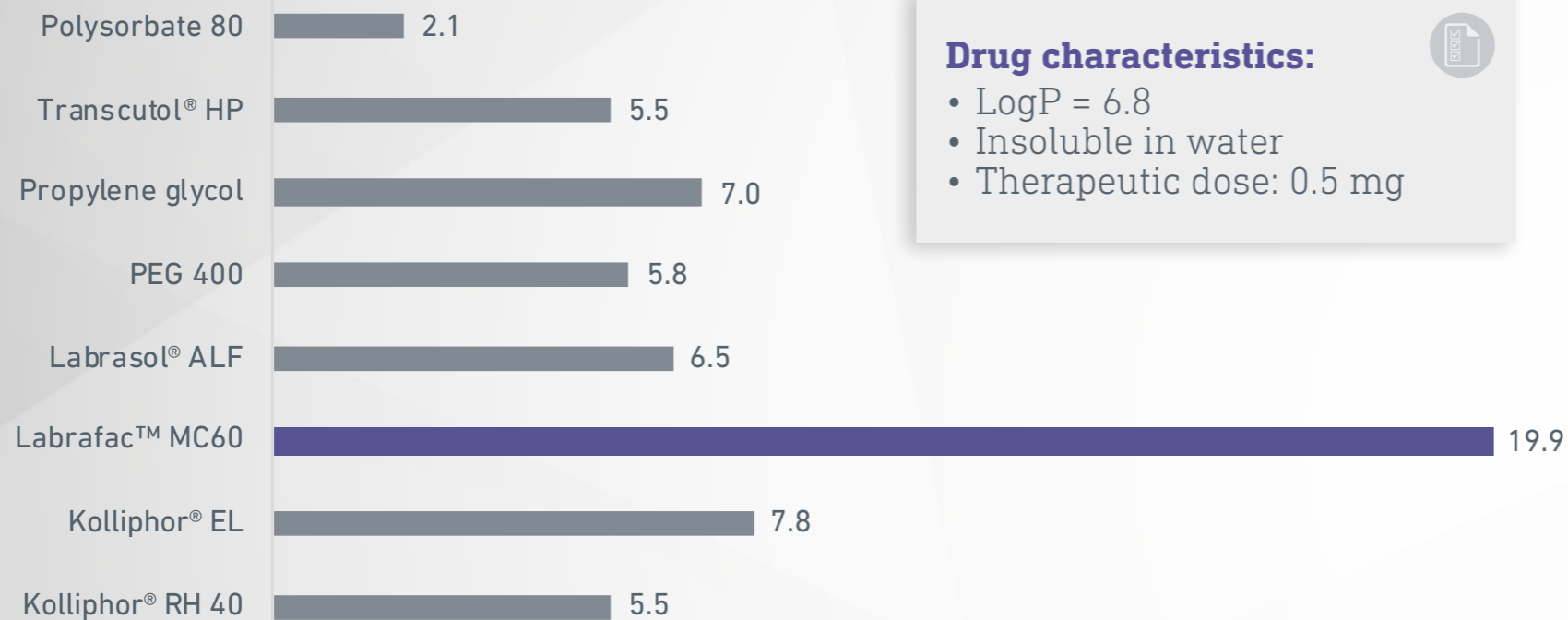


Use in lipid-based formulations

Oily formulations with dutasteride

Solubility screening

Best solubilizing performance for Labrafac™ MC60: ≈ 20 mg/mL



Dutasteride solubility in various excipients at 20°C (mg/mL)

Drug characteristics:

- LogP = 6.8
- Insoluble in water
- Therapeutic dose: 0.5 mg



Patient information leaflet

Active substance:

- dutasteride

Each soft capsule contains 0.5 mg dutasteride.

Inactive excipients:

- inside the capsule: **mono and diglycerides of caprylic/capric acid** and butylated hydroxytoluene
- capsule shell: gelatin, glycerol, titanium dioxide, iron oxide yellow, triglycerides (medium chain), lecithin (may contain soya oil)



More information on Gattefossé method for solubility screening

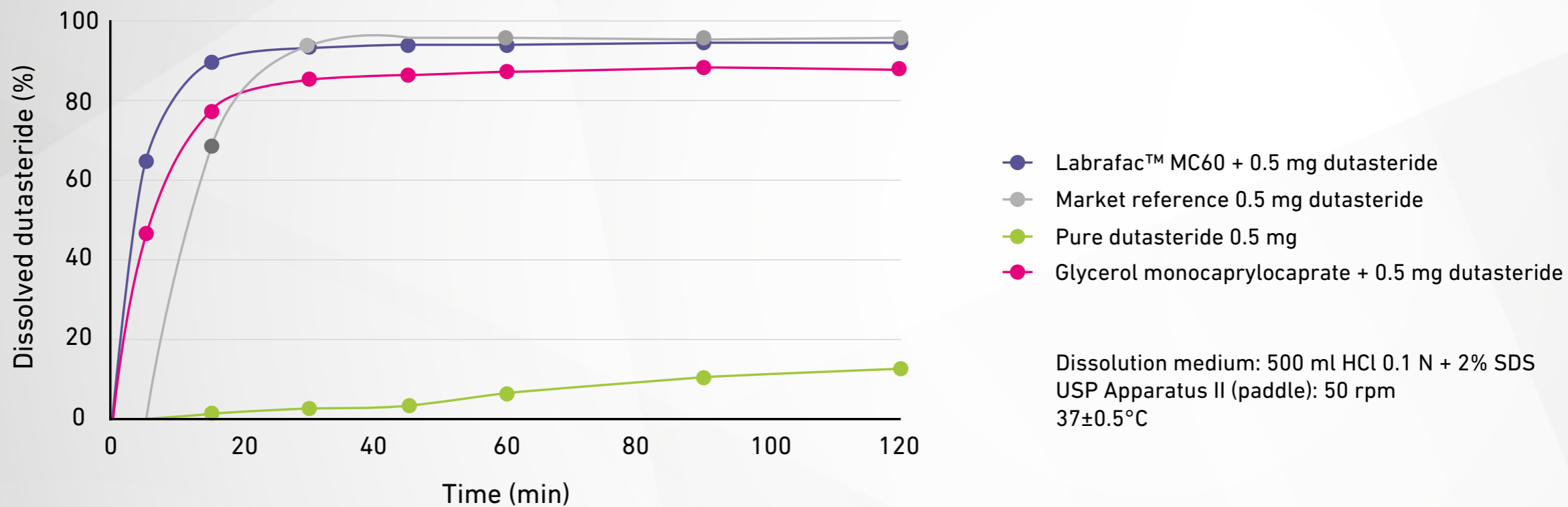




Oily formulations with dutasteride

In vitro dissolution test at 37°C

Similar performance for Labrafac™ MC60 formulation and market reference



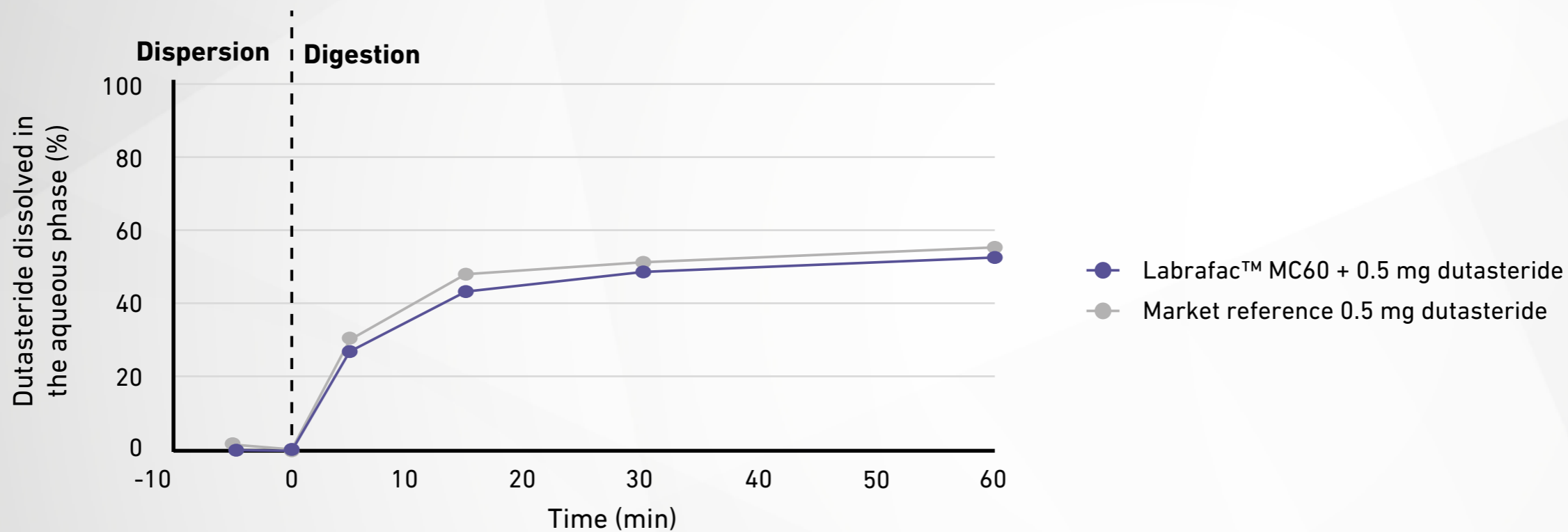


Use in lipid-based formulations

Oily formulations with dutasteride

In vitro lipolysis at 37°C

Equivalent performance for Labrafac™ MC60 formulation and market reference



More information on Gattefossé method for in vitro lipolysis



SEDDS with cinnarizine

Drug characteristics

- Highly lipophilic drug: LogP = 5.9
- Practically insoluble in water
- Commercial product strength: 25 to 75 mg



SEDDS formulation

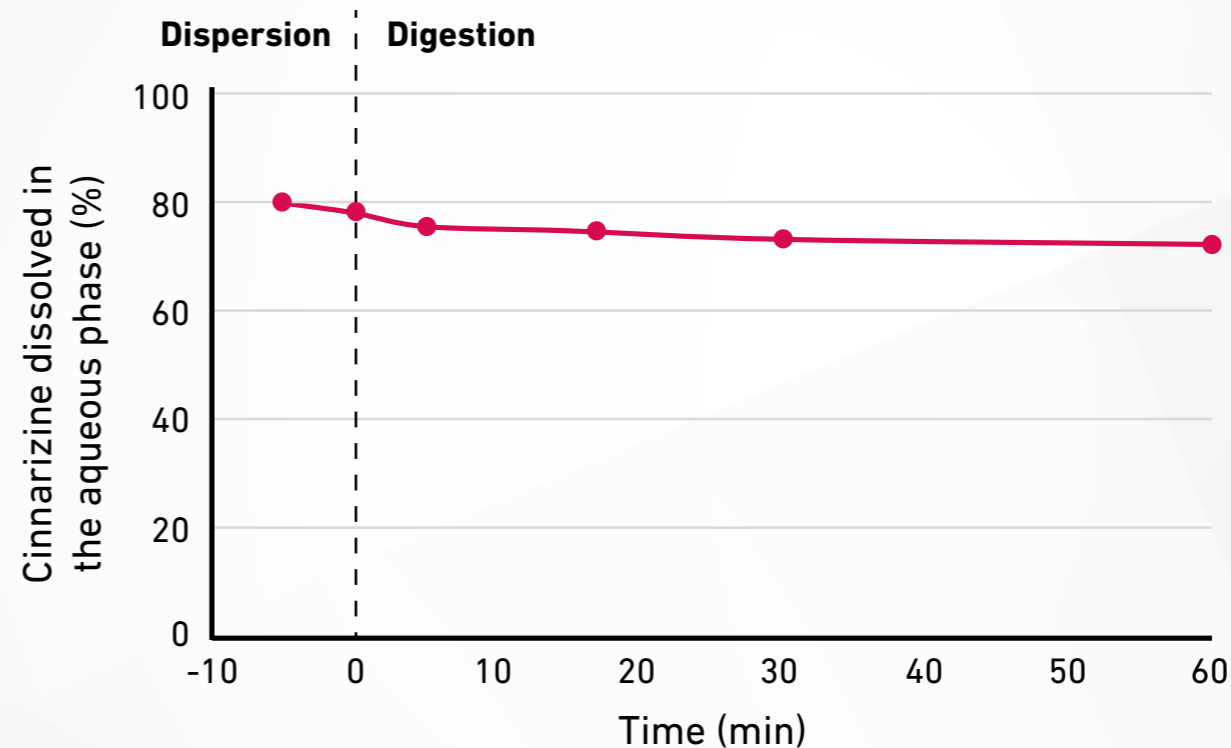
- 75% Kolliphor® EL
- 10% Labrafac™ MC60
- 15% Maisine® CC
- 25 mg of cinnarizine per gram of SEDDS



Drug solubility in individual excipients

	Solubility at 37°C (mg/mL)
Labrafac™ MC60	30.0
Kolliphor® EL	19.6
Maisine® CC	18.8

In vitro lipolysis at 37°C



The SEDDS formulation was able to successfully maintain cinnarizine in solution during lipolysis.



SEDDS with terfenadine

Drug characteristics

- Highly lipophilic drug: LogP = 6.5
- Practically insoluble in water
- Commercial product strength: 30 to 60 mg



SEDDS formulation

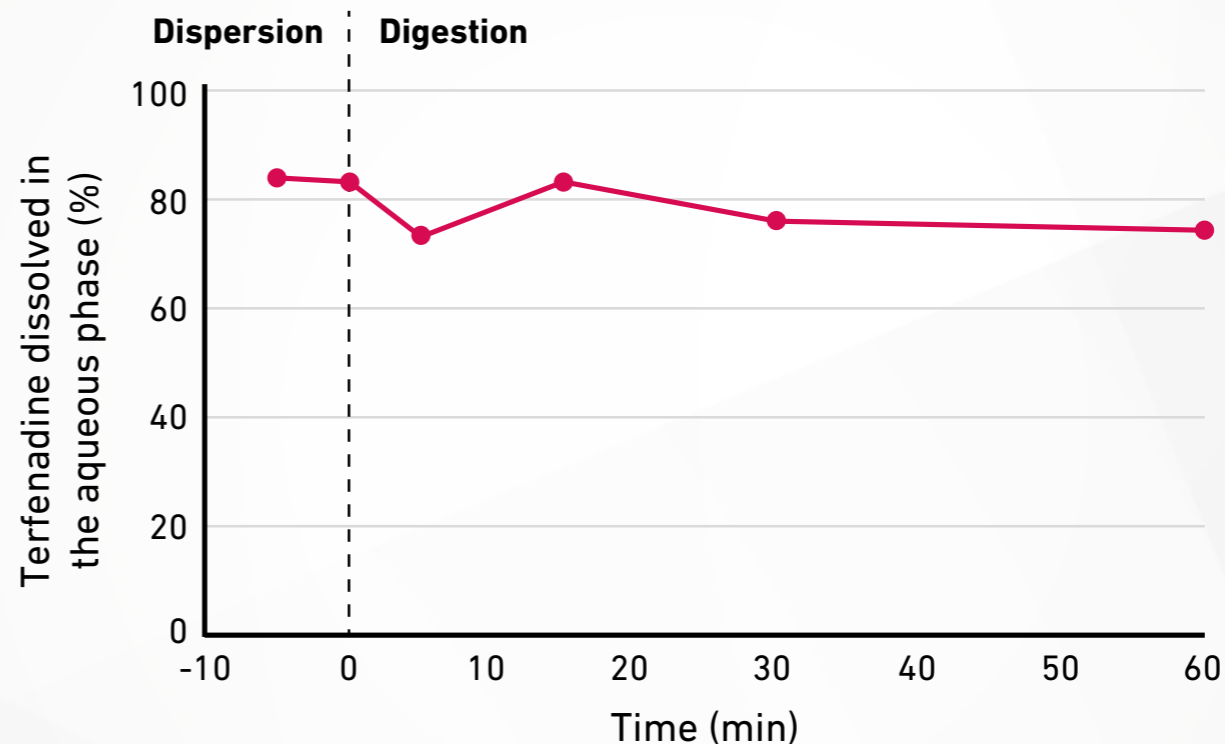
- 45% Kolliphor® RH 40
- 40% Capryol® 90
- 15% Labrafac™ MC60
- 30 mg of terfenadine per gram of SEDDS



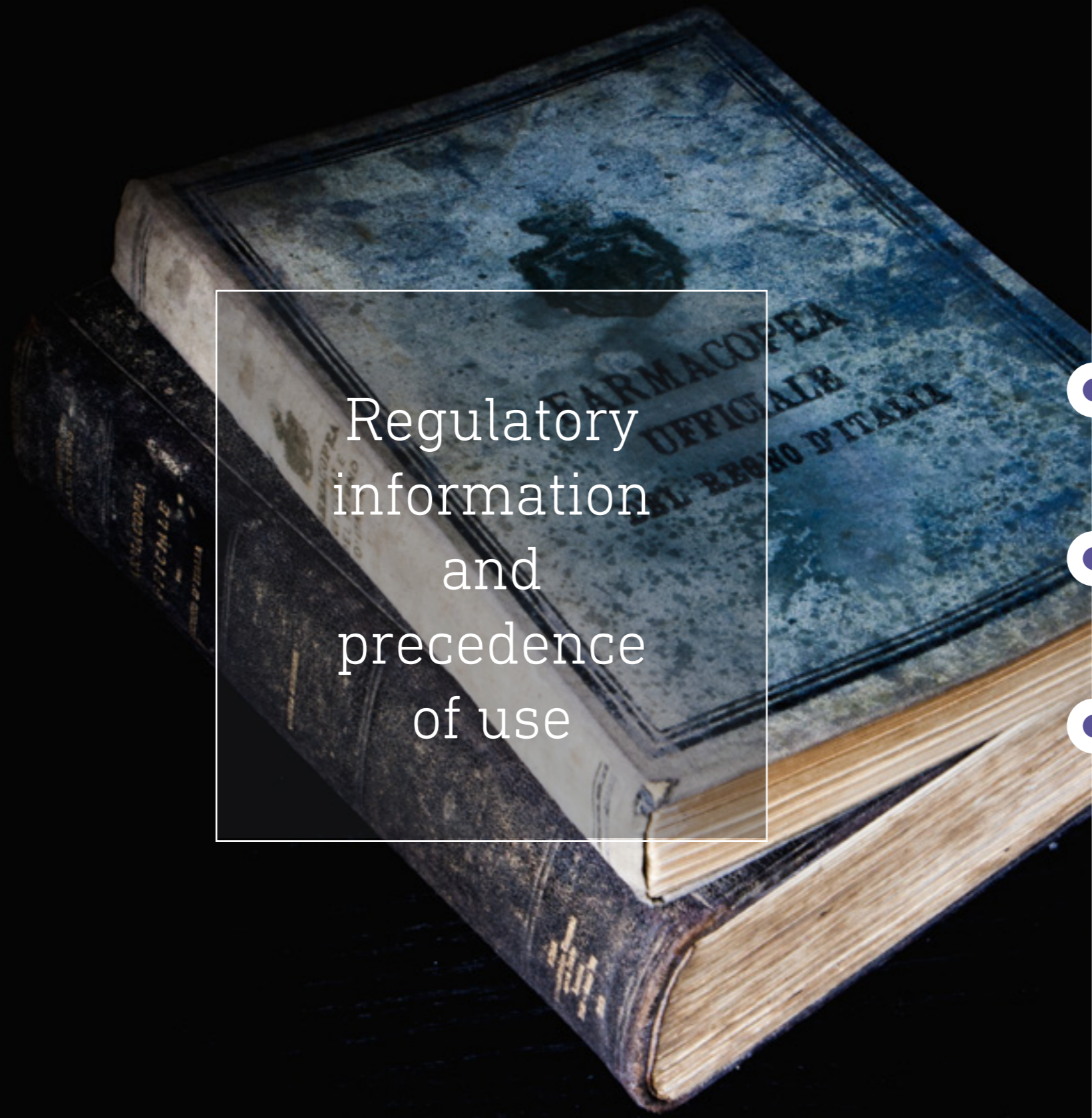
Drug solubility in individual excipients

	Solubility at 37°C (mg/mL)
Capryol® 90	61.8
Labrafac™ MC60	39.6
Kolliphor® RH40	21.5

In vitro lipolysis at 37°C

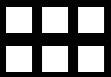


The SEDDS formulation was able to successfully maintain terfenadine in solution during lipolysis.



Regulatory
information
and
precedence
of use





A multi-compendial excipient

USP-NF



Glyceryl Mono and Dicaprylocaprate
[NOTE – May also be labeled as USP Glyceryl Monocaprylocaprate (Type I) until May 1, 2025]

Ph. Eur.



Glycerol monocaprylocaprate (Type I)

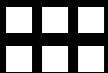
FDA
Substance Registration System



UNII: U72Q2I8C85



other
names



Maximum potency per unit dose (IID)

Chemical equivalent

- Glyceryl mono and dicaprylocaprate (U72Q218C85)
- Capsule: 765 mg
- Solution: 30 mg/mL
- Tablet: 1.3 mg

Most similar chemical

(read across approach)

- Glyceryl monocaprylate (TM2TZD4G4A)
- Glyceryl monocaprylocaprate (G7515SW10N)
- Capsule: 400 mg
- Capsule: 347.5 mg
- Solution: 349.1 mg/mL



Examples of commercial products

(Source: Pharmacricle)

Soft gelatine capsules

- Ciclosporin
- Dutasteride
- Loperamide hydrochloride

Capsules

- Dutasteride
- Tamsulosin hydrochloride and dutasteride
- Esomeprazole magnesium trihydrate
- Esomeprazole magnesium

Tablets

- Ibuprofen and hydrocodone bitartrate
- Emtricitabine and tenofovir disoproxil
- Fumarate
- Ezetimibe and bempedoic acid
- Potassium chloride
- Metoprolol succinate
- Ibuprofen and paracetamol
- Mycophenolic acid
- Chlorpromazine hydrochloride
- Leflunomide
- Sirolimus
- Fesoterodine fumarate
- Tiopronin

Oral powder for suspension

- Colesevelam hydrochloride



Technical support





For technical support
and more information

www.gattefosse.com

Contact us



Labrafac™ MC60 in a nutshell

- ▶ Labrafac™ MC60, Glycerol monocaprylocaprate (type I) EP / Glyceryl Mono and Dicaprylocaprate NF
- ▶ Used to increase oral bioavailability of drugs thanks to:
 - High solubilizing capacity
 - Intestinal permeation enhancing effect
- ▶ Used in lipid-based formulations type I, II and III



References

[Bandivadeka, Mithun Mohanrao](#); Pancholi, Shyam Sundar; Kaul-Ghanekar, Ruchika; Choudhari, Amit; Koppikar, Soumya (2012) Self-microemulsifying smaller molecular volume oil (Capmul MCM) using non-ionic surfactants. A delivery system for poorly water-soluble drug. In : *Drug Development and Industrial Pharmacy*, vol. 38, n° 7, p. 883–892. DOI: 10.3109/03639045.2011.631548.

[Brayden, David J.](#); Gleeson, John; Walsh, Edwin G. (2014) A head-to-head multi-parametric high content analysis of a series of medium chain fatty acid intestinal permeation enhancers in Caco-2 cells. In : *European journal of pharmaceuticals and biopharmaceutics : official journal of Arbeitsgemeinschaft fur Pharmazeutische Verfahrenstechnik e.V.*, vol. 88, n° 3, p. 830–839. DOI: 10.1016/j.ejpb.2014.10.008.

[Brayden, David J.](#); Maher, Sam; Bahar, Bojlul; Walsh, Edwin (2015) Sodium caprate-induced increases in intestinal permeability and epithelial damage are prevented by misoprostol. In : *European journal of pharmaceuticals and biopharmaceutics : official journal of Arbeitsgemeinschaft fur Pharmazeutische Verfahrenstechnik e.V.*, vol. 94, p. 194–206. DOI: 10.1016/j.ejpb.2015.05.013.

[Dixit, Adhvait R.](#); Rajput, Sadhana J.; Patel, Samir G. (2010) Preparation and bioavailability assessment of SMEDDS containing valsartan. In : *AAPS PharmSciTech*, vol. 11, n° 1, p. 314–321. DOI: 10.1208/s12249-010-9385-0.

[Heade, Joanne](#); Maher, Sam; Bleiel, Sinead B.; Brayden, David J. (2018) Labrasol® and salts of medium chain fatty acids can be combined in low concentrations to increase the permeability of a macromolecule marker across isolated rat intestinal mucosae. In : *Journal of pharmaceutical sciences*, vol. 107, n° 6, p. 1648–1655. DOI: 10.1016/j.xphs.2018.02.012.

[Mahmood, Arshad](#); Prüfert, Felix; Efiana, Nuri Ari; Ashraf, Muhammad Imtiaz; Hermann, Martin; Hussain, Shah; Bernkop-Schnürch, Andreas (2016) Cell-penetrating self-nanoemulsifying drug delivery systems (SNEDDS) for oral gene delivery. In : *Expert opinion on drug delivery*, vol. 13, n° 11, p. 1503–1512. DOI: 10.1080/17425247.2016.1213236.

[McCartney, Fiona](#); Gleeson, John P.; Brayden, David J. (2016) Safety concerns over the use of intestinal permeation enhancers. A mini-review. In : *Tissue barriers*, vol. 4, n° 2, e1176822. DOI: 10.1080/21688370.2016.1176822.

[Na, Young-Guk](#); Byeon, Jin-Ju; Wang, Miao; Huh, Hyun Wook; Son, Gi-Ho; Jeon, Sung-Hoon et al. (2019) Strategic approach to developing a self-microemulsifying drug delivery system to enhance antiplatelet activity and bioavailability of ticagrelor. In : *International Journal of Nanomedicine*, vol. 14, p. 1193–1212. DOI: 10.2147/IJN.S190426.

[Nekkanti, Vijaykumar](#); Rueda, Javier; Wang, Zhijun; Betageri, Guru (2016) Comparative evaluation of proliposomes and self micro-emulsifying drug delivery system for improved oral bioavailability of nisoldipine. In : *International Journal of Pharmaceuticals*, vol. 505, n° 1, p. 79–88. DOI: 10.1016/j.ijpharm.2016.03.065.

[Nollet, M.](#); Boulghobra, H., Calligaro, E., Rodier, J-D. (2019) An efficient method to determine the Hydrophile-Lipophile Balance of surfactants using the phase inversion temperature deviation of CiEj/n-octane/water emulsions. *Int J Cosmet Sci*, 41: 99-108.

[Nornoo, Adwoa O.](#); Zheng, Haiyan; Lopes, Luciana B.; Johnson-Restrepo, Boris; Kannan, Kurunthachalam; Reed, Rachel (2009) Oral microemulsions of paclitaxel. In situ and pharmacokinetic studies. In : *European journal of pharmaceuticals and biopharmaceutics : official journal of Arbeitsgemeinschaft fur Pharmazeutische Verfahrenstechnik e.V.*, vol. 71, n° 2, p. 310–317. DOI: 10.1016/j.ejpb.2008.08.015.

[Patel, Vandana](#); Kukadiya, Hirenkumar; Mashru, Rajshree; Surti, Naazneen; Mandal, Surjyanarayan (2010) Development of microemulsion for solubility enhancement of clopidogrel. In : *Iranian journal of pharmaceutical research : IJPR*, vol. 9, n° 4, p. 327–334.

[Pouton, Colin W.](#) (2000) Lipid formulations for oral administration of drugs. Non-emulsifying, self-emulsifying and 'self-microemulsifying' drug delivery systems. In : *European Journal of Pharmaceutical Sciences*, vol. 11, S93-S98. DOI: 10.1016/S0928-0987(00)00167-6.

[Rajpoot, Pooja](#); Bali, Vikas; Pathak, Kamla (2012) Anticancer efficacy, tissue distribution and blood pharmacokinetics of surface modified nanocarrier containing melphalan. In : *International Journal of Pharmaceutics*, vol. 426, n° 1-2, p. 219–230. DOI: 10.1016/j.ijpharm.2012.01.027.

[Sarkar, Biresch](#); Hardenia, S. S. (2011) Microemulsion drug delivery system : for oral bioavailability enhancement of glipizide. In : *Journal of Advanced Pharmacy Education and Research*, vol. 1, n° 4, p. 195–200.

[Solanki, Shailendra Singh](#); Sarkar, Brajesh; Dhanwani, Rakesh Kumar (2012) Microemulsion drug delivery system. For bioavailability enhancement of ampelopsin. In : *ISRN pharmaceuticals*, vol. 2012, p. 108164. DOI: 10.5402/2012/108164.

[Twarog, C.](#); Fattah, S.; Heade, J.; Maher, S.; Fattal, E.; & Brayden, D. J. (2019). Intestinal permeation enhancers for oral delivery of macromolecules: a comparison between salcaprozate sodium (SNAC) and sodium caprate (C10). *Pharmaceutics*, 11(2), 78.

[Yadav, Pankajkumar S.](#); Yadav, Ekta; Verma, Amita; Amin, Saima (2014) Development, characterization, and pharmacodynamic evaluation of hydrochlorothiazide loaded self-nanoemulsifying drug delivery systems. In : *TheScientificWorldJournal*, vol. 2014, p. 274823. DOI: 10.1155/2014/274823.

[Yellepeddi, Venkata K.](#); Mohammadpour, Raziye; Kambhampati, Siva P.; Sayre, Casey; Mishra, Manoj K.; Kannan, Rangaramanujam M.; Ghandehari, Hamidreza (2018) Pediatric oral formulation of dendrimer-N-acetyl-L-cysteine conjugates for the treatment of neuroinflammation. In : *International Journal of Pharmaceutics*, vol. 545, n° 1-2, p. 113–116. DOI: 10.1016/j.ijpharm.2018.04.040.

[Yeom, Dong Woo](#); Song, Ye Seul; Kim, Sung Rae; Lee, Sang Gon; Kang, Min Hyung; Lee, Sangkil; Choi, Young Wook (2015) Development and optimization of a self-microemulsifying drug delivery system for atorvastatin calcium by using D-optimal mixture design. In : *International Journal of Nanomedicine*, vol. 10, p. 3865–3877. DOI: 10.2147/IJN.S83520.

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