MilliporeSigma

Polyvinyl alcohol for hot melt extrusion

Parteck® MXP: two polymers, unparalleled value.

With two specifically engineered grades of polyvinyl alcohol, our Parteck® MXP polymers are optimal for generating high performing, solubility enhanced formulations via hot melt extrusion.

SAFC®

Pharma & Biopharma Raw Material Solutions

Enhancing drug solubility

Parteck® MXP polyvinyl alcohol for HME

Poor active pharmaceutical ingredient (API) solubility is a critical challenge in drug development. One formulation technique to increase solubility and, consequently, improve bioavailability of drugs is hot melt extrusion (HME). With this technology, the API is dispersed within a polymer matrix to form an amorphous solid dispersion. Hot melt extrusion is a solvent-free process and so also provides unique benefits from a sustainability perspective.

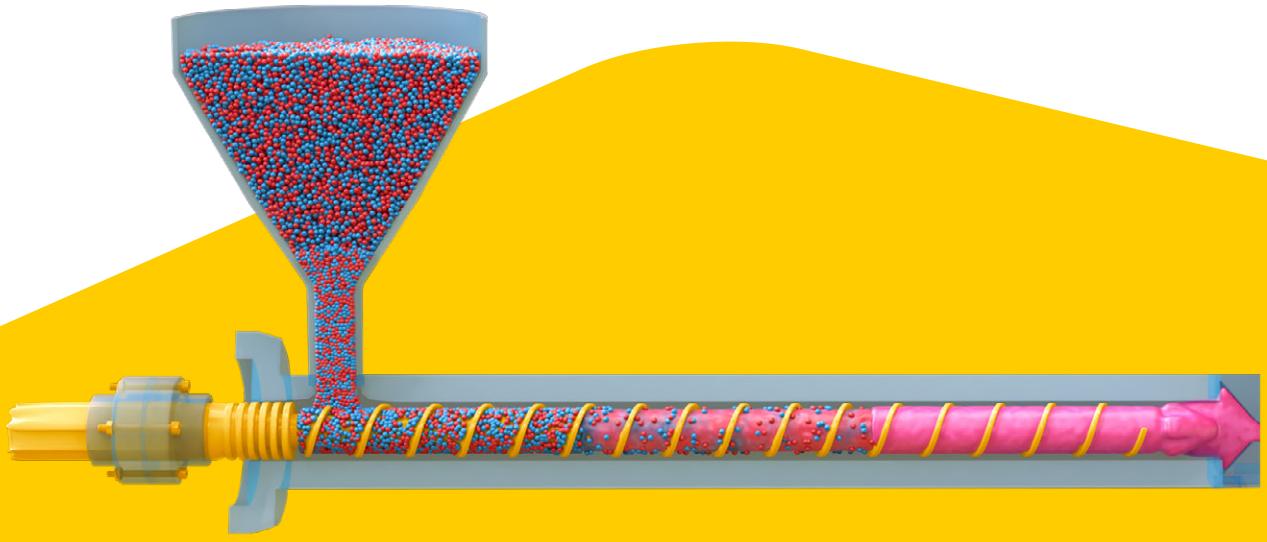
Polyvinyl alcohol (PVA), from a chemical perspective, is ideal for application in HME due to its capabilities in stabilization of amorphous APIs, solubility enhancement, and precipitation inhibition. From a regulatory and safety perspective, PVA has a strong track record in oral solid dosage forms and is Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration.

Our Parteck® MXP range, Parteck® MXP 3-82 and Parteck® MXP 4-88, has been specifically designed with HME performance in mind.

Low melt viscosity, prolongation of supersaturation and the ability to stabilize active APIs over a broad temperature range are important assets of the Parteck® MXP range. Finally, both of our Parteck® MXP products come supported with extensive and market leading Emprove® dossiers of quality information.

Interested in learning more?

You can count on our extensive global network of scientists, engineers, regulatory experts and state-of-the-art Application Service Labs to support you in your request.



Graphical representation of the Hot Melt Extrusion Process

Parteck® MXP 3-82 polymer

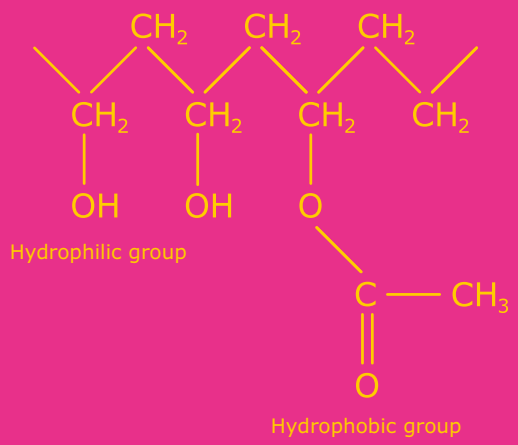
Key parameters

Parameters	Ranges
Angle of repose [°]	30 – 31
Bulk density [g/mL]	0.6
Tapped density [g/mL]	0.8 – 0.9
Particle size d_v(0.10) [µm]	**22 – 32**
Particle size d_v(0.50) [µm]	**70 – 90**
Particle size d_v(0.90) [µm]	**140 – 22**
pH value of 4 % solution	5.0 – 6.5
Hydrolysis degree [%]:	80 – 82
Mass average molar mass Mw [g/mol]	47000

Presented values are considered for technical information only.

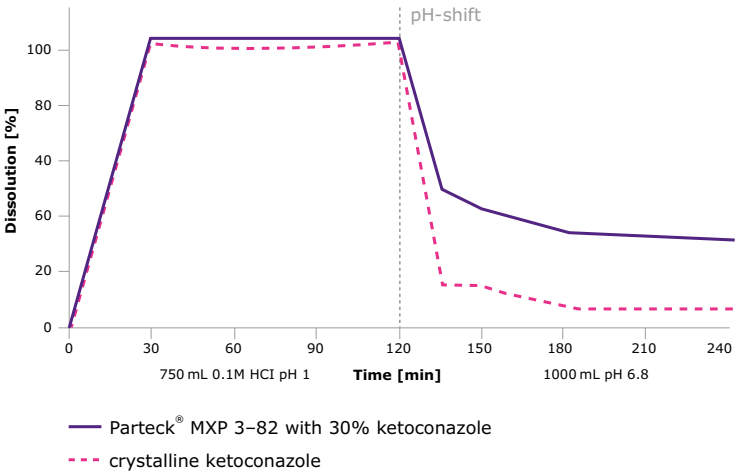
With a lower degree of hydrolysis along the PVA chain, Parteck® MXP 3-82 polyvinyl alcohol is especially beneficial in forming strong interactions with hydrophobic drug molecules – in the solid state and in solution. Due to this, Parteck® MXP 3-82 excipient has very high capabilities as a precipitation inhibitor and can maintain high levels of supersaturation for physiologically relevant timescales. As a result, Parteck® MXP 3-82 polyvinyl alcohol can provide solubility enhancement for even the most challenging molecules. Furthermore, Parteck® MXP 3-82 is compliant with Ph. Eur.

Polyvinyl alcohol structure



The PVA grade naming convention (e.g. 4-88) specifies the apparent viscosity in mPa • s of a 4 % aqueous solution at 20 °C (first number) and the hydrolysis grade (second number). So, Parteck® MXP 3-82 shows a viscosity of 3 mPa • s and a hydrolysis grade of 82 %, while Parteck® MXP 4-88 shows a viscosity of 4 mPa • s and a hydrolysis grade of 88 %.

Parteck® MXP 3-82 dissolution with a strong precipitation inhibition profile



There's no such thing as a one-size-fits all formulation, all APIs have individual and specific needs. With our two grades of polyvinyl alcohol for hot melt extrusion, we provide you with the possibility to fine tune your formulation to your specific API.

Parteck® MXP 4-88 polymer

Key parameters

Parameters	Ranges
Angle of repose [°]	35
Bulk density [g/mL]	0.53
Tapped density [g/mL]	0.74
Particle size d_v(0.10) [µm]	**17 – 35**
Particle size d_v(0.50) [µm]	**59 – 79**
Particle size d_v(0.90) [µm]	**137 – 156**
pH value of 4 % solution	5.0 – 6.5
Hydrolysis degree [%]:	85 – 89
Mass average molar mass Mw [g/mol]	32000

Presented values are considered for technical information only.

With a hydrolysis grade of 88 %, Parteck® MXP 4-88 polyvinyl alcohol is more hydrophilic, which provides unique benefits for stabilization of certain molecules in the amorphous form. Furthermore, with a uniquely high thermal application range, Parteck® MXP 4-88 excipient can be utilized for molecules across a broad range of melting temperatures while still providing strong performance, including those classically seen as unsuitable for extrusion due to high melting points.

Application range

API	T_m of API [°C]	Loading [%]	Solubility Enhancement (max.)**
Ibuprofen*	78	min. 30	2-fold
Cinnarizine	118 – 122	20	10-fold
Indomethacin	151	min. 50	3-fold
Ketoconazole	**146**	**min. 35**	**17-fold**
Naproxen	152	min. 30	4-fold
Atorvastatin	**159 – 160**	**min. 55**	**154-fold**
Itraconazole	166.5	min. 30	80-fold
Carbamazepine	204 – 206	30	2-fold
Telmisartan*	260	min. 15	35-fold

*Plasticizer is required to make the extrusion feasible or easier.
**Dissolution studies were performed using recommended conditions from the FDA.

Parteck® MXP Polymers Provide:

Optimal performance

Our Parteck® MXP product range is designed for HME, supporting superior process development.

High thermal stability

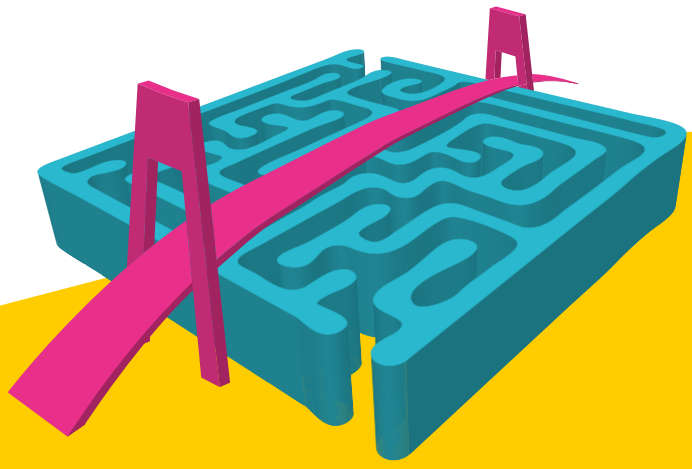
Parteck® MXP polymers are resistant to high extrusion temperatures, extending the potential application range.

Stable, high drug loads

Parteck® MXP polyvinyl alcohol is able to stabilize a range of molecules in the amorphous form.

Flexible

Our PVAs for HME are compatible with several downstream processing capabilities.



The Emprove® Program

Your fast track through regulatory challenges.

Ensuring the compliance of your pharma and biopharma products involves the compilation of a vast amount of data, which can be time and resource intensive. Our Emprove® Program helps you meet the latest regulatory requirements for risk assessment and offers assistance in developing more robust processes.

To help you optimize your process, our Emprove® Program provides comprehensive and thorough documentation for approximately 400 raw and starting materials as well as a selection of filters, single-use devices and components. It not only covers the latest regulatory requirements, but also anticipates industry expectations not yet covered by regulation. The Emprove® Program is organized into three different types of dossiers. Every dossier supports you throughout different stages of your operations: qualification, risk assessment, and optimization – so you can speed your way through the regulatory maze.

Find out more at:
SigmaAldrich.com/emprove

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Parteck® Product Portfolio

Excipients for oral solid dosage forms featuring unique particle properties and outstanding individual functionalities such as suitability for direct compression or controlled release.
For more information, visit:

sigmaaldrich.com/parteck-excipients

Formulation Product Finder App

Find the right product for specific applications at:

formulation-app.sigmaaldrich.com

Need plasticizers?

Our polyol portfolio and meglumine excipient provide effective performance in HME.

Ordering information

Cat. No.	Product	Pack size	Packaging
1.41544.1000	Parteck® MXP 3-82 EMPROVE® ESSENTIAL, Ph. Eur.	1 kg	PE bottle
1.41544.9025	Parteck® MXP 3-82 EMPROVE® ESSENTIAL, Ph. Eur.	25 kg	PE bag (in corrugated cardboard box)
1.41464.1000	Parteck® MXP 4-88 EMPROVE® ESSENTIAL, Ph. Eur., ChP, JPE, USP	1 kg	PE bottle
1.41464.9025	Parteck® MXP 4-88 EMPROVE® ESSENTIAL, Ph. Eur., ChP, JPE, USP	25 kg	PE bag (in corrugated cardboard box)

The typical technical data above serve to generally characterize the excipient. These values are not meant as specifications and they do not have binding character. The product specification is available separately at: **EMDMillipore.com**

We provide information and advice to our customers on application technologies and regulatory matters to the best of our knowledge and ability, but without obligation or liability. Existing laws and regulations are to be observed in all cases by our customers. This also applies in respect to any rights of third parties. Our information and advice do not relieve our customers of their own responsibility for checking the suitability of our products for the envisaged purpose.

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