klucel™ xtend
hydroxypropylcellulose

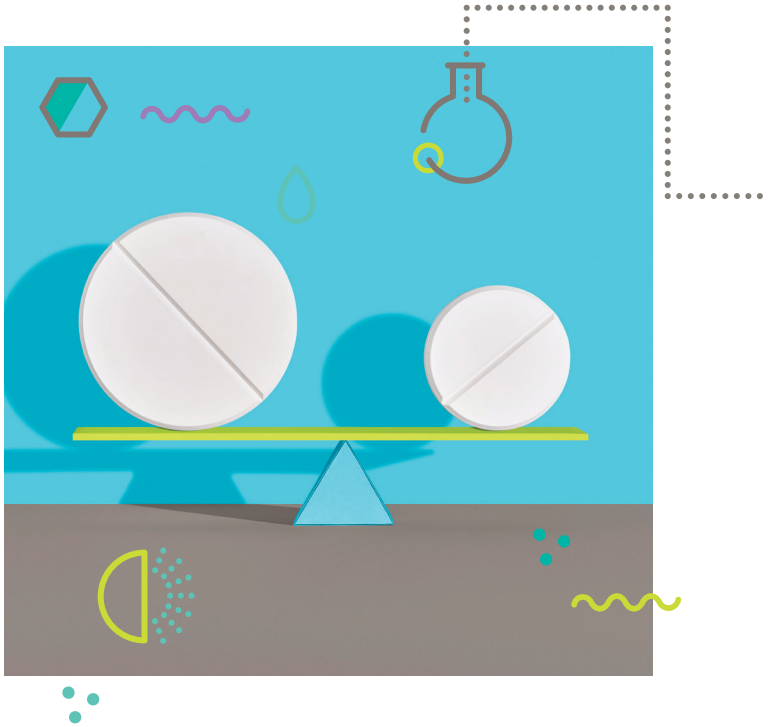
controlled release matrix former

description

Klucel™ xtend hydroxypropylcellulose (HPC) is the new gold standard in oral matrix formers for controlled release tablets. Klucel™ xtend HPC is a step change product that has been shown to match the release profile of hypromellose controlled-release formulations at half the polymer concentration. The highly reduced polymer concentration achievable with Klucel™ xtend HPC offers the possibility of smaller pills with higher dosage.

The need for hot-melt extrusion (HME) polymers is expected to grow as the pharma industry moves to implement more continuous and sustainable processes. Klucel™ xtend HPC is the only cellulosic excipient that provides a compendial extended-release polymer option for plasticizer-free HME.

By extending your options we are allowing you to do more with less.



key features and benefits

features

- high gel strength
- low melt processing temperature
- process versatility

benefits

- consistent release profiles at lower concentrations than hydroxypropyl methylcellulose (HPMC)
- reduced burst effect in highly soluble APIs
- smaller tablets maximize capacity of plant equipment
- excellent performance in direct compression, wet granulation, dry granulation, and hot melt extrusion
- meets all compendia for HPC

certificate of analysis specifications

grade (X = Fine)	weight average molecular weight	typical Brookfield viscosity (mPa•s)	solution concentration (%)
klucel™ xtend hxf pharm	1,150,000	1,500–3,000	1

klucel™ xtend hpc

extending your options for

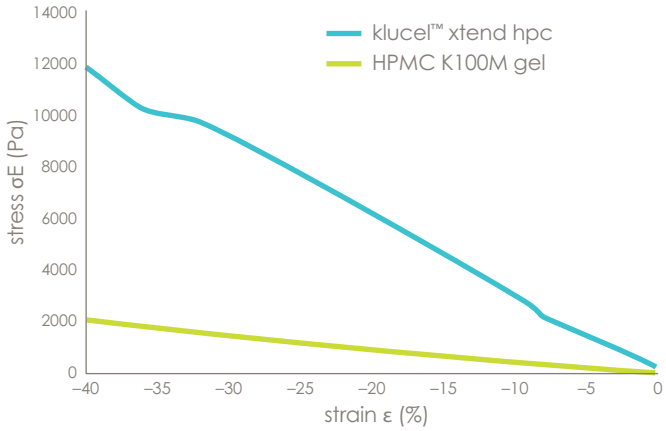
- highly soluble APIs
- high drug load formulations
- melt granulation or HME processing
- increased patient compliance
- complex formulations

effective at half the concentration of HPMC

Klucel™ xtend hydroxypropylcellulose (HPC) has significantly higher gel strength (53.3%) than hydroxypropyl methylcellulose (HPMC) K100M, indicating that this new HPC grade can maintain better hydrated tablet integrity.

This higher gel strength enables consistent release profiles at lower concentrations than HPMC, allowing the design and development of smaller tablets to improve patient compliance with prescription drug regimens.

figure 1. tablet gel strength



case study 1

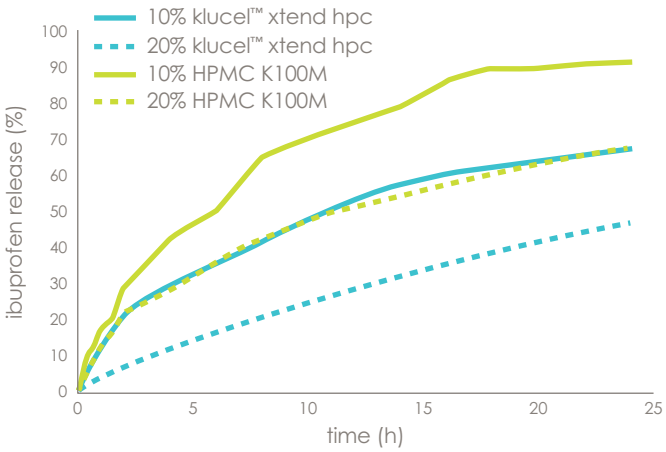
comparison of CR polymer concentration impact on ibuprofen in direct compression

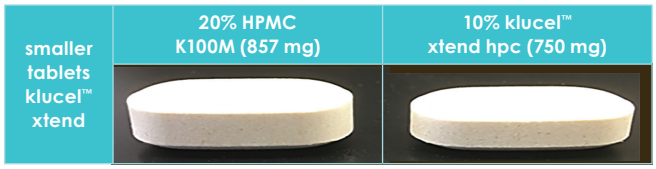
- CR polymers used in this study were klucel™ xtend hpc and HPMC K100M
- 857 mg tablets were made using 0.374 x 0.7480-inch concave oblong tooling at 37 RPM on a StylCam compaction simulator modeling a Fette 2090 press

table 1. ibuprofen tablet formulations (direct compression method)

no.	ingredient	formulation 1 (% w/w)	formulation 2 (% w/w)
1	ibuprofen	70.0	80.0
2	CR polymer	20.0	10.0
3	DC lactose	8.5	8.5
4	fumed silica	1.0	1.0
5	magnesium stearate	0.5	0.5
total		100.0	100.0

figure 2. klucel™ xtend hpc exhibits better extended release – enabling smaller tablets





only compendial HME matrix former

The growth of continuous manufacturing is driving the need for melt granulation and HME solutions. Klucel™ xtend hydroxypropylcellulose (HPC) is the only compendial cellulosic matrix former processable via hot melt-extrusion (HME) without plasticizers. HME process has also been shown to increase the hardness and efficiency of extended-release formulations.

case study 2

HME processability of metformin HCl tablet

A 1 kg batch of Metformin HCl with each polymer of each granulation formulation was blended and extruded at a processing temperature at 120°C and screw speed of 150 rpm using a Leistritz ZSE 18HP. Extrudate of each granulation was milled and blended with ingredient 3 and 4 for 10 minutes, then lubricated with magnesium stearate.

HPMC K100M was not processable via HME at 120°C. The Klucel™ xtend HPC HME formulation was comparable to Metformin in direct compression.

figure 3. klucel™ xtend hpc exhibits better controlled release in HME than higher concentrations of K100M in direct compression

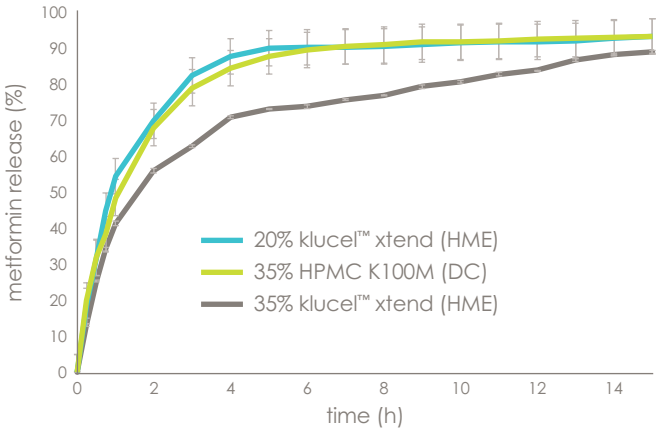


table 2. tablet formulations using HME method

no	ingredients	HME formulation 1			HME formulation 2		
		granulation	tablet formulation		granulation	tablet formulation	
		w/w (%)	tablet w/w (%)	tablet wt (mg)	w/w (%)	tablet w/w (%)	tablet wt (mg)
1	metformin HCl	80	65.0	500	60	50	500
2	CR polymer (klucel™ xtend hpc or HPMC K100M)	20	20.0	153.8	40	35	350
3	microcrystalline cellulose		13.5	103.8		13.5	132.4
4	fumed silica		1.0	7.7		1.0	9.8
5	magnesium stearate		0.5	3.8		0.5	4.9
total		100	100	769.2	100	100.0	980.4

most versatile extended-release polymer

Klucel™ xtend HPC has shown unsurpassed extended-release performance across a wide range of APIs and processing methods.

case study 3

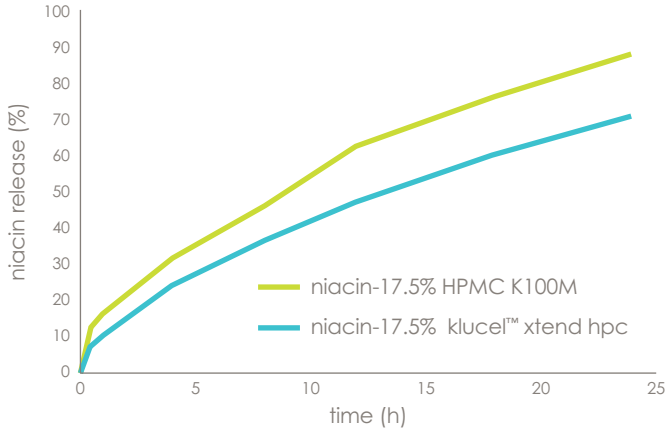
wet granulation of niacin

- CR polymers used in this study were klucel™ xtend hpc and HPMC K100M XR
- 1233 mg tablets were compressed using 0.3740 x 0.7480" modified oval tooling and StylCam tablet to do production run at 37 rpm

table 3. niacin tablet formulation (wet granulation method)

no.	ingredient	wet granulation (%w/w)	tablet (%w/w)	tablet wt (mg)
1	niacin	82.34	81.0	1000.0
2	CR polymer	17.66	17.5	214.5
3	fumed silica		0.6	7.4
4	sodium stearyl fumarate		0.9	11.1
total		100.0	100.0	1233.0

figure 4. klucel™ xtend exhibits slower release profile in wet granulation and potential to reduce burst effect of highly soluble drug



regional centers

North America
Wilmington, DE USA
Tel: +1 877 546 2782

Europe
Switzerland
Tel: +41 52 560 55 00

India
Maharashtra
Tel: +91 22 62828700

Asia Pacific
Singapore
Tel: +65 6775 5366

Middle East, Africa
Istanbul, Turkey
Tel: +00 90 216 538 08 00

Latin America
Mexico
Tel: +52 55 52 76 6169

Brazil
Tel: +55 11 36 49 0435

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