VIO CHEMICALS

OUR SCIENCE, YOUR PRODUCT

Sodium glycocholate & Glycocholic acid

Key ingredients for improved drug delivery

ADVANTAGES

Recently, there has been a growing use of bile acids and their derivatives as absorption enhancers for drug delivery. Due to their high solubility, bile acid derivatives act as emulsifying agents and drug carriers in the form of mixed micelles, bilosomes and chemical conjugates with drug molecules.

Sodium glycocholate and Glycocholic acid, together with soy phosphatidylcholine, have frequently been used in mixed micelles dosage forms for intravenous administration.

The role of bile acid derivatives in promoting drug permeation has been experimentally illustrated in various pharmaceutical formulations. Applications include oral, nasal, occular, pulmonary and rectal drug delivery, as well as parenteral techniques to overcome the blood-brain-barrier.

VIO Chemicals offers Sodium glycocholate and Glycocholic acid as advanced bile acid components for robust drug formulation and delivery.

FEATURES

- Excellent biocompatibility
- Natural emulsifying ability
- Amphiphilicity
- High aqueous solubility

BENEFITS

The use of mixed micelles of bile acids as solubilizers has great benefits for drug formulation and delivery:

- They are biocompatible
- They are natural components of the blood
- They are available in parenteral quality
- They are easy to manufacture
- And, unlike synthetic solubilizers, they do not bear any risks for anaphylactic reactions.

APPLICATIONS

Mixed micelles formulations based on Sodium glycocholate or Glycocholic acid are used in several injectable products to solubilize poorly water soluble drug substances for intravenous administration, such as Konakion MM®, Rycarfa®, Cernevit®, Phosphogliv® and many more.

VIO CHEMICALS AG
Dufourstrasse 107
CH-8008 Zurich
Switzerland

@VIOChemicals
/VIO Chemicals
www.viochemicals.com

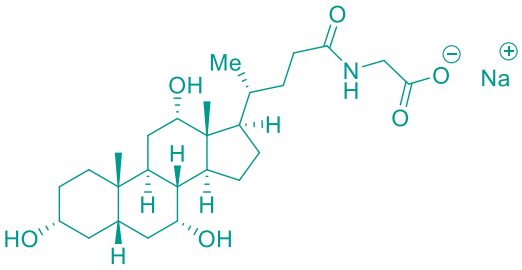
VIO CHEMICALS

OUR SCIENCE, YOUR PRODUCT

TECHNICAL PROFILE

- Technical name: Sodium glycocholate
- CAS No: 863-57-0
- Empirical formula: $C_{26}H_{42}NNaO_6$
- Molecular weight: 487.60

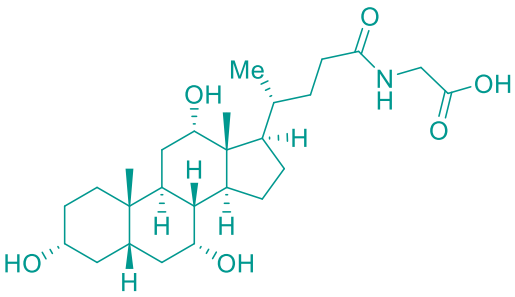
CHEMICAL STRUCTURE



TECHNICAL PROFILE

- Technical name: Glycocholic acid
- CAS No: 475-31-0
- Empirical formula: $C_{26}H_{43}NO_6$
- Molecular weight: 465.62

CHEMICAL STRUCTURE



TEST	SPECIFICATION
Appearance	White to white creamed powder, odourless or practically odourless
Identification	
IR	has to confirm with reference material
TLC	has to confirm with reference material
Specific optical rotation (2.5% (w/v) in water)	For Sodium: 28.0° to 31.0° For Acid: 29.5° to 33.5°
Assay (calculated on dried substance)	For Sodium: 98.5% to 101.0% For Acid: 98.0% to 101.0%
Water content	max. 7.0%
Sulphated ash	For Sodium: 12.5% to 15.5% For Acid: max. 0.2%
Heavy metals	max. 20 ppm
Hg	max. 1 ppm
As and Fe	max. 3 ppm
Cd, Cu and Pb	max. 2 ppm
Co, Cr, Mn, Mo, Ni, Pd, Pt, V, Zn	max. 5 ppm
Ir + Rh + Ru + Os	max. 5 ppm
Related impurities	
Sodium cholate / Cholic acid	max. 1.0%
Sodium glycodeoxycholate / Glycodeoxycholic acid	max. 0.3%
Sodium glycilglycocholate / Glycilglycocholic acid	max. 1.0%
Glycine	max. 0.5%
Total other unspecified impurities	max. 0.5%
Residual solvents	has to comply with ICH Q3C
Microbiological burden	TAMC max. 100 CFU/g TYMC max. 10 CFU/g
Specific microorganisms	Escherichia coli, absent in 1 g Staphylococcus aureus, absent in 1 g Pseudomonas aeruginosa, absent in 1 g Candida albicans, absent in 1 g Salmonella, absent in 1 g
Bacterial endotoxins	max. 15 iU/g
TSE/BSE contamination	Supplier declaration or valid CEP

Products which are subject to patent protection are currently not offered or made available in countries where patents are in force. No orders or deliveries are possible prior to the expiry date of valid patents.

For inquiries, contact us on +41 44 380 24 44 or send us an e-mail at info@viochem.com