Thermostability of Fungi, Mite, and Dander Raw Materials under Temperature Stress Conditions

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Abstract

Background: While extensive data regarding the thermostability of allergenic extracts is available, similar information for the associated raw materials is limited. This experiment investigated the thermostability of various raw materials stored under two temperatures.

Methods: One lot of each Alternaria alternate (Aa), Dermatophagoides pteronyssinus (Dp), and dog dander (Dd) materials were stored at 30-35°C for 16 weeks (W16) and at 60-65°C for 30 days (D30). In addition, cat dander (C) was stored at 30-35°C for 8 weeks (W8). Moisture contents were determined at regular intervals. Materials stored at 0°C were used as controls (T0). Percentages of the parameters obtained at W16, D30, and W8 compared to T0 were calculated (% T0).

Results: Percentages of the parameters obtained at W16, W8, and D30 were compared to T0. Percentages of the parameters obtained at W16, D30, and W8 compared to T0 were calculated (% T0).

Conclusions: Raw materials have selective thermostability profiles. Aa, Dp, and Dd samples were stable at 30-35°C for 16 weeks and C for 8 weeks without any obvious deterioration. This stability could have practical applications and should be investigated further.

Introduction

The stability of raw materials used for the production of allergenic extracts has not been studied. Stability indicator tests to assess the stability of allergenic extracts have not been defined, and are limited by the reagents available for testing.

Objective

Obtain information regarding the stability of fungi, mite, and epithelia homologous groups placed under temperature stress conditions over short periods.

Identify proper stability indicator tests for each material.

Materials and Methods

Source Materials

One lot of each Alternaria alternate, Dermatophagoides pteronyssinus, dog dander, and cat dander.

Thermal Stress Protocol

Ambient Relative Humidity: 40-50%

Temperatures:

- 30-35°C

- 60-65°C

Protocol Design:

- Materials were stored at each temperature for 16 weeks for Aa, Dp, and Dd, and 30 days for C.

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Materials Extraction and Testing

For the purpose of consistency, all materials were extracted and tested simultaneously by the same individual at the end of the study period.

Half a gram of each source material was extracted in 1.2 M (w/v) in Caco-2 solution.

The extracts were prepared at 2.0°C overnight under constant agitation. Extracts were clarified by centrifugation at 2,000 rpm for 30 minutes at room temperature followed by paper filtration under vacuum.

The associated allergenic extracts were stored at 2.0°C until testing, which was completed within two weeks after extraction.

The test methods used and the criteria to evaluate results are described in Table I.

Table I: Testing intervals for the raw materials stored at 30-35°C and 60-65°C

<table>
<thead>
<tr>
<th>Temperature</th>
<th>30-35°C (%)</th>
<th>60-65°C (%)</th>
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<tbody>
<tr>
<td>0</td>
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<td>30</td>
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Table H: Test Methods and Specifications for the Materials

- Moisture Content
- Total Protein
- Major Allergens

Figure 1: Moisture content obtained for A. alternata, D. pteronyssinus, dog dander, and cat dander stored at 30-35°C (A) and 60-65°C (B)

Figure 2: Total Protein and Major Allergen Levels in A. alternata Stored at 30-35°C (A) and at 60-65°C (B)

Figure 3: Total Protein and Major Allergen Levels in D. pteronyssinus Stored at 30-35°C (A) and at 60-65°C (B)

Figure 4: Total Protein and Major Allergen Levels in Dog Dander Stored at 30-35°C (A) and at 60-65°C (B)

Figure 5: Total protein and Fel d 1 contents obtained for cat dander stored at 30-35°C for 8 weeks

Conclusions

Raw materials have selective thermostability profiles. A. alternata, D. pteronyssinus, and dog dander samples were stable at 30-35°C for 16 weeks and cat dander for 8 weeks without any obvious deterioration, as determined by the parameters tested. These findings could have practical applications and should be investigated further.

The results obtained for the materials stored at 60-65°C confirmed the suitability of the parameters measured as stability indicator tests. These observations should be confirmed with other raw materials.

Additional testing, including relative potency measurements, should be performed.

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