fluitec
mixing + reaction solutions

Fluitec Georg AG Seuzachstrasse CH-8413 Neftenbach
Tel: +41 52 305 00 40 Fax: +41 52 305 00 44
info@fluitec.ch www.fluitec.ch

Fluitec Documentation No. 11.118 Rev. 2

CSE-W® and CSE-X® Static Mixers
for Sterile Processes

Thanks to the wide range of CSE® mixer geometries, processes involving high and low-viscosity fluids can be carried out continuously with unit operations such as mixing, stripping, dispersing, gasification and mass transfer. Stainless steel mixers from Fluitec have been used throughout the process industry for many years. The very high – and individual – quality requirements that must be met for sterile processes are described in this document.

Introduction
In no other industry does the quality of the end product more closely depend on the process components than in pharmaceuticals and biotechnology. The individual quality requirements of each process are determined by the following factors:

- Process stability / quality assurance (contamination, dead spots, dead legs, etc.)
- GMP and CIP aspects
- Cost effectiveness with regard to plant engineering and operation

The pipe joint elements commonly used in the pharmaceutical industry have to comply not only with guidelines based on each company's own experience but also with recommendations issued by FDA, BGA, etc. as well as with the relevant DIN and ISO standards. All the major manufacturers (e.g. Bayer, Novartis, Roche, Böhringer, Schering, Baxter) additionally have their own standards for pipes. Smaller suppliers without a separate pipe classification (for whatever reason) tend to use one of the widely recognised standards. The following pipe joint elements can be combined with Fluitec mixers:

- Dairy couplings acc. to DIN 11851
- Clamp connections (Tri-Clamp®)
- BioConnect couplings (Neumo)
- BBS couplings
- Aseptic pipe connections (Südmo)
- Small flange connections acc. to DIN 11850

One type of connection frequently encountered in Europe is the so-called dairy coupling with a round thread according to DIN 11851. Dairy couplings were originally employed in the food industry. Made of 1.4301 and 1.4404 steel with EPDM seals for metric tubes according to DIN 11850 Series 2, they are inexpensive and readily available.

Fig. 1 CSE-W mixer with dairy coupling acc. to DIN 11851, suitable for simple mixing tasks

The world's most popular connection for pharmaceutical applications is the Tri-Clamp, however.

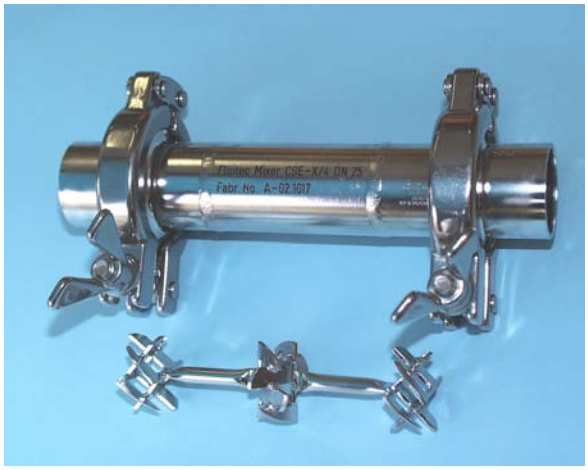

Fig. 2 CSE-X DN25 mixer with Tri-Clamp connection for fluids with a large viscosity difference / Swiss Finish 1 version

Sterile couplings are another kind of separable connection found in pipe construction. Sterile couplings have the following advantages:
- Defined preloading of the seal
- Metallic facing of the joint elements, so that pipe movements do not result in gaps at the sealing edge
- Defined sealing edge directly at the medium
- Compact design
- Standard O-ring seal
- Suitable for orbital welding

Sterile couplings also have the following disadvantages:
- Male and female parts
- Sensitive sealing edges

Strict quality requirements

Once the type of connection has been selected, the next step is to define the welding method and the surface treatment. A variety of requirements are specified here. The following European regulation is generally applicable, however:
- Pressure Equipment Directive 97/23/EC (PED) (Directive 97/23/EC of the European Parliament and the European Council dated May 29, 1997, which aims to harmonise national laws of Member States regarding pressure equipment).

Fluitec Georg AG is in possession of the approvals necessary to manufacture in accordance with the PED. Every mixer made by Fluitec is classified under the PED and issued with a certificate of conformity if required.

Nevertheless, any new plant features apparatus that is outside the scope of the standards or the engineer's or technician's experience. This becomes clear as soon as the components for the new plant are specified. As a result, the specifications regularly contain discrepancies regarding:
- Surface finish
- Freedom from contamination and dead spots
- Drainability

Since both CSE-W and CSE-X mixers offer perfect self-cleaning efficiency, freedom from contamination and dead spots is guaranteed, providing it is possible to drain the equipment and the welded joints are expertly made.

Two qualities are defined for the pharmaceutical industry: Swiss Finish 1 and Swiss Finish 2.

Swiss Finish 1 (low-cost version)

This is a TIG welded mixer (141), assembled by qualified welders, with a maximum ferrite content in the weld seams of 1.5 to 2% (< 3%). The welds, which have a fine ground finish, are pickled and then electropolished, so that the surfaces in contact with the medium have a roughness RA < 0.8 μm while those not required to contact the medium have a roughness RA > 0.8 μm.

The ports are prepared for orbital welding and adequately protected for transport. All medium contacting parts are newly stamped, labelled and identified in the documentation with an EN 10204 - 3.1 certificate. The mixer is accompanied by a declaration of conformity based on the PED as well as an in-process inspection plan.

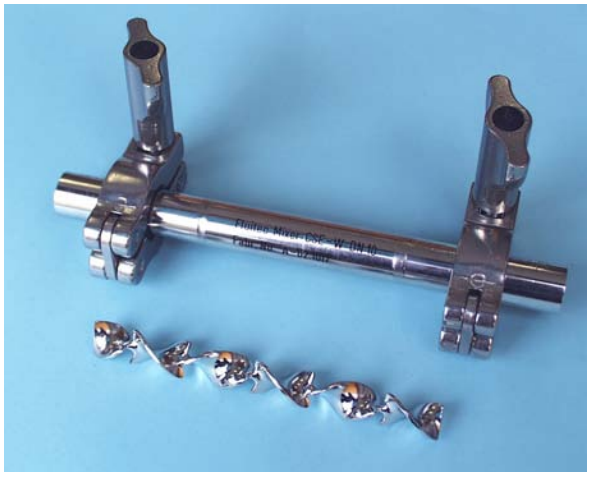

Fig. 3 CSE-W DN10 mixer with Tri-Clamp connection / Swiss Finish 2 version

Swiss Finish 2 (high-end version)

This is an orbitally welded mixer with a maximum ferrite content in the weld seams of < 0.5%. The welds are unfinished and electropolished, so that the surfaces in contact with the medium have a roughness Ra < 0.8 μm while those not required to contact the medium have a roughness Ra > 0.8 μm. The ports are prepared for orbital welding and adequately protected for transport. All medium contacting parts are newly stamped, labelled and identified in the documentation with an EN 10204 - 3.1 B certificate. The mixer is accompanied by a declaration of conformity based on the PED as well as an in-process inspection plan.

The ferrite content measurement at the weld is invoiced on an actual cost basis.