VITAMIN C

Date: September 14, 2007

Proper name(s): Vitamin C (Sweetman 2007; IOM 2003; O’Neil et al. 2001)

Common name(s): Ascorbic acid, vitamin C (Sweetman 2007; IOM 2003; O’Neil et al. 2001)

Source material(s):
- Ascorbic acid/Vitamin C (Sweetman 2007; IOM 2003; O’Neil et al. 2001)
- Ascorbyl palmitate (Sweetman 2007; IOM 2003)
- Calcium ascorbate (Sweetman 2007; IOM 2003; O’Neil et al. 2001)
- Magnesium ascorbate (Sweetman 2007)
- Niacinamide ascorbate/Nicotinamide ascorbate (IOM 2003; O’Neil et al. 2001)
- Potassium ascorbate (Sweetman 2007)
- Sodium ascorbate (Sweetman 2007; IOM 2003; O’Neil et al. 2001)

Note: The slash (/) indicates that the terms are synonyms. Either term may be selected by the applicant.

Route(s) of administration: Oral

Dosage form(s): Those pharmaceutical dosage forms suited to oral administration, including but not limited to chewable tablets, caplets, capsules, strips, lozenges, powders or liquids where the dose is measured in drops, teaspoons or tablespoons, are acceptable. This monograph is not intended to include food-like dosage forms such as bars, chewing gums or beverages.
Use(s) or Purpose(s):  Statement(s) to the effect of:

**General:**
A factor in the maintenance of good health (IOM 2006; IOM 2000).

**Specific:**
- Helps the body to metabolize fats (IOM 2006; Shils et al. 2006; Groff and Gropper 2000; IOM 2000).
- Helps the body to metabolize proteins (Shils et al. 2006; Groff and Gropper 2000; IOM 2000).
- Helps in the development and maintenance of bones, cartilage, teeth and gums (Shils et al. 2006; Groff and Gropper 2000; IOM 2000).
- Helps in connective tissue formation (IOM 2006; Shils et al. 2006; Groff and Gropper 2000; IOM 2000).
- An antioxidant (IOM 2006; Shils et al. 2006; Groff and Gropper 2000; IOM 2000) for the maintenance of good health.

**Dose-specific:**
For products providing daily doses of vitamin C at or above the Recommended Dietary Allowance (RDA) (adjusted for the life stage groups), the following use or purpose is acceptable:
- Helps to prevent vitamin C deficiency (IOM 2006; Shils et al. 2006; Groff and Gropper 2000; IOM 2000).

[Note: Vitamin C deficiency is rare in North America (IOM 2006; Shils et al. 2006; Groff and Gropper 2000; IOM 2000).]

See Appendix 1 for definitions and Table 2 in Appendix 2 for RDA values.

**Dose(s):**

Table 1: Dose information for vitamin C presented as dose per day

<table>
<thead>
<tr>
<th>Life stage group</th>
<th>Vitamin C (mg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Minimum&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>Children</td>
<td></td>
</tr>
<tr>
<td>1-3 y</td>
<td>2.2</td>
</tr>
<tr>
<td>4-8 y</td>
<td>2.2</td>
</tr>
<tr>
<td>Adolescents</td>
<td></td>
</tr>
<tr>
<td>9-13 y</td>
<td>2.2</td>
</tr>
<tr>
<td>14-18 y</td>
<td>6.0</td>
</tr>
<tr>
<td>Adults&lt;sup&gt;3&lt;/sup&gt;</td>
<td>6.0</td>
</tr>
</tbody>
</table>

<sup>1</sup>Based on approximately 5% of the highest RDA (IOM 2006). See Appendix 1 for definitions and Table 2 in Appendix 2 for RDA values.

<sup>2</sup>Maximum dose based on the Tolerable Upper Intake Level (UL) which applies to total vitamin C intake from food and supplements (IOM 2006).

<sup>3</sup>Includes pregnant and breastfeeding women.
Duration of use: No statement required.

Risk information: Statement(s) to the effect of:

Caution(s) and warning(s): No statement required.

Contraindication(s): No statement required.

Known adverse reaction(s): No statement required.

Non-medicinal ingredients: Must be chosen from the current NHPD List of Acceptable Non-medicinal Ingredients and must meet the limitations outlined in the list.

Specifications: Must comply with the minimum specifications outlined in the current NHPD Compendium of Monographs.

References:


Appendix 1: Definitions

**Recommended Dietary Allowances (RDA):** The average daily dietary nutrient intake level sufficient to meet the nutrient requirements of nearly all (97-98%) healthy individuals in a particular life stage and gender group (IOM 2006).

**Tolerable Upper Intake Level (UL):** The highest average daily nutrient intake level that is likely to pose no risk of adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects may increase (IOM 2006).

Appendix 2: RDA Values

The RDA values for vitamin C are provided below. For the purpose of this monograph, these values are intended to:
- provide targets for setting appropriate supplement dosage levels;
- provide the minimum dose for the use of the dose-specific use or purpose: “Helps to prevent vitamin C deficiency”;
- facilitate the optional labelling of % RDA values.

<table>
<thead>
<tr>
<th>Life stage group</th>
<th>Vitamin C (mg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children 1-3 y</td>
<td>15</td>
</tr>
<tr>
<td>Children 4-8 y</td>
<td>25</td>
</tr>
<tr>
<td>Adolescent males 9-13 y</td>
<td>45</td>
</tr>
<tr>
<td>Adolescent males 14-18 y</td>
<td>75</td>
</tr>
<tr>
<td>Adult males ≥ 19 y</td>
<td>90</td>
</tr>
<tr>
<td>Adolescent females 9-13 y</td>
<td>45</td>
</tr>
<tr>
<td>Adolescent females 14-18 y</td>
<td>65</td>
</tr>
<tr>
<td>Adult females ≥ 19 y</td>
<td>75</td>
</tr>
<tr>
<td>Pregnancy 14-18 y</td>
<td>80</td>
</tr>
<tr>
<td>Pregnancy 19-50 y</td>
<td>85</td>
</tr>
<tr>
<td>Breastfeeding 14-18 y</td>
<td>115</td>
</tr>
<tr>
<td>Breastfeeding 19-50 y</td>
<td>120</td>
</tr>
</tbody>
</table>