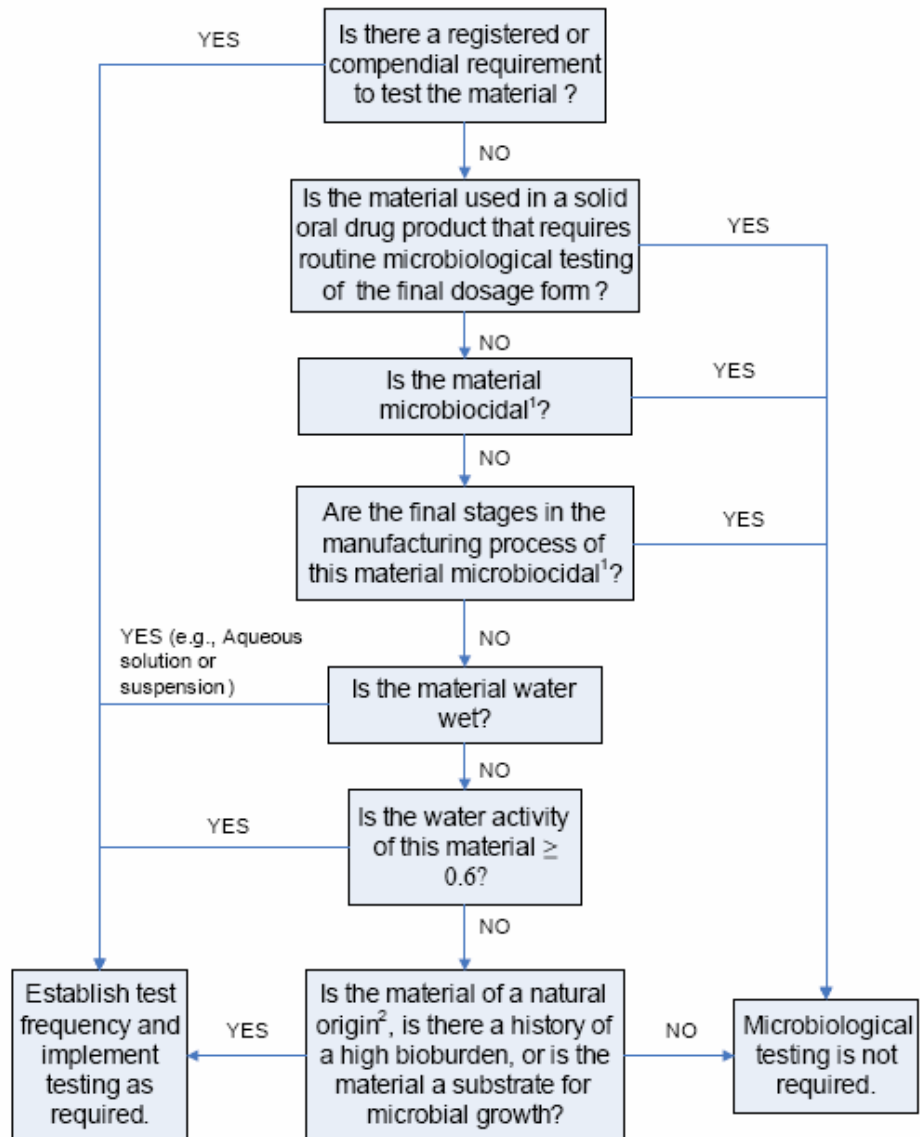


## Guidance Number 110:

Figure 1. Testing rational for excipients and non -sterile APIs used in the manufacture of non -sterile solid oral dosage forms



<sup>1</sup> Microbiocidal is defined as being an organic solvent or strong acid /base (pH ≤ 3 or ≥ 10) or exposed to these materials or high temperature conditions (>121°C for ≥ 15 min.).

<sup>2</sup> Natural origin is defined as not chemically modified. (e.g., extraction or purification.). APIs are not considered of a natural origin.

Figure 2. Testing rational for non -sterile solid oral dosage forms .

