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## 20 General References

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## 22 Date of Revision

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# Chitosan

## 1 Nonproprietary Names

BP: Chitosan Hydrochloride

PhEur: Chitosan Hydrochloride

USP–NF: Chitosan

## 2 Synonyms

2-Amino-2-deoxy-(1,4)- $\beta$ -D-glucopyranan; *Chitopharm*; chitosani hydrochloridum; deacetylated chitin; deacetylchitin;  $\beta$ -1,4-poly-D-glucosamine; poly-D-glucosamine; poly-(1,4- $\beta$ -D-glucopyranosamine); *Protasan*; *Protasan UP CL 113*.

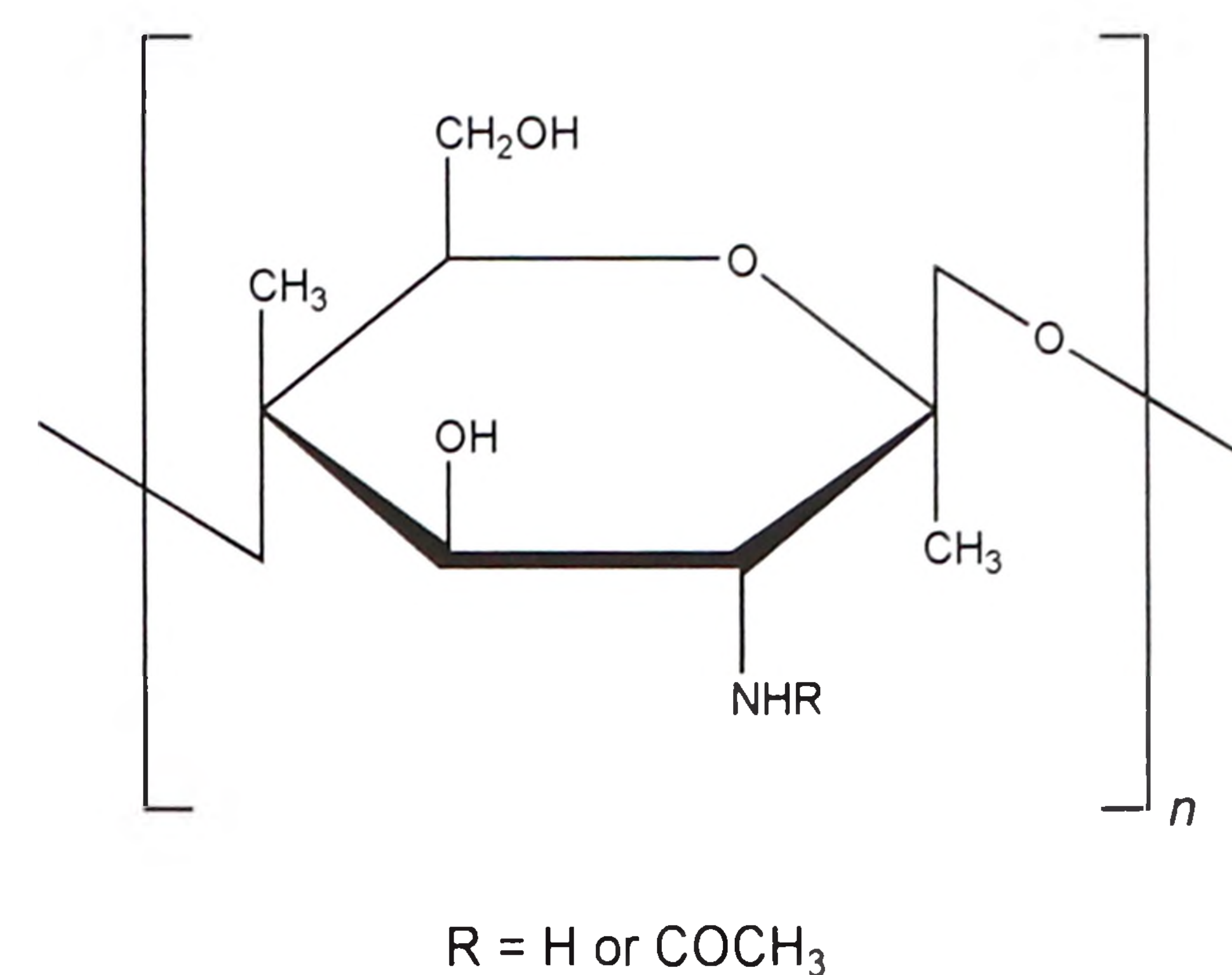
## 3 Chemical Name and CAS Registry Number

Poly- $\beta$ -(1,4)-2-amino-2-deoxy-D-glucose [9012-76-4]

## 4 Empirical Formula and Molecular Weight

Partial deacetylation of chitin results in the production of chitosan, which is a polysaccharide comprising copolymers of glucosamine and *N*-acetylglucosamine. Chitosan is the term applied to deacetylated chitins in various stages of deacetylation and depolymerization and it is therefore not easily defined in terms of its exact chemical composition. A clear nomenclature with respect to the different degrees of *N*-deacetylation between chitin and chitosan has not been defined,<sup>(1–3)</sup> and as such chitosan is not one chemical entity but varies in composition depending on the manufacturer. In essence, chitosan is chitin sufficiently deacetylated to form soluble amine salts. The degree of deacetylation necessary to obtain a soluble product must be greater than 80–85%. Chitosan is commercially available in several types and grades that vary in molecular weight by 10 000–1 000 000, and vary in degree of deacetylation and viscosity.<sup>(4)</sup>

## 5 Structural Formula



## 6 Functional Category

Coating agent; tablet and capsule disintegrant; bioadhesive material; film-forming agent; tablet and capsule binder; viscosity-increasing agent.

## 7 Applications in Pharmaceutical Formulation or Technology

Chitosan is used in cosmetics and is under investigation for use in a number of pharmaceutical formulations. The suitability and performance of chitosan as a component of pharmaceutical formulations for drug delivery applications has been investigated in numerous studies.<sup>(3,5–8)</sup> These include controlled drug delivery applications,<sup>(9–14)</sup> use as a component of mucoadhesive dosage forms,<sup>(14–16)</sup> rapid release dosage forms,<sup>(17,18)</sup> improved peptide delivery,<sup>(19,20)</sup> colonic drug delivery systems,<sup>(21,22)</sup> and use for gene delivery.<sup>(23)</sup> Chitosan has been processed into several pharmaceutical forms including gels,<sup>(24,25)</sup> films,<sup>(11,12,26,27)</sup> beads,<sup>(28,29)</sup> microspheres,<sup>(30,31)</sup> tablets,<sup>(32,33)</sup> and coatings for liposomes.<sup>(34)</sup> Furthermore, chitosan may be processed into drug delivery systems using several techniques including spray-drying,<sup>(15,16)</sup> coacervation,<sup>(35)</sup> direct compression,<sup>(32)</sup> and conventional granulation processes.<sup>(36)</sup>