

### Kollidon<sup>®</sup> 90 Evo

#### Highly Effective Binder With Exceptional Purity

#### **BASF Pharma Solutions**



#### Kollidon<sup>®</sup> 90 Evo is a Highly Effective Binder with Exceptional Purity

Join the Evolution and Move Towards a Sustainable Future With Us

Outstanding Purity	<ul> <li>Impurity profile significantly improved compared to Kollidon® 90 F</li> <li>Tightest 2-pyrrolidone specification</li> <li>Analytical methods remain unchanged</li> </ul>
Regulatory Compliance, Quality	<ul> <li>Fulfills Pharmacopoeial requirements of PhEur, USP, JP and goes beyond</li> <li>Pharma regulatory documentation and submission support</li> <li>Equivalent application properties</li> </ul>
Supply Reliability	<ul> <li>New packaging: 50kg fiber drum</li> <li>Made out of high-quality fiber certified by FSC<sup>®</sup>,100% recyclable</li> <li>Peroxide-protective PeroXeal<sup>®</sup> approach with inert filling</li> <li>Same retest period of 36months</li> </ul>
BASF Services	<ul> <li>Product details available via MyProduct World</li> <li>Regulatory documentation available in RegXcellence<sup>®</sup></li> <li>Formulation guidance with ZoomLab<sup>™</sup></li> <li>BASF technical service support and equivalency report available for Kollidon<sup>®</sup> 90 Evo</li> </ul>

99

#### → Kollidon<sup>®</sup> 90 Evo is available starting November 1, 2023



## Kollidon<sup>®</sup> 90 Evo Has a Significantly Improved Impurity Profile and Narrowed Specification

Specification comparison

Parameter	Pharmacopoeial limit <sup>1</sup> [max]	Kollidon <sup>®</sup> 90 F [max]	Kollidon <sup>®</sup> 90 Evo [max]		
2-pyrrolidone [%]	3.0	3.0	0.50		Tightest 2-pyrroli
Hydrazine [ppm]	1	1	1.0	k	
Aldehydes (ex. as acetaldehyde) [ppm]	500	500	200	'\	Increased transparer Hydrazine results rep CoA as values (LOQ
Lead [ppm]	10	10	1		
Formic acid [%]	0.5	0.5	0.3	$\mathbf{N}$	
1-Vinylpyrrolidin-2- one (NVP)[ppm]	10	10	10		
Appearance of solution	Color not more intensely than reference solution BY6/B6/R6	Color not more intensely than reference solution BY6/B6/R6	Color not more intensely than reference solution BY7/B7/R7	$\searrow$	Tightest limits for lea formic acid and appearance of solution
Sulfated Ash [%]	0.1	0.1	0.05		

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All other specification parameters remain the same<sup>2</sup>

Analytical methods remain the same

1 Ph. Eur. Limit harmonized with USP-NF and JP

3 2 Except: deletion of heavy metals test which will be deleted in Povidone monograph of JP18 starting Dec 2023



#### **New 50 kg Fiber Drum With Liner Provides Excellent Product Protection**





✓ BASF seal assuring packaging integrity

 Removable lid and clip for convenient drum re-closure after opening (all openings are fully closed)





- ✓ Peroxide protective PeroXeal<sup>®</sup> approach with inert filling in PE / EVOH / PE liner (sealed)
   ✓ Retest period of 36 months
  - Handle slots in drum, lid and clip to further support safe handling



- ✓ FSC<sup>®</sup> labeled drum, made from high quality fiber and 100% recyclable
- ✓ Dimensions: 95 cm height, square
   base 37cm x 37cm for efficient storage

#### Kollidon<sup>®</sup> 90 Evo Globally Available in New 50 kg Squared Fiber Drums

Brand name BASF	Kollidon® 90 Evo			
Chemical name	Polyvinylpyrrolidone, PVP, linear polymer of 1-ethenylpyrrolidin-2-one, 1-Vinyl-2-pyrrolidinone polymer, chain polymer of 1-vinyl-2-pyrrolidone			
Compendial name	Povidone, Povidonum			
CAS number	9003-39-08			
Appearance	almost white free-flowing powder			
Retest period	36 months			
PRD number	30768117			
Packaging and article numbers Sample article number	50 kg squared fiber drum, ART: 50810372 0,5 kg plastic pail, ART: 50712043			
Storage and transport	No specific temperature			
Manufacturing site	BASF SE Ludwigshafen			
Manufacturing process	Synthetic			
Regulatory & Quality	<ul> <li>USP-NF, Ph. Eur., JP monographs compliant</li> <li>IPEC-PQG GMP for Excipients</li> </ul>			
Certified	Kosher and Halal			

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#### **Experienced BASF Team and Virtual Pharma Assistants Happy to Support You**

Quality & Regulatory – all relevant quality documents accessible digitally via **RegXcellence**®

- Kollidon<sup>®</sup> 90 Evo is compliant to Ph. Eur., USP-NF, JP monographs
- Equivalency report available
- Halal & Kosher certifications
- GMP statement
- Formulation guidance offered via **ZoomLab™** and product details via MyProductWorld



Global technical service team is ready to support you Our global footprint of technical service laboratories enables us to swiftly address your formulations needs



#### Contact us at E-mail: pharma-solutions@basf.com

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Regulatory

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