

## METERED DOSE INHALERS TEMPLATE

Complete the plain text information in each section, and delete all italicized text. See also USP Guideline for Submitting a Request for Revision of the USP/NF. Note that the terms Metered Dose Inhaler and Inhalation Aerosol are considered interchangeable, but Inhalation Aerosol should be used for labeling purposes. These items included in the template are listed below for convenience.

- 1 Name of monograph**
- 2 Description**
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- 4 Packaging and storage**
- 5 Labeling**
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**Name of monograph<sup>1</sup>**  
[Drug] Inhalation Aerosol

*The proposed name should be a United States Adopted Name (USAN) as described in USP General Chapter <1121> Nomenclature.*

**Description<sup>2</sup>**  
[Drug] Inhalation Aerosol is a [solution/suspension] of [drug] in a suitable propellant in a pressurized container which is sealed with a metered dose valve and accompanied by a suitable [actuator/mouthpiece].

*{The description should state whether the drug is in solution or suspension. A specific propellant should not be indicated}.*

**Definition<sup>3</sup>**

It delivers not less than 85.0 percent and not more than 115.0 percent of the labeled amount of [molecular formula of drug] per actuation.

*{Limits of 85.0 to 115.0 percent on a per actuation basis apply for all Metered Dose Inhaler}s.*

**Packaging and storage<sup>4</sup>**

Preserve in pressure-safe containers equipped with metered-dose valves and store at controlled room temperature.

*{The proposed packaging and storage should be consistent with the instructions in USP-NF General Notices and Requirements. The above statement is considered standard and should apply for all Metered Dose Inhalers, although alternate storage temperatures may be proposed if justified}.*

**Labeling<sup>5</sup>**

Warning: Contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120F (49C). Keep out of reach of children.

*{The labeling statement should be consistent with the instructions in the Labeling section of USP General Chapter <1151> Pharmaceutical Dosage Forms. The above statement is considered standard and should apply for all Metered Dose Inhalers}.*

**USP Reference standards <11><sup>6</sup>**

USP [Drug Name] RS.

*{Currently available USP reference standards should be listed}.*

**Identification<sup>7</sup>**

Infrared Absorption <197[method reference letter]>: [Method details]

*or (delete as appropriate)*

A: [Test A name] [<reference number and letter where applicable>]: [Method details]

B: [Test B name] [<reference number and letter where applicable>]: [Method details]

*{Identification should be by IR (as per USP General Chapter <197> Spectrophotometric Identification Tests) or two other tests such as retention time, chemical reaction, or UV spectrum}.*

**Leakage Test<sup>8</sup>**

It meets the requirements under Aerosols, Nasal Sprays, Metered Dose Inhalers, and Dry Powder Inhalers <601>.

*{This test should be conducted on all Metered Dose Inhalers}.*

**Total Number of Discharges per Container<sup>9</sup>**

It meets the requirements under Aerosols, Nasal Sprays, Metered Dose Inhalers, and Dry Powder Inhalers <601>.

*{This test should be conducted on all Metered Dose Inhalers}.*

**Microbial limits <61><sup>10</sup>**

It meets the requirements for specific pathogens, Total Aerobic Microbial Count, and Total Combined Molds and Yeast Count under Microbial Limits <61>.

*{A test and limits for microbial content should be included. Requirements other than those included in Microbial Limits <61> may be considered (see Pharmacopeial Forum 31(4) July-August 2005 Stimuli to the Revision Process: Microbial Testing for Orally Inhaled and Nasal Drug Products).}*

**Delivered-dose uniformity<sup>11</sup>**

It meets the requirements for Metered-Dose Inhalers under Aerosols, Nasal Sprays, Metered Dose Inhalers, and Dry Powder Inhalers <601>.

*{All Metered Dose Inhalers should meet the requirements outlined in USP General Chapter <601>}.*

**Delivered-dose uniformity over the entire contents<sup>12</sup>**

It meets the requirements for Metered-Dose Inhalers under Aerosols, Nasal Sprays, Metered Dose Inhalers, and Dry Powder Inhalers <601>.

*{All Metered Dose Inhalers should meet the requirements outlined in USP General Chapter <601>}.*

**Aerodynamic particle size distribution<sup>13</sup>**

The aerodynamic particle size distribution is tested according to the instructions for Metered-Dose Inhalers under Aerosols, Nasal Sprays, Metered Dose Inhalers, and Dry Powder Inhalers <601>. [Method details.] [Calculation details and definition of Fine Particle Dose.] The Fine Particle Dose is between [lower level]% and [upper level]% of the labeled amount of [molecular formula of drug] per actuation.

*{All Metered Dose Inhalers should be tested as outlined in USP General Chapter <601>. The specific method and calculation details and limits for Fine Particle Dose should be included.}*

#### **Alcohol content**<sup>14</sup>

Method [method number] <611>: [Method details.] Between [lower level]% and [upper level]% of C<sub>2</sub>H<sub>5</sub>OH is found.

*{Where relevant, a test and limits for alcohol content as per USP General Chapter <611> Alcohol Determination should be included.}*

#### **Water content <601>**<sup>15</sup>

The water content is not more than [upper level]%.

*{A test and limits for water content as per USP General Chapter <601> (with reference to USP General Chapter <921> Water Determination) should be included.}*

#### **Leachables**<sup>16</sup>

The container closure system, specifically the [component(s) tested], meets the requirements of <87> Biological Activity Tests, In Vitro and <88> Biological Activity Tests, In Vivo.

*{A test and limits for leachables should be included. Requirements other than those included in <87> Biological Activity Tests, In Vitro and <88> Biological Activity Tests, In Vivo may be considered (see Product Quality Research Institute recommendations regarding extractables and leachables in Orally Inhaled and Nasal Drug Products).}*

#### **Impurities**<sup>17</sup>

[Method details and limits]

*{A test and limits for individual specified, individual unspecified, and total impurities should be included, using the format described in the “Tablets and Capsules Template” addendum of the USP Guideline for Submitting a Request for Revision of the USP/NF.}*

#### **Assay**<sup>18</sup>

The assay per actuation is determined using the mean of the delivered dose uniformity test.

*{As noted in the Definition, above, the assay should be declared on a per actuation basis. This may be determined by calculating the mean of delivered dose uniformity test results, with corrections as necessary to convert from “per dose” amounts to “per actuation” amounts.}*

**USP Guideline for Submitting Requests for Revision to USP-NF**  
*V3.1 April 2007*

**References**

The following references were used in the preparation of this draft monograph:

*{A list of all references used, such as foreign pharmacopeiae, USAN, published papers, etc. should be provided.}*

**Validation**

Validation has been provided for the following methods:

*{Validation for all methods that need instructions beyond those included in USP General Chapters should be conducted as per USP General Chapter <1225> Validation of Compendial Methods and the data provided.}*