Ensuring the precision you need – every time

Excipients for Instant & Modified Release dosage forms

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BASF
We create chemistry

High quality – reliable functionality

With our broad portfolio of functional excipients for instant and modified release dosage forms, we offer a wide range of formulation possibilities to obtain the release profile you desire.
Our high-quality, industry-leading products are manufactured under the appropriate GMP requirements and are accompanied by a comprehensive regulatory package.

At BASF, we have combined our technical expertise and decades of experience in five different platforms:

- Instant & Modified Release
- Solubilization
- Softgels
- Skin Delivery
- Biologics Solutions

Focusing our know-how and efforts on the respective platforms enables us to provide you with state-of-the-art products and the services you need.

Solutions to selected key formulation needs in Instant & Modified Release dosage forms

With our comprehensive know-how, decades of experience and a broad excipient portfolio, we have solutions for all key formulation challenges.

Formulation of oxidation sensitive APIs

Your need: Avoiding oxidation of sensitive active ingredients

Reducing oxidative substances in solid oral dosage forms is of increasing relevance for pharmaceutical formulators in order to protect active ingredients that are prone to oxidation. Peroxides are strong oxidizing agents and are well known to occur in many excipients. Specifically, they can be formed upon contact with atmospheric oxygen and are a particular problem for cost-effective packaging solutions such as multi-dose containers.

Our solution: PeroXeal™, Kollidon® 30 LP, Kollicoat® IR

We offer a comprehensive choice of high-quality functional excipients to ensure the stability of active ingredients. Our innovative PeroXeal™ packaging concept significantly reduces the presence of oxygen and thus limits peroxide formation in povidones and crospovidones to a minimum. In addition, we offer excipients with extremely low and even no peroxide formation at all – all depending on your specific formulation needs.

PeroXeal™

PeroXeal™ is the combination of an oxygen impermeable inner liner packaging and a filling process under inert conditions. The following products are available in PeroXeal™ packaging:

- Kollidon® 12 PF
- Kollidon® 17 PF
- Kollidon® 25
- Kollidon® 30*
- Kollidon® 90F
- Kollidon® CL
- Kollidon® CL-F
- Kollidon® CL-SF

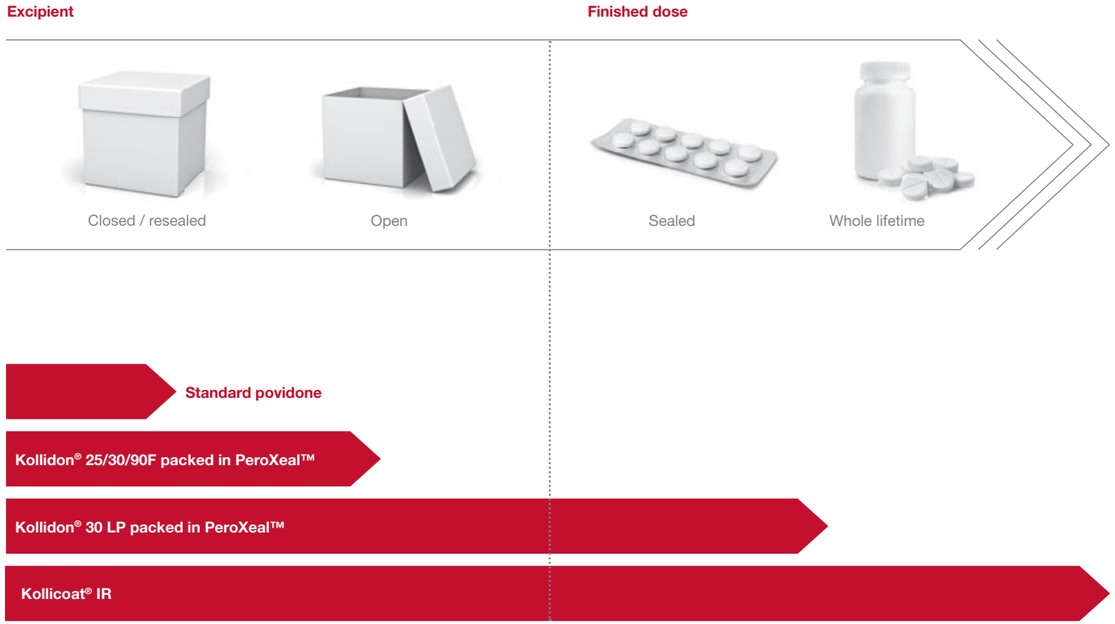
Kollidon® 30 LP

The enhanced low peroxide version of Kollidon® 30 with integrated sulfite-based antioxidant.

Kollicoat® IR

The latest addition to our binder portfolio. Kollicoat® IR exhibits no peroxide formation at all and is therefore particularly suitable for highly sensitive APIs and multi-dose container storage. It provides excellent wet binding performance in addition to application advantages such as low solution viscosity and very fast dissolution (even in cold water).

Your wet binder choice for minimizing peroxides



*Kollidon® 30 with origin Germany is available in PeroXeal™ packaging.

Sustained release formulations meeting the ADD regulations

Your need:
Increase of patient safety through avoidance of alcohol-induced dose dumping

Modified release dosage forms are helpful for patients, as they provide pharmacological advantages and administration convenience. However, dose dumping, which is defined as the rapid release of a large portion or the entire dose, is of growing concern. This is often the consequence of the consumption of alcoholic beverages (so-called alcohol-induced dose dumping, ADD). This is of particular concern as it may unintentional put the patient at significant health risks. Regulatory bodies worldwide have lately adapted regulations in order to avoid the risk of such accidental dose dumping.

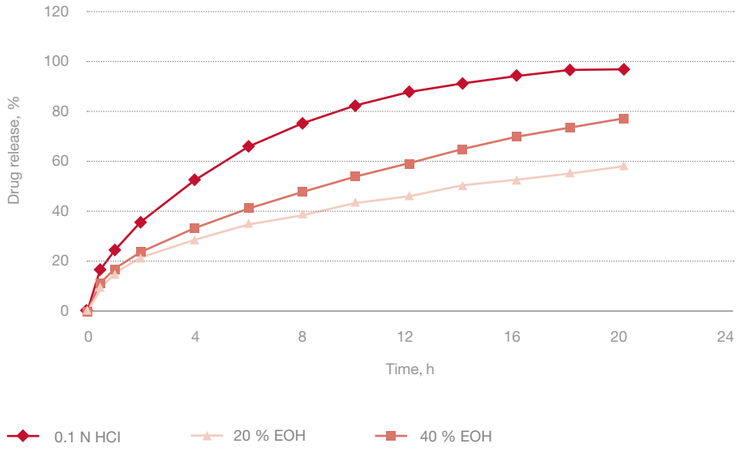
Our solution:
Kollicoat® SR 30 D and Kollidon® SR

Kollicoat® SR 30 D and Kollidon® SR are highly suitable to form non-erodible sustained release matrices with an extensive design space for your desired release profile.

Kollicoat® SR 30 D is a low-viscosity, aqueous polymer dispersion of polyvinyl acetate which can be employed as a pH-independent sustained release excipient in film coating or wet granulation.
In wet granulation it shows excellent processing characteristics due to the very low viscosity of the dispersion, despite the high solid content. Granules can then easily be compressed to matrix tablets due to the high plasticity and bondability of the polymer.

Kollidon® SR is a polyvinyl acetate-based free-flowing powder designed for direct compression of sustained release matrix tablets.
It is highly suitable for the use in formulations resistant to alcohol-induced dose dumping. Kollidon® SR can either be used by itself or in combination with other high-molecular weight excipients such as Kollidon® 90 F (see example on the next page).

Kollidon® SR in combination with Kollidon® 90 F to avoid alcohol-induced dose dumping*



*Kollidon® SR / Kollidon® 90 F (ratio 75:25); 200 mg Tramadol-HCl sustained release tablets manufactured by direct compression

Cost-efficient formulations

Your need: Growing importance of cost-efficiency

The reduction of manufacturing cost is a major topic in pharmaceutical production in order to remain competitive in global markets. High-performance excipients are a significant driver for cost reduction as they can be processed faster, provide more robust production processes and significantly reduce downtimes and failure batches.

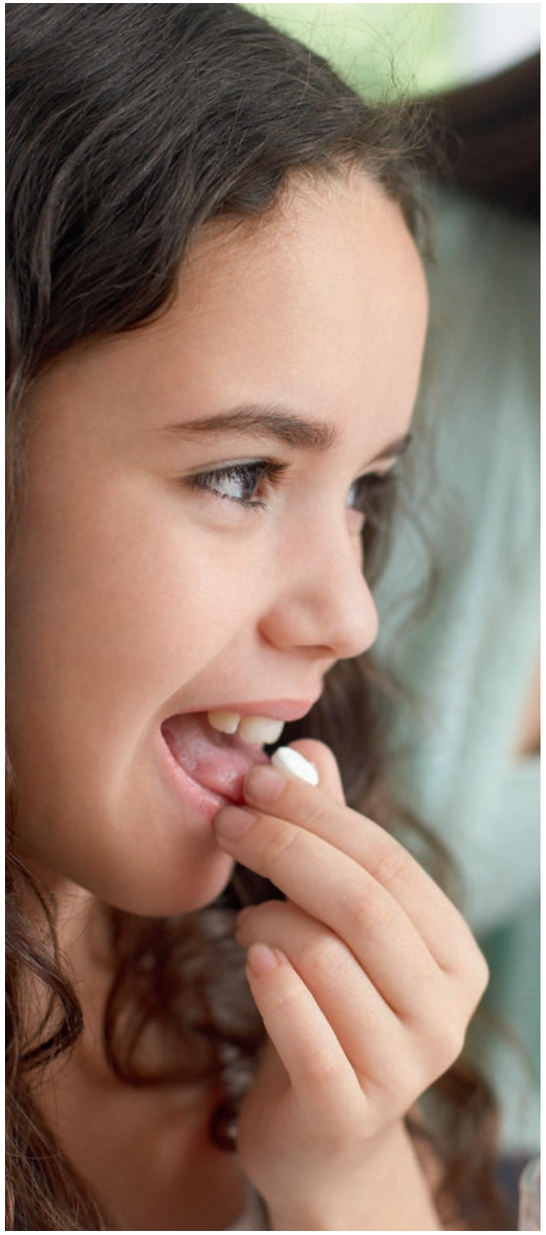
Our solution: Kollicoat® IR, Ludiflash®, Ludipress®, Ludipress® LCE

Kollicoat® IR – for cost-efficient instant release coatings
This is an innovative polymer derived from PEG and polyvinyl alcohol (PVA) which is very flexible and does not require the addition of plasticizers. Kollicoat® IR has an excellent water solubility allowing for both a fast preparation of the coating dispersion and excellent instant release of the finished dosage form. Due its low solution viscosity, Kollicoat® IR-based coating dispersions can be sprayed with comparatively high solid contents resulting in short process times. Moreover, Kollicoat® IR-based coating processes have proven to be very robust even at low temperatures.

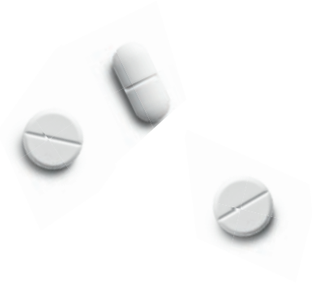
Ludiflash® – the high-performance solution for orally disintegrating tablets
This is particularly tailored for orally disintegrating tablets (ODTs) manufactured by direct compression on standard equipment. Tablets based on Ludiflash® show exceptional hardness and friabillity, making them particularly suitable for blister packaging. Its unique combination of mannitol as a filler, Kollicoat® SR 30 D as a binder and Kollidon® CL-SF as a disintegrant, provides fast disintegration and a highly pleasant mouthfeel.

Ludipress® – easy and fast production of standard instant release tablets
This is a special spray agglomerate made of lactose as a filler, Kollidon® 30 as a binder and Kollidon® CL as a disintegrant. It provides superior performance when compared to granules of the same ingredients produced by standard processes. Ludipress® can simply be combined with active ingredients and other excipients immediately prior to tableting.

Ludipress® LCE – easy and fast production of lozenges, chewables and effervescent tablets
The white free-flowing granules consist of lactose as filler with Kollidon® 30 as binder and are designed for direct compression. Ludipress® LCE can simply be combined with active ingredients and other excipients immediately prior to tableting.



Formulations for patients with special needs



Your need:
Formulations that meet the special requirements of pediatric and geriatric patients

Among all patient groups, a significant percentage of seniors and children have difficulties in swallowing most tablets and capsules. Additionally, these patients' compliance is often influenced by the taste of the formulation. To address the needs of these patient groups, orally disintegrating formulations and taste-masking approaches are intensively being utilized, as they further increase the convenience upon administration.

Our solution:
Ludiflash®, Kollidon® CL-SF, Kollicoat® Smartseal 30 D, Kollicoat® SR 30 D

Ludiflash® – the efficient ready-to-use solution for ODTs and ODMTs

Ludiflash® is particularly tailored for orally disintegrating tablets (ODTs) and mini tablets (ODMTs) manufactured by direct compression on standard equipment. Its unique combination of mannitol as a filler, Kollicoat® SR 30 D as a binder and Kollidon® CL-SF as disintegrant provides fast disintegration and a highly pleasant mouthfeel.

Kollidon® CL-SF – the strong disintegrant for ODTs and ODMTs

Kollidon® CL-SF is a super fine crospovidone grade for very fast disintegration of tablets. Its particles are so fine that the human tongue cannot detect them, which makes Kollidon® CL-SF highly suitable for orally disintegrating dosage forms. It can be employed as a disintegrant in standard processes, such as wet/dry granulation and direct compression. In dry binding applications, Kollidon® CL-SF has the particular benefit of acting as both a binder and a disintegrant ("binding disintegrant").

Kollicoat® Smartseal 30 D – the coating polymer for maximum taste masking in granules, crystals, pellets and tablets

Kollicoat® Smartseal 30 D is an aqueous dispersion of a basic acrylic polymer for taste masking and moisture protection. Polymer films of Kollicoat® Smartseal 30 D stay intact at typical saliva pH values but dissolve below pH 5.5, which ensures dissolution in the stomach. Very low coating levels have been proven to provide efficient taste masking of very bitter APIs like chinin.

Kollicoat® SR 30 D – the coating polymer for moderate taste masking in granules, crystals, pellets and tablets

Kollicoat® SR 30 D is a polyvinylacetate-based aqueous polymer dispersion originally intended for sustained release formulations. However, thin films formulated in conjunction with pore formers can provide taste masking of the particles without significantly delaying their drug release.

Our functional excipients for Instant & Modified Release dosage forms – at a glance

Core formulation

Functionality	Process			Delivery form			Product	Description	Monograph title*/Chemical name
	Direct compression	Dry granulation (incl. roller compaction)	Wet granulation	Tablets	Particles (granules & multiparticulates, pellets, capsules)	ODTs			
Binding			■	■	■		Kollidon® 25 P Kollidon® 30 P	The original. Medium molecular weight binder with low peroxide level thanks to Peroxeal packaging leading to extended shelf life.	Ph. Eur., USP, JP: Povidone
			■	■	■		Kollidon® 30 LP P	Our low peroxide grade with antioxidants.	Ph. Eur., USP, JP: Povidone
			■	■	■		Kollidon® 90 F P	High molecular weight binder with highest binding capacity.	Ph. Eur., USP, JP: Povidone
			■	■	■		Kollicoat® IR	Powerful and peroxide free wet binder for oxidation-sensitive drugs.	Ph. Eur.: Macrogol Poly(vinyl Alcohol) Grafted Copolymer; USP-NF: Ethylene Glycol and Vinyl Alcohol Graft Copolymer; JPE: Polyvinyl Alcohol-Polyethylene Glycol Graft Copolymer
	■	■	■	■	■		Kollidon® VA 64	For direct compression, roller compaction and wet granulation, suitable for markets with higher humidity exposure.	Ph. Eur., USP: Copovidone; JPE: Copolyvidone
	■	■		■	■		Kollidon® VA 64 Fine	Highly efficient binder with fine particle size for roller compaction and direct compression. Suitable for markets with high humidity exposure.	Ph. Eur., USP: Copovidone; JP: Copolyvidone
	■	■			■		Kollidon® CL-M	Roller compaction and direct compression including slight disintegration functionality.	Ph. Eur., USP, JP: Crospovidone Type B
	■	■		■	■	■	Kollidon® CL-SF P	2 in 1 functionality – efficient dry binder & fast disintegrant suitable for roller compaction.	Ph. Eur., USP, JP: Crospovidone Type B
Disintegration	■		■	■	■		Kollidon® CL P	Maximum disintegration.	Ph. Eur., USP, JP: Crospovidone Type A
	■	■	■	■	■	■	Kollidon® CL-F P	Balance of strong disintegration and optimal surface homogeneity.	Ph. Eur., USP, JP: Crospovidone Type A
	■	■	■	■	■	■	Kollidon® CL-SF P	Particularly suitable for small tablets and ODTs, providing very pleasant mouthfeel due to finer particles.	Ph. Eur., USP, JP: Crospovidone Type B
		■			■		Kollidon® CL-M	Disintegrant with micronized particles, delivering slight disintegration when used as binder.	Ph. Eur., USP, JP: Crospovidone Type B

P Packed in PeroXeal™ packaging
*Monograph references were updated at time of printing, please visit us online for the latest status

Core formulation

Functionality	Process			Delivery form			Product	Description	Monograph title*/Chemical name
	Direct compression	Dry granulation (incl. roller compaction)	Wet granulation	Tablets	Particles (granules & multiparticulates, pellets, capsules)	ODTs			
Matrices and fillers	■		■	■	■		Kollidon® SR	For non-erodible matrices using direct compression.	80 % PVAc, 19 % Povidone, 0.8 % SLS, 0.2 % Silica
	■	■		■	■	■	Ludiflash®	Ready-to-use ODT solution with superior mouthfeel.	90 % Mannitol, 5 % Crospovidone, 5 % Polyvinyl Acetate
	■	■		■	■		Ludipress®	Ready-to-use direct compression solution for tablets.	93 % Lactose, 3.5 % Povidone, 3.5 % Crospovidone
	■	■		■	■		Ludipress® LCE	Ready-to-use direct compression solution for lozenges, chewables and effervescent tablets.	96.5% Lactose, 3.5 % Povidone
Wetting and dissolution enhancement	■	■		■			Kolliphor® SLS Fine	Wetting agent in tabletting, reducing disintegration time. Particularly suitable for direct compression.	Ph. Eur.: Sodium Laurilsulfate; USP-NF, JP: Sodium Lauryl Sulfate
	■	■		■			Kolliphor® P 188 micro	Average particle size of 50 µm makes it effective dissolution enhancer, lubricant & wetting agent in direct compression.	Ph. Eur., USP-NF: Poloxamer 188; JPE: Polyoxyethylene (160) Polyoxypropylene (30) Glycol
	■	■		■			Kolliphor® P 407 micro	Average particle size of 50 µm makes it effective dissolution enhancer, lubricant & wetting agent in direct compression.	Ph. Eur., USP-NF: Poloxamer 407; JPE: Polyoxyethylene (196) Polyoxypropylene (67) Glycol
			■	■			Kolliphor® SLS	Wetting agent in wet granulation, reduces disintegration time.	Ph. Eur.: Sodium Laurilsulfate; USP-NF, JP: Sodium Lauryl Sulfate
			■	■			Kolliphor® P 188	Dissolution enhancer, lubricant & wetting agent particularly suitable for wet granulation.	Ph. Eur., USP-NF: Poloxamer 188; JPE: Polyoxyethylene (160) Polyoxylpropylene (30) Glycol
			■	■			Kolliphor® P 407	Dissolution enhancer, lubricant & wetting agent particularly suitable for wet granulation.	Ph. Eur., USP-NF: Poloxamer 407; JPE: Polyoxyethylene (196) Polyoxypropylene (67) Glycol
Lubrication	■	■		■			Kolliphor® SLS Fine	Hydrophilic lubricant. Due to its water solubility particularly suitable for effervescent tablets.	Ph. Eur.: Sodium Laurilsulfate; USP-NF, JP: Sodium Lauryl Sulfate
	■	■		■			Kolliphor® P 188 micro	Hydrophilic lubricant. Due to its water solubility particularly suitable for effervescent tablets.	Ph. Eur., USP-NF: Poloxamer 188; JPE: Polyoxyethylene (160) Polyoxypropylene (30) glycol
	■	■		■			Kolliphor® P 407 micro	Hydrophilic lubricant. Due to its water solubility particularly suitable for effervescent tablets.	Ph. Eur., USP-NF: Poloxamer 407; JPE: Polyoxyethylene (196) Polyoxypropylene (67) glycol
	■	■		■			Kolliwax® SA	Lipophilic lubricant, especially for sensitive acidic APIs.	Ph. Eur., USP-NF, JP: Stearyl Alcohol
	■	■		■			Kolliwax® S Fine	Lipophilic lubricant. Particularly suitable for sensitive APIs.	Ph. Eur., USP-NF, JP: Stearic Acid 50
	■	■		■			Kolliwax® HCO	Lipophilic lubricant. Particularly suitable for sensitive APIs.	Ph. Eur., Castor Oil, Hydrogenated, USP-NF: Hydrogenated Castor Oil, JPE: Hydrogenated Oil

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Coating formulation

Functionality	Process		Release			Delivery form		Product	Description	Monograph title*/Chemical name
	Aqueous	Other	Instant	Enteric	Sustained	Tablets	Particles (granules & multiparticulates, pellets, capsules)			
Film forming	■	■	■			■	■	Kollicoat® IR	Robust yet flexible water soluble instant release coating polymer. Efficient and easy to handle due to low viscosity and high flexibility.	Ph. Eur.: Macrogol Poly(vinyl Alcohol) Grafted Copolymer; USP-NF: Ethylene Glycol and Vinyl Alcohol Graft Copolymer; JPE: Polyvinyl Alcohol-Polyethylene Glycol Graft Copolymer
	■		■			■	■	Kollicoat® Protect	Instant release coating polymer for the formulation of of oxygen and moisture protective coatings.	Excipient based on Kollicoat® IR and monographed raw materials
	■		■			■	■	Kollicoat® Smartseal 30 D	Highly effective taste masking at very low coating levels. Specifically suitable for pellets & particles for ODTs due to easy and non-tacky processability.	Methyl-Methacrylate - Diethylaminoethyl Methacrylate Copolymer
	■			■		■	■	Kollicoat® MAE 30 DP	Enteric coating with release above pH 5.5, available as a 30 % solids content dispersion.	Ph. Eur.: Methacrylic Acid – Ethyl Acrylate Copolymer (1:1) Dispersion 30 per cent; USP: Methacrylic Acid Copolymer Dispersion; JPE: Methacrylic Acid Copolymer LD
	■	■		■		■	■	Kollicoat® MAE 100 P	Enteric coating with release above pH 5.5, available as partially preneutralized powder saving you the neutralization step.	Ph. Eur.: Methacrylic Acid – Ethyl Acrylate Copolymer (1:1), Type B; USP-NF: Partially-Neutralized Methacrylic Acid and Ethyl Acrylate Copolymer
	■	■		■		■	■	Kollicoat® MAE 100-55	Non-neutralized, fast redispersing, completely dust-free powder grade for aqueous & organic coating.	Ph.Eur.: Methacrylic Acid - Ethyl Acrylate Copolymer (1:1) Type A; USP-NF: Methacrylic Acid and Ethyl Acrylate Copolymer; JPE: Dried Methacrylic Acid Copolymer LD
	■				■	■	■	Kollicoat® SR 30 D	pH-independent sustained release film coating polymer used to film coat small particles, pellets, granules and tablets.	Ph. Eur.: Poly(vinyl Acetate) Dispersion 30 per cent; USP: Polyvinyl Acetate Dispersion
		■			■		■	Kolliwax® HCO	For sustained release melt coating.	Ph. Eur.: Castor Oil, Hydrogenated; USP-NF: Hydrogenated Castor Oil; JP: Hydrogenated Oil
	■	■	■			■	■	Kollidon® VA 64	Aqueous sugar film coating for thinner films and a faster process. Organic subcoating for highly moisture sensitive cores.	Ph. Eur., USP: Copovidone; JPE: Copolyvidone
Plasticizing						■	■	Kollisolv® GTA	Plasticizer particularly suitable for tablet coatings.	Ph. Eur., USP: Triacetin
						■	■	Kolliphor® RH 40	Plasticizer used in coatings and in solid polymeric matrices.	Ph. Eur.: Macrogolglycerol Hydroxystearate; USP: Polyoxyl 40 Hydrogenated Caster Oil
						■	■	Kollisolv® PG	Liquid plasticizer with high ADI.	Ph. Eur., JP, FCC, USP: Propylene Glycol
						■	■	Kollisolv® PEG 300	Liquid plasticizer commonly used in tablet coatings. Also used as solvent in liquid formulations.	Ph. Eur.: Macrogols; USP: Polyethylene Glycol, JPE: Macrogol 300; FCC: Polyethylene Glycols
						■	■	Kollisolv® PEG 400	Liquid plasticizer commonly used in tablet coatings. Also used as solvent in liquid formulations.	Ph.Eur: Macrogols; USP: Polyethylene Glycol; JP: Macrogol 400; FCC: Polyethylene Glycols
						■	■	Kollisolv® P 124	Liquid plasticizer commonly used in tablet coatings.	Ph. Eur., USP-NF: Poloxamer 124; JPE: Polyoxyethylene (20) Polyoxypropylene (20) Glycol
Taste masking	■		■			■	■	Kollicoat® Smartseal 30 D	Highly effective taste masking, providing efficacy already at very low coating levels. Specifically suitable for pellets and particles for ODTs due to its easy and non-tacky processability.	Methyl-Methacrylate – Diethylaminoethyl Methacrylate Copolymer
	■		■			■	■	Kollicoat® SR 30 D	Thin coating layer provides basic taste masking properties.	Ph. Eur.: Poly(vinyl Acetate) Dispersion 30 per cent; USP: Polyvinyl Acetate Dispersion
	■			■		■	■	Kollicoat® MAE 30 DP	Thin coating layer for taste masking; suitable for particles.	Ph. Eur.: Methacrylic Acid – Ethyl Acrylate Copolymer (1:1) Dispersion 30 per cent; USP: Methacrylic Acid Copolymer Dispersion; JPE: Methacrylic Acid Copolymer LD

P Packed in PeroXeal™ packaging

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Coating formulation

Functionality	Process		Release			Delivery form		Product	Description	Monograph title*/Chemical name
	Aqueous	Other	Instant	Enteric	Sustained	Tablets	Particles (granules & multiparticles, pellets, capsules)			
Moisture protection	■		■			■	■	Kollicoat® Protect	Provides an effective moisture barrier in combination with pigments or talc.	Excipient based on Kollicoat® IR and monographed raw materials
	■		■			■	■	Kollicoat® Smartseal 30 D	Very low water vapor permeation; can be applied as clear coating to provide full moisture protection.	Methyl-Methacrylate – Diethylaminoethyl Methacrylate Copolymer
	■		■			■	■	Kollidon® VA 64	In combination with Kollicoat® IR or Kollicoat® Protect, Kollidon® VA64 further reduces the water vapor permeation rate.	Ph. Eur., USP: Copovidone; JPE: Copolyvidone
Pore forming	■		■			■	■	Kollicoat® IR	Peroxide-free water-soluble pore former for sustained release tablets and pellet coating.	Ph. Eur.: Macrogol Poly(vinyl Alcohol) Grafted Copolymer; USP-NF: Ethylene Glycol and Vinyl Alcohol Graft Copolymer; JPE: Polyvinyl Alcohol-Polyethylene Glycol Graft Copolymer
	■			■		■	■	Kollicoat® MAE 30 DP	Aqueous dispersion for use as pore former for targeted opening in the intestine to avoid release in the stomach.	Ph. Eur.: Methacrylic Acid - Ethyl Acrylate Copolymer (1:1) Dispersion 30 per cent; USP: Methacrylic Acid Copolymer Dispersion; JPE: Methacrylic Acid Copolymer LD
	■	■		■		■	■	Kollicoat® MAE 100 P	Pre-neutralized powderous pore former for targeted opening in the intestine to avoid release in the stomach.	Ph. Eur.: Methacrylic Acid - Ethyl Acrylate Copolymer (1:1), Type B; USP-NF: Partially-Neutralized Methacrylic Acid and Ethyl Acrylate Copolymer
	■		■			■	■	Kollidon® 12 PF **P**	Soluble pore formers for sustained release tablet or pellet coating.	Ph. Eur., USP, JP: Povidone
	■		■			■	■	Kollidon® 17 PF **P** Kollidon® 25 **P** Kollidon® 30 **P** Kollidon® 90 F **P**	Soluble pore formers for sustained release tablet or pellet coating.	Ph. Eur., USP, JP: Povidone
	■		■			■	■	Kollidon® VA 64	Soluble pore former for sustained release tablet coatings.	Ph. Eur., USP: Copovidone; JPE: Copolyvidone
	■				■	■	■	Kolliwax® HCO	Slows down drug release when used as pore former in sustained release formulations.	Ph. Eur.: Castor Oil, Hydrogenated; USP-NF: Hydrogenated Castor Oil; JP: Hydrogenated Oil
	■	■			■	■	■	Kolliwax® S Fine	In combination with Kollicoat® SR 30 D, Kolliwax® S Fine creates sustained release profiles.	Ph. Eur., USP-NF, JP: Stearic Acid 50

P Packed in PeroXeal™ packaging
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Our service offer

We enable our customers to create value-adding, unique and differentiating formulations by:

- Providing in-depth expertise in all steps of the production of solid and liquid oral dosage forms
- Offering a broad and effective portfolio of functional excipients with best-in-class performance
- Sharing our expert know-how in excipients and formulations

Our tools

- Application support based on expertise and data, using major processing equipment
- Publications
- Seminars, workshops, trainings

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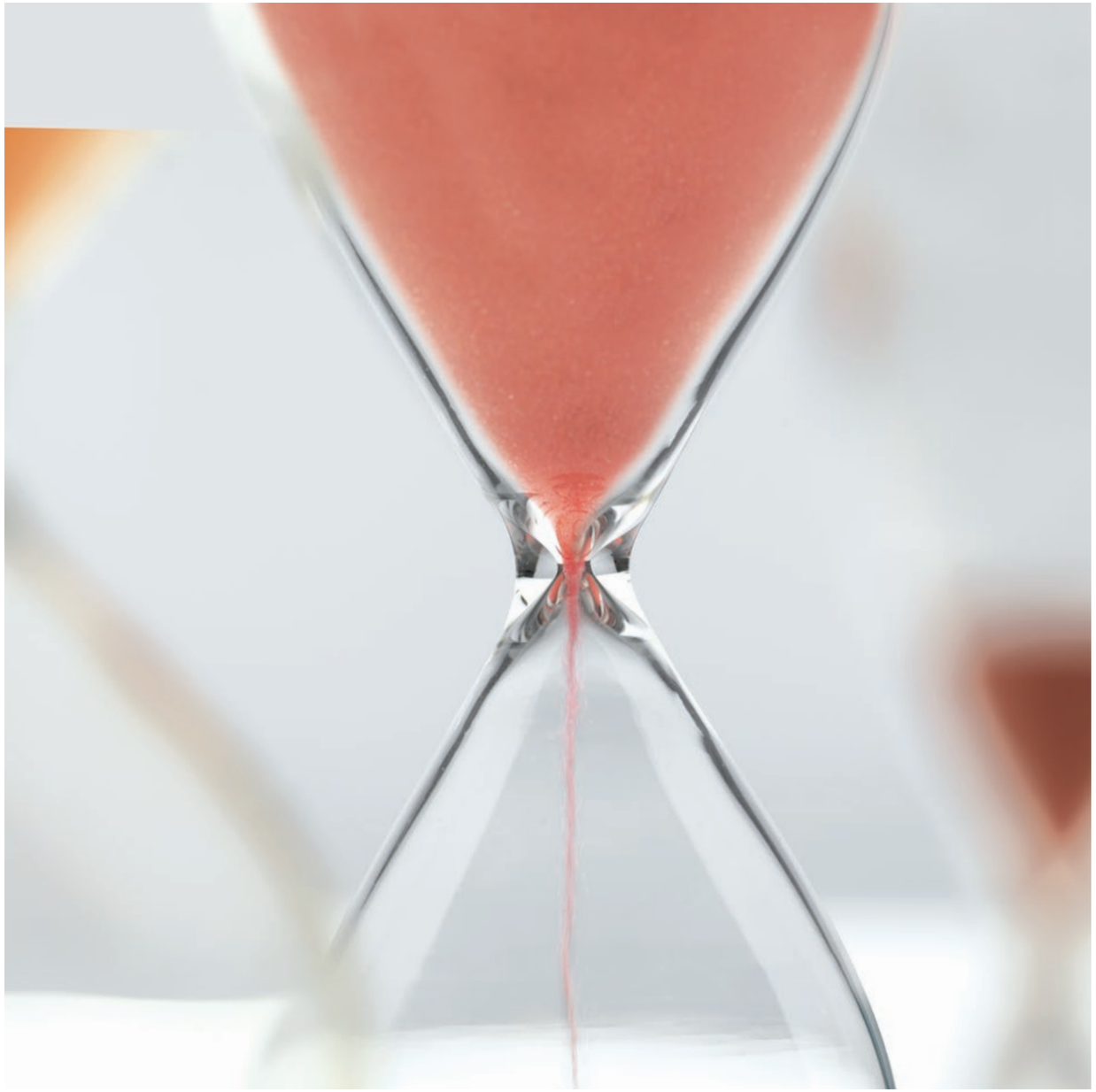

Kollicoat® MAE 100-55
A complete match – just better.

- Direct substitution in commercial formulations
- Easier handling due to dust-free material
- Compliant with respective monographs

Kollicoat® MAE 100-55 is the latest addition to our functional excipient portfolio, extending our offer of pH > 5.5 enteric release products based on a methacrylic acid-ethylacrylate copolymer.

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