

Content Uniformity for Inhalation Drug Products
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FDA DCU for MDIs/DPIs

- **1st Tier (10 MDIs/DPIs, 1 determination each):**
 - NMT 1 determination outside 80-120% target emitted dose
 - None outside 75-125%
 - Mean within 85-115%
- **If 2 or 3 determinations outside 80-120%, none outside 75-125%, and the mean within 85-115%, then,**
- **2nd Tier (20 additional MDIs/DPIs, 1 determination each):**
 - NMT 3 determinations (n = 30) outside 80-120%
 - None outside 75-125%
 - Mean within 85-115%

FDA DCU Through Container Life (MDI/DPI)

- **1st Tier (3 MDIs/DPIs, 1 determination each; B, M, E) :**
 - NMT 1 determination (n = 9) outside 80-120% target emitted dose
 - None outside 75-125%
 - Means for each B, M, E within 85-115%
- **If 2 or 3 determinations outside 80-120%, none outside 75-125%, and each mean within 85-115%, then,**
- **2nd Tier (6 add. MDIs/DPIs, 1 determination each, B, M, E):**
 - NMT 3 determinations (n = 27) outside 80-120%
 - None outside 75-125%
 - Means for each B, M, E, within 85-115%