

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

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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 | ≤ 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 | ≤ 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 |

[illegible]

| 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