IUPAC Nomenclature

The International Union of Pure and Applied Chemistry (IUPAC) is a systematic method of naming organic and inorganic chemical compounds. IUPAC was formed in 1919 by chemists from industry and academia.

The root name is then modified due to the presence of different functional groups which replace hydrogen or carbon atoms in the parent structure. There are a number of different ways to modify the root name to indicate the functional groups present:

- **Substitutive**: (most common): the highest priority functional group modifies the suffix of the root name, while all other groups, or substituents, are added as prefixes to the root name.
- **Functional group**: names the compound based on the highest priority functional group, i.e. as an alcohol, esters, halogens, etc.
- **Replacement**: used to indicate when an atom, usually carbon, is replaced by another atom.
- **Conjunctive**: used to combine named subunits
- **Common or trivial**: due to widespread use, some compounds with simple names have been adopted into basic IUPAC nomenclature.

Using IUPAC nomenclature gives consistency and allows every compound to have a unique name.

Pronunciation of Non-Proprietary Names

The USAN Program provides nonproprietary (generic) names for all drugs marketed in the United States. We also determine the pronunciation of these names. However, there is great variation in how the names are actually pronounced by patients and health care professionals, which could cause drug mix-ups.

Some medications are pronounced differently based on a patient's/provider's place of origin, and sometimes misunderstandings can arise and potential drug prescription mix-ups.
There have been several initiatives to help eliminate mispronunciations. When reviewing a proposed non-proprietary name, the USP/APhA/USAN along with the FDA, considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted throughout the medication use system.

The spelling of the proposed non-proprietary name is compared with established names of existing and proposed non-proprietary drug products because similarly spelled names are more likely to sound similar to one another when spoken, or look similar to one another when scripted. In addition, there are some existing applications already available to help improve pronunciation of drug names. Some of these tools include Drug Pronunciation by HippoSoft ($2.99), Drug Pronunciation Unlimited Lite by BG1 (Free), ClinCalc.com (Free) and others. While effective, these tools are more frequently used by medical professionals than patients.

Preferred Format for Amino Acid Sequence Submissions

In order to initiate the review of your biologic, the USAN Program needs an electronic version of the amino acid sequence submitted in an editable MS Word document. The ideal format for your heavy chain and light chain sequence submission is the following example of a table format:

**Heavy chain**

<table>
<thead>
<tr>
<th></th>
<th>ABCDEFGHIJ</th>
<th>KLMNOPQRST</th>
<th>UVWXYZABCD</th>
<th>EFGLJKMN</th>
<th>OPQRSTUVWX</th>
<th>50</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ABCDEFGHIJ</td>
<td>KLMNOPQRST</td>
<td>UVWXYZABCD</td>
<td>EFGLJKMN</td>
<td>OPQRSTUVWX</td>
<td>100</td>
</tr>
<tr>
<td></td>
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<td>KLMNOPQRST</td>
<td>UVWXYZABCD</td>
<td>EFGLJKMN</td>
<td>OPQRSTUVWX</td>
<td>150</td>
</tr>
<tr>
<td></td>
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<td>KLMNOPQRST</td>
<td>UVWXYZABCD</td>
<td>EFGLJKMN</td>
<td>OPQRSTUVWX</td>
<td>200</td>
</tr>
<tr>
<td></td>
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<td>KLMNOPQRST</td>
<td>UVWXYZABCD</td>
<td>EFGLJKMN</td>
<td>OPQRSTUVWX</td>
<td>250</td>
</tr>
<tr>
<td></td>
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<td>UVWXYZABCD</td>
<td>EFGLJKMN</td>
<td>OPQRSTUVWX</td>
<td>300</td>
</tr>
</tbody>
</table>

**Light chain**

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<th>UVWXYZABCD</th>
<th>EFGLJKMN</th>
<th>OPQRSTUVWX</th>
<th>50'</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>EFGLJKMN</td>
<td>OPQRSTUVWX</td>
<td>100'</td>
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<tr>
<td></td>
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<td>OPQRSTUVWX</td>
<td>150'</td>
</tr>
<tr>
<td></td>
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<td>KLMNOPQRST</td>
<td>UVWXYZABCD</td>
<td>EFGLJKMN</td>
<td>OPQRSTUVWX</td>
<td>200'</td>
</tr>
</tbody>
</table>

Disulfide bridges

<table>
<thead>
<tr>
<th></th>
<th>28-228</th>
<th>28'-228'</th>
<th>28''-228''</th>
<th>28'''-228'''</th>
<th>78'-178'</th>
<th>78''-178''</th>
<th>230'</th>
</tr>
</thead>
</table>

Glycosylation sites (N)

This format allows you to ensure you’re submitting an accurate sequence. Also, for practical purposes, this format allows for easier calculation and saves time in the processing of the application. Please send the electronic version of your sequence to brad.wells@ama-assn.org and include a reference to your company’s compound code or assigned USAN file number.
**Turn Back the Clock – Color Additives**

According to the FDA, and as defined by regulation, “a color additive is any dye, pigment, or other substance that can impart color to a food, drug, or cosmetic” (www.cfsan.fda.gov). In a further examination of the role of color within the history of drugs, color additives in medication have always played an important role in identification, perception, dosage and trade protection of medications.

The history of color additives can be traced back to ancient times with the use of vegetable and mineral sources such as paprika, turmeric, iron and lead oxides, and copper sulfate to color foods, drugs and cosmetics. Coating pills with gold or silver leaf to make them palatable and easier to consume was a common practice as early as the 9th century. However, the color revolution really had its launch when, in 1858, William Henry Perkin discovered the first synthetic organic dye, mauve. Following this, other similar discoveries came rapidly, but the safety of color additives in foods, drugs and cosmetics was not actually researched until the late 19th century.

In 1881, the US Department of Agriculture’s Bureau of Chemistry began research on the use of colors in food. This was a dangerous time for consumers because many of the color additives used in coloring foods were poisonous materials such as lead, arsenic and mercury and were often used as a cover to hide inferior or defective foods. The 1906 Food and Drugs Act prohibited use of poisonous or deleterious colors in confectionary and the coloring or staining of food to conceal damage or inferiority. Later, the Federal Food, Drug and Cosmetic Act of 1938 further increased government oversight of foods and drugs and made listings of colors and certification programs for batches mandatory (samples must be submitted from batches of color produced by color manufacturers ensuring safety, see e-CFR Title 21 Part 80).

With further regulation in place manufacturers were able to explore color use as greater technology became available. The 1960s and 1970s produced the first soft gel capsules and the first colors used were red, green, and yellow. Colors became associated with the identification of drugs as well as the perception of what type, speed of symptom relief and action of the drug might have. Color subsequently became an important monitor for the patient in self-administering correct dosages. Also, within trade protection, color has become a barrier against counterfeit drugs in an age where this has become rampant and allows consumers to discern what they are taking based on color.

Within every facet of world history, within daily perceptions, intellectual property, common foods and life-saving medications, color is everything.
Upcoming Events

✓ USAN Council Summer Meeting – July 13th, 2018
✓ 67th INN Fall Consultation – October 23-26th, 2018
About USAN

The purpose of the United States Adopted Names (USAN) Council is to serve the health professions of the United States by selecting simple, informative and unique nonproprietary names for drugs by establishing logical nomenclature classifications based on pharmacological and/or chemical relationships.

The USAN Council is tri-sponsored by the American Medical Association (AMA), the United States Pharmacopeial Convention (USP) and the American Pharmacists Association (APhA). The USAN Council aims for global standardization and unification of drug nomenclature and related rules to ensure that drug information is communicated accurately and unambiguously. It works closely with the International Nonproprietary Name (INN) Program of the World Health Organization (WHO) and various national nomenclature groups.

Edited by brad.wells@ama-assn.org