

# Zein

## 1 Nonproprietary Names

USPNF: Zein

## 2 Synonyms

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## 3 Chemical Name and CAS Registry Number

Zein [9010-66-6]

## 4 Empirical Formula      Molecular Weight

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≈ 38 000

## 5 Structural Formula

See Section 8.

## 6 Functional Category

Coating agent; extended release agent; tablet binder.

## 7 Applications in Pharmaceutical Formulation or Technology

Zein is used as a tablet binder in wet-granulation processes or as a tablet-coating agent. It is used primarily as an enteric-coating agent or in extended-release oral tablet formulations.<sup>(1)</sup> Zein is also used in food applications as a coating agent. See Table I.

**Table I:** Uses of zein.

Use	Concentration (%)
Tablet coating agent	15
Tablet sealer	20
Wet granulation binder	30

## 8 Description

Zein is a prolamins obtained from corn (*Zea mays* Linné (Fam. Gramineae)). It occurs as a granular, straw- to pale yellow-colored amorphous powder or fine flakes and has a characteristic odor and bland taste.

For amino acid composition, see Section 18.

## 9 Pharmacopeial Specifications

See Table II.

**Table II:** Pharmacopeial specifications for zein.

Test	USPNF 20
Identification	+
Microbial limits	+
Loss on drying	≤ 8.0%
Residue on ignition	≤ 2.0%
Heavy metals	≤ 0.002%
Organic volatile impurities	+
Nitrogen content (dried basis)	13.1–17.0%

## 10 Typical Properties

Density: 1.23 g/cm<sup>3</sup>

Melting point: when completely dry, zein may be heated to 200°C without visible signs of decomposition.

Particle size distribution: 100% less than 840 μm in size.

Solubility: practically insoluble in acetone, ethanol, and water; soluble in aqueous alcohol solutions, aqueous acetone solutions (60–80% v/v), and glycols. Also soluble in aqueous alkaline solutions of pH 11.5 and above.

## 11 Stability and Storage Conditions

Zein should be stored in an airtight container, in a cool, dry place. It has not been reported to polymerize.<sup>(2,3)</sup>

## 12 Incompatibilities

Incompatible with oxidizing agents.

## 13 Method of Manufacture

Zein is extracted from corn gluten meal with dilute propan-2-ol.

## 14 Safety

Zein is used in oral pharmaceutical formulations and food products and is generally regarded as an essentially nontoxic and nonirritant material at the levels employed as an excipient. However, it may be harmful if ingested in large quantities. See also Section 18.

## 15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Zein may be irritant to the eyes and may evolve toxic fumes on combustion. Eye-protection and gloves are recommended.

## 16 Regulatory Status

GRAS listed. Included in the FDA Inactive Ingredients Guide (oral tablets).

## 17 Related Substances

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## 18 Comments

The EINECS number for zein is 232-722-9.

Zein is a protein derivative that does not contain lysine or tryptophan. For the approximate amino acid content of zein, see Table III.

Zein may be safely consumed by persons sensitive to gluten.

**Table III:** Approximate amino acid content of zein.

Alanine	8.3%	Methionine	2.0%
Arginine	1.8%	Phenylalanine	6.8%
Asparagine	4.5%	Proline	9.0%
Cystine	0.8%	Serine	5.7%
Glutamic acid	1.5%	Threonine	2.7%
Glutamine	21.4%		
Glycine	0.7%		
Histidine	1.1%	Tyrosine	5.1%
Isoleucine	6.2%	Valine	3.1%
Leucine	19.3%		

## 19 Specific References

- 1 Katayama H, Kanke M. Drug release from directly compressed tablets containing zein. *Drug Dev Ind Pharm* 1992; **18**: 2173–2184.
- 2 Porter SC. Tablet coating. *Drug Cosmet Ind* 1996; **May**: 46–93.
- 3 Seitz JA, Mehta SP, Yeager JL. Tablet coating. In: Lachman L, Liebermann HA, Kanig JL, eds. *The Theory and Practice of Industrial Pharmacy*. Philadelphia: Lea and Febiger, 1986: 346–373.

## 20 General References

Beck MI, Tomka I, Waysek E. Physico-chemical characterization of zein as a film coating polymer: a direct comparison with ethyl cellulose. *Int J Pharm* 1996; **141**: 137–150.

## 21 Author

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## 22 Date of Revision

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