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Suggested Formula Addendum

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Please note that Medisca Network formulas are developed based on current information and available scientific literature <u>at the time</u> of formulation development. As formulations may be in a constant state of change, certain Medisca Network formulas may require a number of updates based on modifications in information and guidelines specific to the Active Pharmaceutical Ingredients (APIs), dosage forms or other legal/regulatory and organizational standards and guidelines. As we continue to update our database, prior to utilizing a Medisca Network formula, please verify that the following are current and up to date:

Corrections for water content

Refer to the chemical certificate of analysis, as well as the USP monograph to determine if water content calculations should be taken into account for any active pharmaceutical ingredients listed in the formula.

Corrections for salt/base conversions

Refer to the USP monograph or any other acceptable resources to determine if a salt/base conversion or any other conversion is necessary for any API listed in the formula.

Calculations for assay results

Refer to the chemical certificate of analysis, as well as USP or any other applicable pharmacopeia monograph to determine if potency calculations from the assay results should be taken into account for any active pharmaceutical ingredients listed in the formula

BUD updates

For current recommendations on Beyond-Use Dating for non-sterile preparations, refer to USP <795> or the "Addendum to the Assignment of Beyond-Use Dates for Non-Sterile Preparations", which is located on the formula search site.

For current recommendations on Beyond-Use Dating for sterile preparations, refer to USP <797> or the "Addendum to the Assignment of Beyond-Use Dates for Sterile Preparations", which is located on the formula search site.

Sensitivities

Refer to the API SDS for additional information on API sensitivities.



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Sterile formulas

In relation to the chemical composition of the formulation, final packaging, etc., select and validate an end-stage sterilization method and follow the manufacturer's specifications.

Capsule formulas

Please note that for your convenience, we have changed the location of the table to calculate the quantity of excipient(s) required for the batch in our capsule formulas. As such, current capsule formulas have the tables attached at the end of the formula in the appendix section, whereas the previous formulas had the tables embedded within the formulas.

Please also note disclaimers, indications of Registered or Trademarked items, special instructions, ingredient nomenclature, USP, USP-NF or other official pharmacopeia monograph status and logos may differ among the formulations. It is the responsibility of the compounder to assess the relevance to their practice for disclaimer and special instruction changes. It is the responsibility of the compounder to determine the appropriateness for use of ingredients in a compounded preparation in accordance to Federal and State laws. In the presence or absence of an officially recognized compendia, the licensed pharmacist must employ appropriate measures to qualify the ingredient(s) for use in the final compounded preparation.

If additional information and/or clarification is required, please e-mail our Technical Support Services Department at technicalservices@medisca.net or call 1-866-333-7811.

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