

M-CERSI Pediatric Workshop

Breakout Session: Dosing Vehicles

Pre-Read Material

- Use of liquids and /or soft foods as vehicle for drug administration: General considerations for selection and in vitro methods for product quality assessments. (DRAFT) <https://www.fda.gov/media/114872/download>
- Guidance for Industry: Stability testing of new drug substances and products. <https://www.fda.gov/media/71707/download>

Dosing Vehicles

Breakout Discussion Topics

- How do you select dosing vehicles to be studied when dosing vehicle is needed for administration?
- What kind of dosing vehicle compatibility studies/attributes are tested with dosing vehicles?
 - Physical and chemical stability, dose uniformity, extractability, taste/palatability, drug release/bioavailability, dosing accuracy
- What analytical challenges are faced while conducting these studies?
 - Sample preparation related
 - Analytical procedure/validation related
- Are there any region specific compatibility studies conducted?
 - Considerations for food types and brands world-wide.
- Considerations for including dosing vehicle in the packaging