

## Physical specifications required for different dosage forms

不同剂型的物理性状的要求

Dosage Form 剂型	Physical Specifications Required 物理性状的要求
Capsule 胶囊剂	Filling variation 装量差异
	Water content 含水量
	Disintegration 崩解时限
Granules 颗粒剂	Filling/filling variation (for single dose packing) 装量/装量差异 (单剂量包装的产品)
	Water content 含水量
	Granules size variation 粒度
	Dispersibility 溶化性
Liquid (Mixture) 合剂	Filling/filling variation (for single dose packing) 装量/装量差异 (单剂量包装的产品)
	pH
	Relative density 相对密度
	Sucrose content (where applicable) 含糖量 (如果有)
Liquid (Syrup) 糖浆剂	Preservatives (where applicable) 防腐剂含量 (如果有)
	Filling/filling variation (for single dose packing) 装量/装量差异 (单剂量包装的产品)
	pH
	Relative density 相对密度
Liquid (Tincture) 酊剂	Sucrose content (where applicable) 含糖量 (如果有)
	Preservatives (where applicable) 防腐剂含量 (如果有)
	Filling/filling variation (for single dose packing) 装量/装量差异 (单剂量包装的产品)
	Determination of ethanol 乙醇含量
Pills 丸剂	Determination of methanol 甲醇含量 (如果有)
	Filling/filling variation (for single dose packing) 装量/装量差异 (单剂量包装的产品)
	Weight variation 重量差异
	Water content 含水量
Powder 散剂	Disintegration 溶散时限
	Filling/filling variation (for single dose packing) 装量/装量差异 (单剂量包装的产品)
	Water content 含水量
	Uniformity 外观均匀度
Suppository 栓剂	Particle size variation 粒度
	Weight variation 重量差异
	Disintegration 融变时限

Tablet 片剂	Weight variation 重量差异
	Disintegration 崩解时限
Tea 茶剂	Filling/filling variation (for single dose packing) 装量/装量差异 (单剂量包装的产品)
	Water content 含水量
	Weight variation (for tea lumps only) 重量差异 (仅适用于块状茶)
	Dispersibility (for sugar containing tea lumps only) 溶化性 (仅适用于含糖块状茶)

**Please note that for all dosage forms, in addition to the above, the following must be specified:** 请注意，所有剂型，除以上要求外，还必须注明：

- i. **unit weight** 单位重量
- ii. **minimum fill (for multiple dose product)** 最低装量 (多剂量包装的产品)