POLYPUBLIE

Chitosan powders and Ortho-R, a chitosan-containing finished product, are stable long term when stored in proper conditions

Anik Chevrier, Dong Wang, Elizabeth Ladd, Jean-Simon Blais, Marc Lavertu

Document en libre accès dans PolyPublie
Open Access document in PolyPublie

Date	2025
Type	Article de revue/Article
Version	
URL de PolyPublie PolyPublie URL	https://publications.polymtl.ca/64339/
Évaluation par les pairs Peer reviewed	Révisé par les pairs / Refereed
Conditions d'utilisation Terms of use	Creative Commons Attribution 4.0 International (CC BY)
Référence Citation	Chevrier, A., Wang, D., Ladd, E., Blais, J.-S., & Lavertu, M. (2025). Chitosan powders and Ortho-R, a chitosan-containing finished product, are stable long term when stored in proper conditions. Carbohydrate Polymer Technologies and Applications, 10, 100777 (12 pages). https://doi.org/10.1016/j.carpta.2025.100777

Publication officielle
Official publication

Titre de la revue Journal title	Carbohydrate Polymer Technologies and Applications (vol. 10)
Maison d'édition Publisher	Elsevier BV
URL officielle Official URL	https://doi.org/10.1016/j.carpta.2025.100777
Mention légale Legal notice	© 2025 The Authors. Published by Elsevier Ltd. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/).

Ce fichier a été téléchargé à partir de PolyPublie, le dépôt institutionnel de Polytechnique Montréal
This file has been downloaded from PolyPublie, the institutional repository of Polytechnique Montréal
https://publications.polymtl.ca

Table S1. Additional testing performed on the finished Ortho-R product (50 mg format)-Accelerated conditions (40°C/75% RH).

Tests	Specifications	Results		
		Initial	3 months	6 months
Before reconstitution:				
Appearance	White to off-white dry powder either in a plug form or as a powder	Dry white powder in a plug form	White dry powder in a plug form	White dry powder in a plug form
Identification A (IR)	IR spectrum of sample must correspond to the reference standard	IR spectrum of sample corresponds to the reference standard	N/A	N/A
Identification B (NMR)	NMR spectrum of sample must be consistent with chitosan structure	NMR spectrum of sample is consistent with chitosan structure	N/A	N/A
Sterility	Sterile	Sterile	N/A	Sterile
Endotoxin	$\leq$ 100 EU/g	8.7 EU/g	N/A	N/A
After reconstitution in 5.0 mL Water for Injection (WFI):				
Particulate matter	≥ 10 µm: NMT 6000 particles/vial	167 particles/vial	N/A	268 particles/vial
	≥ 25 µm: NMT 600 particles/vial	10 particles/vial	N/A	14 particles/vial
After reconstitution in 5.0 mL Platelet-Rich Plasma (PRP) isolated from commercial sheep blood:				

Tests	Specifications	Results		
		Initial	3 months	6 months
Coagulation	Coagulated at 30 min	Coagulated at 30 min	Coagulated at 30 min	Coagulated at 30 min
Clot Homogeneity	Homogeneity score + or +/-	Score +	Score +/-	Score +/-

N/A: Non applicable

Table S2. Additional testing performed on the finished Ortho-R product (50 mg format)-Long-term conditions (25°C/60% RH).

Tests	Specifications			Results				
		Initial	3 months	6 months	12 months	18 months	24 months	36 months
Before reconstitution:								
Appearance	White to off-white dry powder either in a plug form or as a powder	Dry white powder in a plug form	White dry powder in a plug form	White dry powder in a plug form	White dry powder in a plug form	Off-white dry powder in a plug form	White powder in a plug form	White dry powder in a plug form
Identification A (IR)	IR spectrum of sample must correspond to the reference standard	IR spectrum of sample corresponds to the reference standard	N/A	N/A	N/A	N/A	N/A	N/A
Identification B (NMR)	NMR spectrum of sample must be consistent with chitosan structure	NMR spectrum of sample is consistent with chitosan structure	N/A	N/A	N/A	N/A	N/A	N/A
Sterility	Sterile	Sterile	N/A	N/A	Sterile	N/A	N/A	Sterile

Tests	Specifications	Results						
		Initial	3 months	6 months	12 months	18 months	24 months	36 months
Endotoxin	≤ 100 EU/g	8.7 EU/g	N/A	N/A	N/A	N/A	N/A	N/A
After reconstitution in 5.0 mL Water for Injection (WFI):								
Particulate matter	≥ 10 µm: NMT 6000 particles/vial	167 particles/vial	N/A	271 particles/vial	92 particles/vial	N/A	70 particles/vial	336 particles/vial
	≥ 25 µm: NMT 600 particles/vial	10 particles/vial	N/A	11 particles/vial	35 particles/vial	N/A	12 particles/vial	56 particles/vial
After reconstitution in 5.0 mL Platelet-Rich Plasma (PRP) Isolated from Commercial Sheep Blood:								
Coagulation	Coagulated at 30 min	Coagulated at 30 min	Coagulated at 30 min	Coagulated at 30 min	Coagulated at 30 min	Coagulated at 30 min	Coagulated at 30 min	Coagulated at 30 min
Clot Homogeneity	Homogeneity score + or +/-	Score +	Score +/-	Score +/-	Score +	Score +	Score +	Score +

N/A: Non applicable

Table S3. Additional testing performed on the finished Ortho-R product (100 mg format)-Accelerated conditions (40°C/75% RH).

Tests	Specifications	Results		
		Initial	3 months	6 months
Before reconstitution:				
Appearance	White to off-white dry powder either in a plug form or as a powder.	White dry powder in a plug form	White dry powder in a plug form	White dry powder in a plug form
Identification A (IR)	IR spectrum of sample must correspond to the reference standard.	IR spectrum of sample corresponds to the reference standard	N/A	N/A
Identification B (NMR)	Consistent with structure. Characteristic	Consistent with structure. Characteristic chitosan peaks	N/A	Consistent with structure. Characteristic chitosan peaks

Tests	Specifications	Results		
		Initial	3 months	6 months
	chitosan peaks at approximately: 2.3ppm, 3.5ppm, between 3.6-4.2ppm, 4.9 ppm and 5.2 ppm were observed. Trehalose excipient peaks at approximately 3.7 ppm and 5.4 ppm are present	at approximately: 2.3ppm, 3.5ppm, between 3.6-4.2ppm (partially obscured by the trehalose excipient signal), 4.9 ppm and 5.2 ppm were observed. Trehalose excipient peaks at approximately 3.7 ppm and 5.4 ppm were present		at approximately: 2.3ppm, 3.5ppm, between 3.6-4.2ppm (partially obscured by the trehalose excipient signal), 4.9 ppm and 5.2 ppm were observed. Trehalose excipient peaks at approximately 3.7 ppm and 5.4 ppm were present
Sterility	Sterile	Sterile	N/A	Sterile
Endotoxin	$\leq$ 100 EU/g	$<$ 3.85 EU/g	NA	NA
After reconstitution in 10.0 mL Water for Injection (WFI):				
Particulate matter	≥ 10 µm: NMT 6000 particles/vial	121 particles/vial	N/A	75 particles/vial
	≥ 25 µm: NMT 600 particles/vial	39 particles/vial	N/A	13 particles/vial
After reconstitution in 10.0 mL Platelet-Rich Plasma (PRP) isolated from commercial sheep blood:				
Coagulation	Coagulated at 30 min	Coagulated at 30 min	Coagulated at 30 min	Coagulated at 30 min
Clot Homogeneity	Homogeneity score + or +/-	Score +	Score +	Score +

N/A: Non applicable

Table S4. Additional testing performed on the finished Ortho-R product (100 mg format)-Long-term conditions (25°C/60% RH).

Tests	Specifications	Results				
		Initial	3 months	6 months	12 months	18 months
Appearance	White to off-white dry powder either in a plug form or as a powder.	White dry powder in a plug form	White dry powder in a plug form	White dry powder in a plug form	White dry powder in a plug form	White dry powder in a plug form

Tests	Specifications	Results				
		Initial	3 months	6 months	12 months	18 months
Identification A (IR)	IR spectrum of sample must correspond to the reference standard.	IR spectrum of sample corresponds to the reference standard	N/A	N/A	N/A	N/A
Identification B (NMR)	Consistent with structure. Characteristic chitosan peaks at approximately: 2.3ppm, 3.5ppm, between 3.6-4.2ppm, 4.9 ppm and 5.2 ppm were observed. Trehalose excipient peaks at approximately 3.7 ppm and 5.4 ppm are present	Consistent with structure. Characteristic chitosan peaks at approximately: 2.3ppm, 3.5ppm, between 3.6-4.2ppm, 4.9 ppm and 5.2 ppm were observed. Trehalose excipient peaks at approximately 3.7 ppm and 5.4 ppm are present	N/A	Consistent with structure. Characteristic chitosan peaks at approximately: 2.3ppm, 3.5ppm, between 3.6-4.2ppm, 4.9 ppm and 5.2 ppm were observed. Trehalose excipient peaks at approximately 3.7 ppm and 5.4 ppm are present	N/A	N/A
Sterility	Sterile	Sterile	Sterile	Sterile	N/A	Sterile
Endotoxin	$\leq$ 100 EU/g	$<$ 3.85 EU/g	NA	NA	N/A	N/A
After reconstitution in 10.0 mL Water for Injection (WFI):						
Particulate matter	≥ 10 µm: NMT 6000 particles/vial	121 particles/vial	N/A	N/A	N/A	42 particles/vial
	≥ 25 µm: NMT 600 particles/vial	39 particles/vial	N/A	N/A	N/A	3 particles/vial
After reconstitution in 10.0 mL Platelet-Rich Plasma (PRP) isolated from commercial sheep blood:						
Coagulation	Coagulated at 30 min	Coagulated at 30 min	Coagulated at 30 min	Coagulated at 30 min	Coagulated at 30 min	Coagulated at 30 min

Tests	Specifications	Results				
		Initial	3 months	6 months	12 months	18 months
Clot Homogeneity	Homogeneity score + or +/-	Score +	Score +	Score +	Score +	Score +

N/A: Non applicable