



We create chemistry

**Kollidon® 30**

The Original from BASF

BASF Pharma Solutions | BASF SE



# General procedures for today's training



Please **mute yourself**.



Please **send** all your **questions** related to the training **via the chat** function of WebEx **to Claudia**.

We will answer the questions at the end of the training.

## Presentations



**Internal only**



**External**



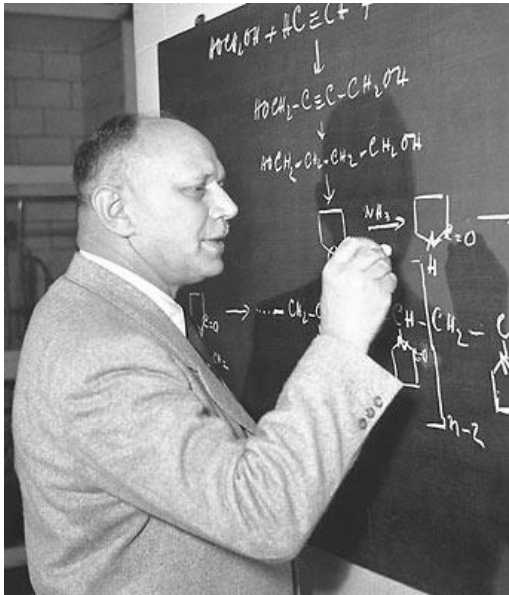
**External**

*will be available on MAPP*

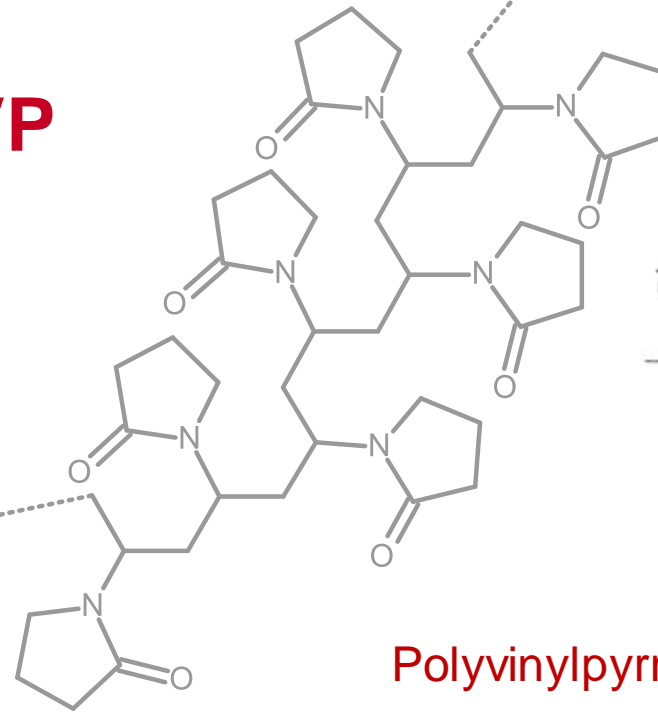


# Kollidon® 30

## The Originator PVP



Prof. Dr. Walter Reppe, the inventor of povidone and the "Reppe-Chemistry".  
BASF lab, Ludwigshafen Germany, 1929



Polyvinylpyrrolidone (PVP)  
is an invention of BASF

Kollidon® is the originator PVP brand

Our commitment  
into Kollidon®  
is high ever since



# Kollidon® 30

## one of the most popular pharmaceutical polymers

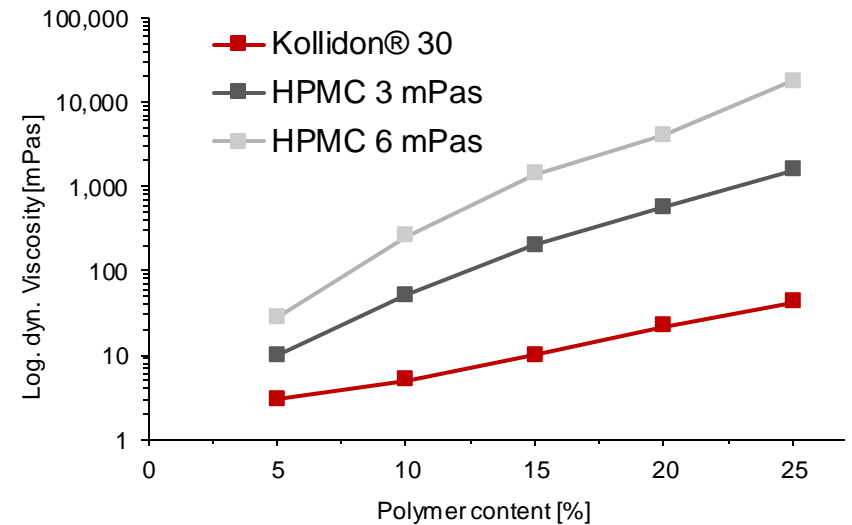
- ✓ wet binder
- ✓ dry binder
- ✓ solubilizer
- ✓ monographs in all main pharmacopeias



Kollidon® 30

is an excellent wet binder

- can be used with all fillers
- superior low solution viscosity compared to celluloses



# Kollidon® 30 is produced in three different sites



**Global GMP production sites for your regional supply safety in a globalized world.**



# Kollidon® 30

## The premium PVP K 30

### Kollidon® 30

Pharmacopoeial compliance	Ph.Eur., USP/NF, JP (ChP for Origin China)
Regulatory dossiers	CEP (LU), US-DMF (GE, SH), China-DMF (Lu, SH, GE)
Packaging material	EVOH liner, inert filling (LU only)
Packaging sizes	25 kg card box (LU only) 50 kg PE drum
Sample	Like commercial packaging: EVOH liner, inert filling (LU only)
Retest period	48 months (LU), 36 months (GE, SH)
Audits	✓
3rd party audit reports	✓

Abbreviations:  
 LU = Ludwigshafen, Germany  
 GE = Geismar, USA  
 SH = Shanghai, China



# Kollidon<sup>®</sup> 30 is provided with a big service package

	Kollidon <sup>®</sup> 30
Sharing of stability data reports	✓
Sharing of analytical in-house methods	✓
Sharing of validation reports for analytical in-house methods	✓
Support upon analytical testing / exchange on methods/ method transfer	✓
Lot history data shared	✓ (if necessary)
Reg & QA statements	All standard statements accessible 24/7 at BASF World Account; Additional customized statements possible
ICH Q3D	Full data set available
Tox abstract, and tox service	✓
Tox expert report under CDA	✓



# Kollidon® 30 is available in PeroXeal®: The best packaging for high quality PVP

PeroXeal™ minimizes peroxide formation by excluding oxygen in the packaging



## BASF PeroXeal®

Heat-seal  
Liner closed by air-tight heat-seal

Inert filling\*  
Filling under nitrogen followed by  
vacuumization

Oxygen impermeable liner  
based on EVOH\*\*

## Market standard

goose neck with cable tie

No inert filling  
air in packaging / no vacuum

PE liner (oxygen permeable)

\* only for origin Germany material

\*\* EVOH = Ethylene-vinylalcohol-copolymer

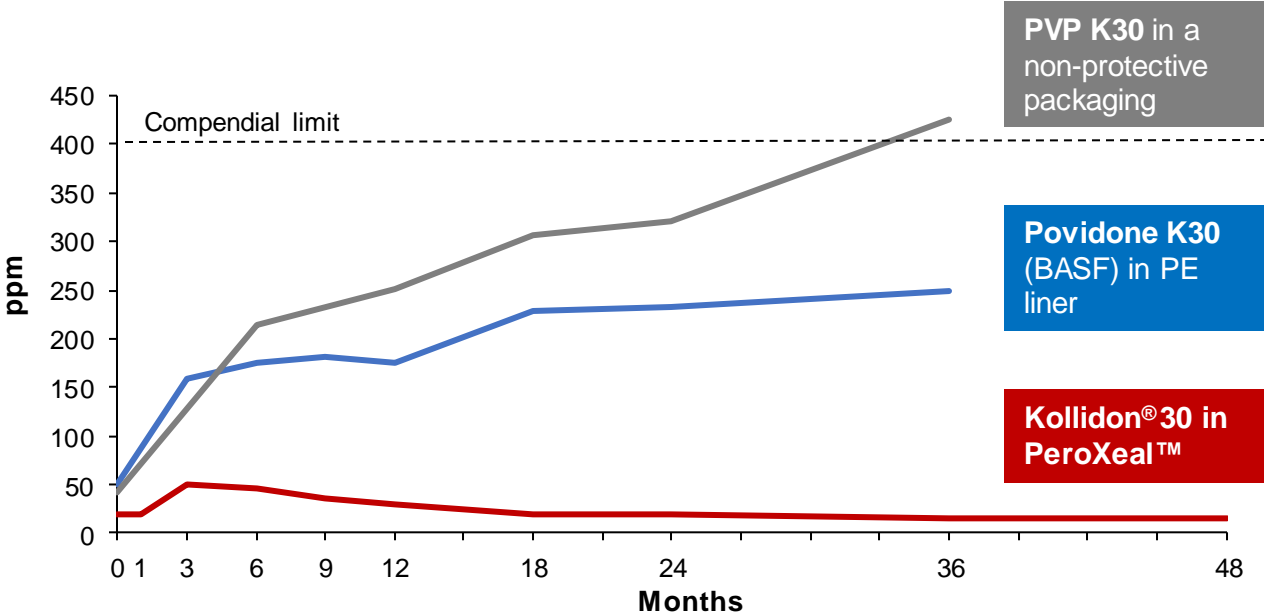


**BASF**  
We create chemistry



# The PeroXeal<sup>®</sup> Effect: Preventing Peroxide Formation in PVP

■ PeroXeal<sup>®</sup> effectively prevents peroxide formation in Kollidon<sup>®</sup> 30



# Kollidon® 30 Fact Sheet

	<b>Kollidon® 30 Origin Germany</b>	<b>Kollidon® 30 Origin Germany</b>	<b>Kollidon® 30 Origin USA</b>	<b>Kollidon® 30 Origin China</b>
Compendial compliance	Ph. Eur.: Povidone USP/NF: Povidone JP: Povidone	Ph. Eur.: Povidone USP/NF: Povidone JP: Povidone	Ph. Eur.: Povidone USP/NF: Povidone JP: Povidone	Ph. Eur.: Povidone USP/NF: Povidone JP: Povidone ChP:Povidone
CAS number	9003-39-8	9003-39-8	9003-39-8	9003-39-8
PRD number	30034974	30525451	30403404	30660388
Article number	57254693	50022331	55087337	50486018
Packaging size	25 kg	50 kg	50 kg	50 kg
Packaging material	Cardboard box with EVOH liner and inert filling (PeroXeal®)	PE drum with EVOH liner and inert filling (PeroXeal®)	PE drum with EVOH liner	PE drum with EVOH liner
Sample size	500 g	500 g	1 kg	500 g
Sample article no.	50347950	50347978	51598135	50498559
Manufacturing site	Ludwigshafen (Germany)	Ludwigshafen (Germany)	Geismar (Louisiana, USA)	Shanghai (China)
Physical form	Spray dried powder	Spray dried powder	Spray dried powder	Spray dried powder
Retest period	48 months	48 months	36 months	36 months



 **BASF**

We create chemistry

# Your wet binder choice for minimizing peroxides

Timeline for peroxide protection for different PVP K30 grades:

