

## Guidance Number: 030

### Option 2: Normalization Example

- Option 2: Normalize the dose whenever a pediatric product is involved in the calculation. Document the average body weight factor for the adult (usually a 70 kg adult) and for the pediatric patient used for  $MAR_T$  calculations. Refer to the following example.

Product to be cleaned [Numerator in $MAR_T$ formula]	Next Product (Number of units/day x unit weight) [Denominator in $MAR_T$ formula]	Calculation for dose normalization
For Pediatric use $T_A =$ Reported to be 2mg/kg	For Adult use (3 tabs x 300 mg/tab = 900 mg)	For $MAR_T$ calculations Normalize $T_A$ pediatric dose to an adult, assuming a 70 kg adult = 2mg/kg x 70 kg = 140 mg $T_A$ normalized = 140 mg (Numerator in $MAR_T$ formula)
For Adult use $T_A =$ 100 mg	For Pediatric use 10 mg/kg	For $MAR_T$ calculations Normalize the pediatric maximum daily dose to Adult dose, assuming a 70 kg adult = 10mg/kg x 70 kg = 700 mg Normalized pediatric maximum daily dose = 700 mg (Denominator in $MAR_T$ formula)

- For topical products:
  - Use the published minimum therapeutic dose ( $T_A$ ) for the numerator of the  $MAR_T$  calculations
    - $MAR_T$  calculations for topical liquid products can be performed using  $T_A$  expressed in mg or  $\mu$ l.  
For example refer below for the calculation of  $T_A$  in mg and in  $\mu$ l:

$$T_A = 2 \text{ ml} \quad \text{Product concentration} = 50 \text{ mg/ml}$$

$$T_A(\text{mg}) = 2 \text{ ml} \times \text{Product dosage concentration (mg/ml)}$$

$$T_A(\mu\text{l}) = 2 \text{ ml} \times \text{Volume conversion (1,000 } \mu\text{l/ml)}$$

Examples:

$$T_A (\text{mg}) = 2 \text{ ml} \times 50 \text{ mg/ml} = 100 \text{ mg OR}$$

$$T_A (\mu\text{l}) = 2 \text{ ml} \times 1,000 \mu\text{l/ml} = 2,000 \mu\text{l}$$

Refer to GPB-T4036 for  $T_A$  and cleaning limits calculation examples.

OR

- o Estimate a standard minimum formulated dosage as  $T_A$  for topical products (such as topical liquids, non-sterile ointments and creams) for  $MAR_T$  calculation if it is not specified in the insert or reference book (e.g. apply as needed or X times a day). Document the assumptions made in the calculation for the dose (e.g. standard minimum formulated dose).

For example if product X is a cream with 1.0% active ingredient and each dose is about 1.7 g cream/dose, the maximum dose is 4-8 doses/day. Refer below for an example for  $T_A$  calculation.

Determine the g of active per application

$$\begin{aligned} \text{g of active per application} &= \text{g per dose} \times (\%) \text{ of active ingredient in the product}/100 \\ &= 1.7 \text{ g of cream} \times 1.0/100 \\ &= 0.017 \text{ g of active/application} \end{aligned}$$

$$\begin{aligned} T_A &= \text{g of active per application} \times \text{minimum number of applications per day} \\ &= 0.017 \text{ g/application} \times 4 \text{ applications} = 0.068 \text{ g} \end{aligned}$$

- o Estimate the  $T_A$  when a topical product (wound irrigation) is followed by a non-topical product, the  $T_A$  for the topical product can be estimated by the volume of irrigant used per application. The therapeutic dose could then be calculated (e.g. ml volume of irrigant X mg/ml concentration of active in the irrigant). Justify the assumptions and document the rationale in the calculations.