Strength Conversion in Drug Listing

Leyla Rahjou-Esfandiary, Pharm. D.
Drug Registration and Listing Branch
Office of Compliance
CDER | US FDA

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Learning Objectives

- Describe strength conversion in drug listing
- Provide dosage form examples of strength conversion in listing SPLs
- List potential consequences of incorrect strength conversion in listing SPLs

Electronic Format

- Registrations and listings (including the submission of updated information) shall be submitted to the Secretary **by electronic means.**
- All information submitted under [part 207] must be transmitted to FDA in **electronic format** by using our electronic drug registration and listing system, **in a form that we can process, review, and archive**.

Standardization

- Dosage form
- Route of administration
- Strength
- Unit of measure
- Active ingredient and moiety
- Labeling sections

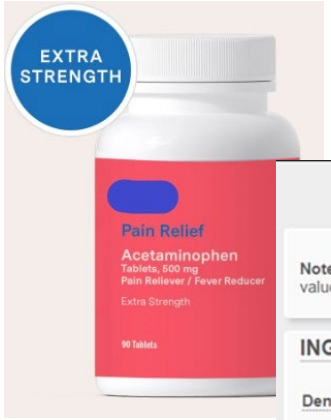
Strength Conversion

- Required for standardization and compatibility
- Strength cannot be expressed in percentage in an SPL format
  - Must be converted
  - Numerator and denominator

Strength Fields

- Numerator (strength)
  - Weight or volume of the active ingredient
- Numerator unit
  - Weight or volume unit of measure
- Denominator strength
  - Weight or volume of drug base, or time
- Denominator unit
  - Weight, volume or time unit of measure, or each

Strength in CDER Direct



SAVE INGREDIENT | DELETE INGREDIENT | << RETURN

Note: The denominator strength and UOM for all Ingredients within a product should be the same. Should you need to change the values, all the ingredients added thus far should be deleted and added with the new values.

INGREDIENT DETAILS

Denominator Strength: * 1

Unit of Measure: * 1

Type: * Active Ingredient, Ingredient is Basis of Strength

Ingredient UNII - Name: * (362O9ITL9D) ACETAMINOPHEN

Strength: * 500

Unit Of Measure: * mg

☐ Moiety Same as Ingredient

Active Moiety: * (362O9ITL9D) ACETAMINOPHEN

ADD ACTIVE MOIETY

Converting a Percentage in SPL

- Mainly depends on the listed drug's dosage form:
  - As w/w - mass (grams) of solute in mass (100 g) of solution, like topical creams and ointments
  - As w/v - mass (grams) of solute in a volume (100 mL) of solution, like oral liquids
  - As v/v - volume (milliliters) of solute in a volume (100 mL) of solution, like alcohol
  - As w/time - mass (grams) of active ingredient released over time, like transdermal and vaginal systems

Examples

Dosage Form	Numerator Unit	Denominator Unit
Oral Solid (e.g., tablet, capsule, oral film)	Weight	Each
Oral Liquid	Weight	Volume
Topical cream or ointment	Weight	Weight
Transdermal systems	Weight	Time
Swab, Cloth, Sponge (Alcohol)	Volume	Volume

Injectable Drugs

Product and strength	SPL Numerator Value	SPL Numerator Unit	SPL Denominator Value	SPL Denominator Unit
Drug A for Injection 100 mg/vial	100	mg	1	Each
Drug B Injection 100 mg/20 mL (5 mg/mL)	100	mg	20	mL

Incorrect Conversion is a Data Deficiency

- Automated validation errors
- No errors generated
  - FDA deficiency letter
  - Compliance case
  - If corrected:
    - Manual override
  - If not corrected:
    - Data inactivation, untitled letter, warning letter

Challenge Question #1

Which statement is correct?

A. SPL automated validations detect any strength conversion error

B. Strength in SPL should always match strength in labeling

C. Strength in SPL should always align with strength in labeling

D. As long as the listing SPL is submitted and accepted by FDA, the strength calculation is done correctly

Challenge Question #2

Which dosage form(s) can be expressed in **weight per volume** in a listing SPL:

A. Topical gels

B. Medical gas

C. Inhalation powder (e.g., dry powder inhaler)

D. Ophthalmic solution, suspension

Resources

- Strength Conversion in Drug Listing | FDA
- Dosage Forms | FDA
- https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/gc-7-ira-20200731.pdf
- List of Error-Prone Abbreviations | Institute For Safe Medication Practices (ismp.org)

U.S. FOOD & DRUG ADMINISTRATION

Questions?

Leyla Rahjou-Esfandiary, Pharm. D.
Leyla.Rahjou-Esfandiary@fda.hhs.gov

eDRLS@fda.hhs.gov