

Characterization of the Performance of a New Bin-blender (Tumbler Cyclops[®])

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Purpose.

To investigate the mixing performance of a new bin-blender, Tumbler Cyclops[®], VIMA IMPIANTI srl (Lucca, Italy). The blender consists of a bin with a rectangular top section and a hopper-like bottom section. The axis of rotation of the bin can be double tilted and the direction of rotation can be alternated between clockwise and counter-clockwise.

Methods.

Blending experiments were performed using a lab scale (50 L) equipment. Three binary cohesive mixtures were studied containing as excipient Avicel[®] PH102 (FMC-B.H. Shilling SpA, Milan, Italy) and $\leq 3\%$ w/w of a model drug. Loading was top-bottom and a sampling template with two positions, one central and the other peripheral, allowed sampling to be properly carried out. By rotating the template, the peripheral port enables sampling in different positions. The mixture was sampled using a side-sampling thief probe (Cohesive Sampler, ERE inc., Montreal, Canada; sampler length 100 cm, \varnothing 2.5 cm, collecting chamber \varnothing 1.7 cm) and the quantity of solid material analyzed for drug content was at least three times smaller than the sample obtained. Drug contents were quantified using HPLC.

Results.

Several experiments were performed to assess parameters such as sampling size, number of samples and location of sampling since it is known from the literature that potentially inaccurate information can derive from sampling procedure. The mixing index used was the relative standard deviation (RSD) of the drug content of the samples; acceptance criteria for blend homogeneity were defined according to FDA recommendations. Preliminary blending trials always gave rise to RSD < 5% within at most 10 min.

Conclusion.

The new tumbler Cyclops[®] turned out to be a promising blender in terms of time to reach blend homogeneity and reproducibility of the mixing performance.