

Patisiran: Temperature Excursions

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SUMMARY

- Per the Prescribing Information, patisiran is to be stored refrigerated at 2°C to 8°C (36°F to 46°F). If refrigeration is not available, patisiran can be stored at room temperature up to 25°C (up to 77°F) for up to 14 days.¹
- In stability analyses, there was no product quality impact to patisiran when subjected to temperature excursions of not lower than -4°C for up to 96 hours or for up to 40°C for up to 24 hours.²⁻⁴

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RELEVANT INFORMATION

Impact of Temperature Excursions

Patisiran is shipped and stored at the storage condition of 2 to 8°C and carries a “do not freeze” recommendation on the label. During shipment or storage, patisiran may potentially be exposed to a temperature below the lower limit of the defined recommended storage condition of 2°C, or above the upper limit of the defined recommended storage condition of 8°C.²

In one analysis, the stability of patisiran following exposure at low temperatures was evaluated using stability-indicating chemical analyses that measured change as a function of time for quantitative attributes (siRNA and lipid excipient content) and adherence to key quality attributes including physical appearance, pH, particle size, drug substance purity, and percent encapsulation of the siRNA. The study concluded that, after exposing patisiran to a low temperature of -4°C for up to 96 hours, patisiran did not freeze and is chemically and physically stable.^{2,3}

In another analysis, the stability of patisiran following exposure at high temperatures was evaluated using stability-indicating chemical analyses that measured change as a function of time for quantitative attributes (siRNA and lipid excipient content) and adherence to key quality attributes including physical appearance, pH, osmolality, particle size, drug substance purity, and percent encapsulation of the siRNA. The study concluded that, due the susceptibility of the drug product to thermal degradation,

storage above 30°C should be limited. The existing stability data conservatively supports short-term temperature excursions of up to 40°C, and these excursions should not exceed 24 hours in duration.^{2,4}

Overall, there is no product quality impact to patisiran when subjected to temperature excursions of not lower than -4°C for up to 96 hours or for up to 40°C for up to 24 hours (**Table 1**).²⁻⁴

Table 1. Temperature Excursion and Duration with No Product Quality Impact to Patisiran.²⁻⁴

Temperature Excursion	Duration
Not lower than -4°C	Up to 96 hours
Up to 40°C	Up to 24 hours

The assessment is based on the abovementioned excursion followed by storage at 2°C to 8°C as per the USPI.

ONPATTRO PRESCRIBING INFORMATION – RELEVANT CONTENT

The **HOW SUPPLIED/STORAGE AND HANDLING** section provides the following information¹:

Store at 2°C to 8°C (36°F to 46°F). Do not freeze. Discard vial if it has been frozen.

If refrigeration is not available, ONPATTRO can be stored at room temperature up to 25°C (up to 77°F) for up to 14 days.

ABBREVIATIONS

siRNA = small interfering ribonucleic acid; USPI = US Prescribing Information.

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REFERENCES

1. ONPATTRO (patisiran) Prescribing Information. Cambridge, MA: Alnylam Pharmaceuticals, Inc.
2. Alnylam Pharmaceuticals. Data on file. MED-ALL-TTR02-2200017.
3. Alnylam Pharmaceuticals. Data on file. MED-ALL-TTR02-2100027.
4. Alnylam Pharmaceuticals. Data on file. MED-ALL-TTR02-1900226.