

Use FDA Guidelines to Switch to the Hanningfield Uni-Mill

Many engineers worry about changing equipment on an existing process, hence if a mill needs replacing they will return to the original manufacturer to seek a replacement.

However, many do not realise that under the FDA SUPAC guidelines this is no longer necessary, and engineers can freely switch between suppliers even once a process has been approved. Indeed, the FDA will sometimes even prefer a change of supplier if there is a cGMP benefit. This allows engineers not only to switch suppliers, but also the type of mill. Hence, the procedure of changing from a hammer mill or oscillating mill is made simple, due to the efficiency improvements.

Below is a table taken directly from the SUPAC Document, showing the typical manufacturers from whom you may wish to switch. The examples column on the right hand side shows suppliers identified by the FDA from whom you may wish to switch.

Table 1 Unit Operation - Particle Size Reduction

Class	Subclass	Examples
Fluid Energy Mills	Tangential Jet	Alpine (Hosokawa) Fluid Energy Aljet Jetpharma Sturtevant
	Loop/Oval	Fluid Energy Aljet
	Opposed Jet	Garlock
	Opposed Jet with Dynamic Classifier	Alpine (Hosokawa) Fluid Energy Aljet
	Fluidized Bed	None Identified
	Fixed Target	None Identified
	Moving Target	None Identified
Impact Mills	Hammer Air Swept	Alpine (Hosokawa) Bepex (Hosokawa) Sturtevant
	Hammer Conventional	Alpine (Hosokawa) Fitzpatrick Fluid Air Mikro (Hosokawa) Rietz (Hosokawa) Stokes-Merrill
	Pin/Disc	Alpine (Hosokawa) Kemutec Sturtevant
	Cage	Stedman
Cutting Mills	None Identified	Alpine (Hosokawa) Fitzpatrick Urschel
Compression Mills	None Identified	MCA International



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Table 1 Unit Operation - Particle Size Reduction (cont.)

Class	Subclass	Examples
Screening Mills	Rotating Impeller	Bepex (Hosokawa) Fitzpatrick Fluid Air Jetpharma Kemutec Quadro Stokes-Merrill Zanchetta (Romaco)
	Rotating Screen	Glatt
	Oscillating Bar	Bepex (Hosokawa) Frewitt Jackson-Crockett Stokes-Merrill Vector
Tumbling Mills	Ball Media	US Stoneware
	Rod Media	None Identified
	Vibrating	Sweco

Table 1 Source: 'Guidance for Industry SUPAC-IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms Manufacturing Equipment Addendum'

The SUPAC document itself can be found at:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070637.pdf>

Questions and answers on the SUPAC guidelines can be found here on the FDA website:

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm124826.htm>

For more information on how the SUPAC guidelines can help you switch suppliers, please contact us and we will be happy to walk you through the simple process.

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