Highly pure PEGs and mPEGs

Custom PEG specialties to meet the highest standards

Evonik offers a unique combination of skills essential to the development and manufacture of highly pure PEGs and mPEGs for pharmaceutical applications.

- Decades of experience handling ethylene oxide for the development and production of polyethylene glycol (PEG) for many industries.
- An integrated global network of sites in Germany and the USA.
- Decades of experience in API production.
- Professional and transparent project management for exclusive projects from one of the leading CMOs.
- Long track record in cGMP production at FDA-inspected production sites.

PEG and mPEG synthesis

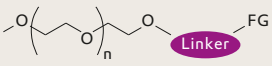
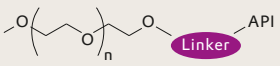
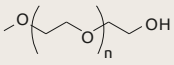
Since 2017, Evonik has operated a specialized plant to produce PEGs for pharmaceutical applications in Hanau, Germany.

- In-house development
- High flexibility for new PEG specialties
- Kg scale production

Offering the whole value chain

Evonik offers the whole value chain for pegylated APIs:

- In-house production of PEG and mPEG specialties
- Linker synthesis and activation
- API synthesis
- Conjugation

1. mPEG SYNTHESIS	2. mPEG ISOLATION	3. mPEG ACTIVATION	4. mPEG CONJUGATION
Different Grades	Analytical measurements	mPEG Functionalization	mPEG-API
2.000 Da	SEC		
5.000 Da	MALDI-TOF		e.g. mPEG-Insulin
10.000 Da	NMR		
15.000 Da	HPLC		
20.000 Da	IR		
30.000 Da	Karl-Fischer	FG = Functional Group	
...			
			

EVONIK
Leading Beyond Chemistry

Activation and conjugation

- Activation and linker synthesis under cGMP at Evonik sites in Germany and the USA.
- Conjugation development in our conjugation lab in Hanau, Germany.
- Further PEGylation development and manufacturing capabilities available at Birmingham, USA (including fill & finish).

PEGs and mPEGs for pharmaceutical applications

Large variety of PEG and mPEG specialties meeting the highest quality requirements:

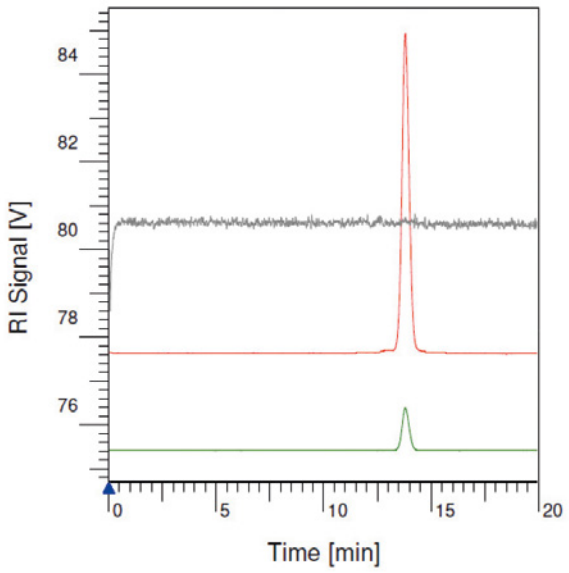
- Polydispersity (Mw/Mn): ≤ 1.05
- Diol content (mPEG): < 1.0%
- Average molecular weight: +/- 5%

Complete analytical setup

Our facilities offer a complete analytical setup for PEGs and mPEGs. This includes the following capabilities:

- Average molecular weight per SEC/GPC and/or MALDI-TOF
- Polydispersity (PDI) per SEC/GPC
- Assay and purity determined per NMR and/or HPLC (CAD, ELSD)
- Diol content (for substituted PEGs) per HPLC (CAD, ELSD)
- GC for residual solvents
- X-Ray Powder Diffraction (XRPD)
- Thermal: DSC, TGA, TG-IR, bomb calorimetry

Example of a highly pure mPEG with a PDI of 1.03



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