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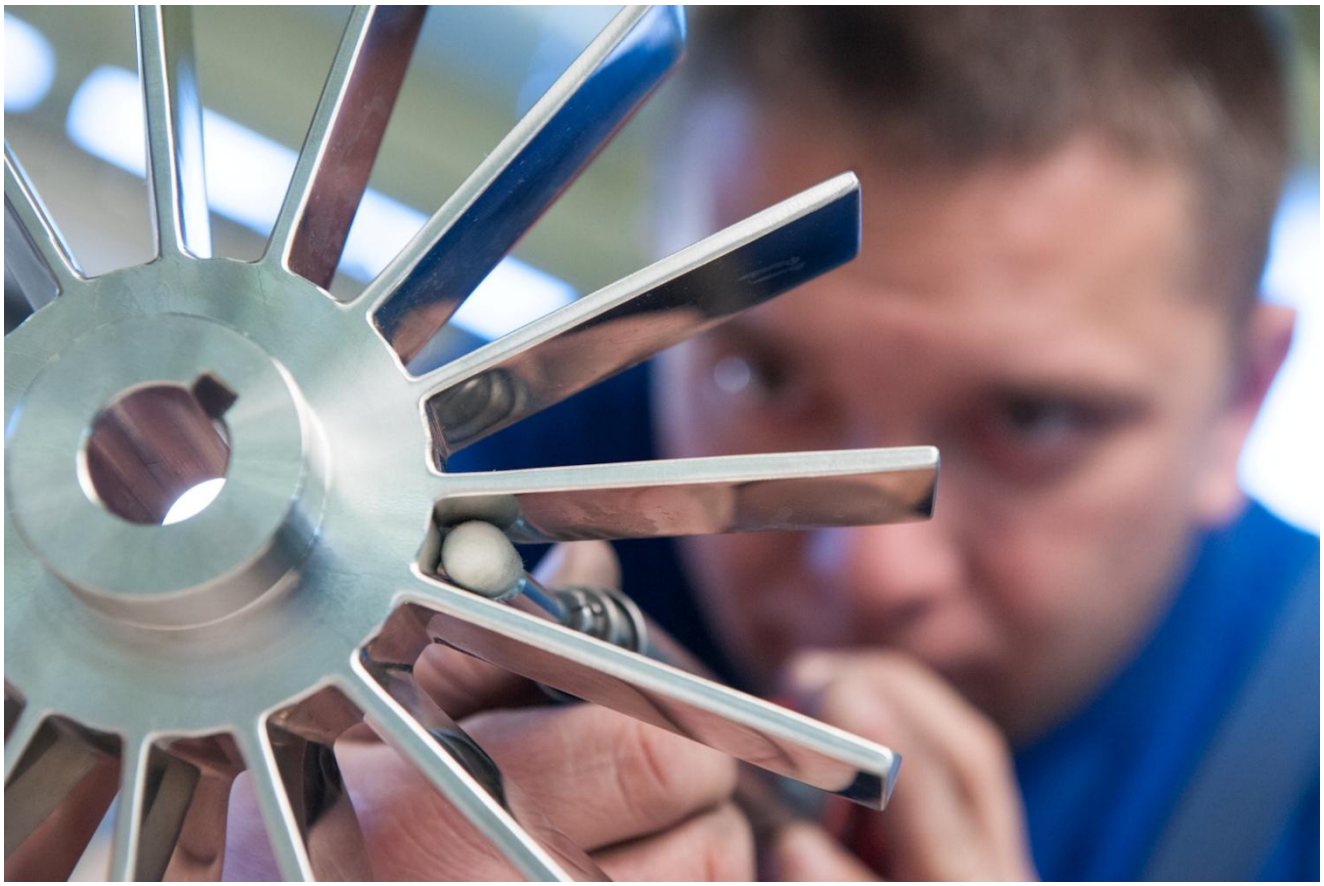

1. SAWA pumps for the pharmaceutical industry

As guidelines for the developement of pumps for the pharmaceutical industry dienen die directives of the *Food and Drug Administration FDA*, the *Good Manufacturing Practices GMP*, the *European Hygienic Engineering and Design Group EHEDG, the 3-A Sanitary Standards* etc. as well as consultations with manufacturers of mechanical seals and aseptic connections.

Particular attention is paid at SAWA pumps for the pharmaceutical industry on the follwing features:

+ Surface roughness
+ Dead space free / Gap-free design
+ Flow optimisation
+ Complete draining
+ Cleanability
+ Documentaton
+ Used materials

Illustration 1 – Self-priming centrifugal pump HDP190 in pharmaceutical design with complete draining velve.

SAWA pharmaceutical pumps are used in various application areas of the pharmaceutical industry, for example for the manufacturing of infusion solutions, for serum and vaccines and for pumping of fluids for example „Water for Injection“. The pumps are made of solid stainless steel 1.4435 / 316L.

Additional areas of application are covered with the SAWA pump type HDP (self-priming centrifugal pump - illustration 1) i.a. as CIP return pump. In this use are an excellent suction capacity and an insensitiveness of the cavitation very important.

The pumps are characterised by their gentle delivery, simplicity of construction, reliability and thus very low life cycle costs.

Illustration 2 – Centrifugal pump LEP190 in pharmaceutical design

+ ATEX: for zones 1, 2, 21, 22
+ Magnetic coupling: hermetically sealed design for crystallising, toxic, flammable and environmentally hazardous liquids
+ vertical option: for easy draining
+ Bearing hoising option: for special requirements
+ Inducer: for low NPSH values < 1 m
+ Mobile: version with sturdy trolley

2. Material - stainless steel 1.4435 / 316L

SAWA pumps for using in the pharmaceutical industry are made of solid austenitic Cr-Ni-Mo-steel (EN WNr. 1.4435 / AISI 316L / Designation X2CrNiMo18-14-3).

+ Good sterilization
+ Good resistane in using of cleaning agents
+ Medically harmless
+ Good surface qualities accomplishable
+ ideal for fast temperature changes due to robust design (e.g. for CIP cleaning)

The composition of this material is similar to the widely spread material 1.4404 and differ in the elevated content of Mo an Ni steel:

+ The generation of δ-ferrite in the structure is reduced, content < 1%
+ Smaller risk of „rouging“
+ Not magnetizable
+ Higher resistance to pitting

Comparison of the chemical composition:

Material	C max.	Si max.	Mn max.	S max.	Cr	Ni	Mo	Ti	P max.	N max.	Fe
WNr. 1.4404 AISI 316L	0.03	1.00	2.00	0.03	16.5 - 18.5	10.0 - 13.0	2.0 - 2.5				
WNr. 1.4435 AISI 316L	0.03	1.00	2.00	0.025	17.0 - 18.5	12.5 - 14.0	2.5 - 3.0		0.045	0.10	BN II <0.5
WNr. 1.4571 AISI 316 Ti	0.07	1.00	2.00	0.03	16.5 - 18.5	10.0 - 13.0	2.0 - 2.5	0.5x% C	0.045	0.10	
WNr. 1.4539 AISI 316	0.02	0.70	2.00	0.010	19.0 - 21.0	24.0 - 26.0	4.0 - 5.0	0.5x% C		0.15	
WNr. 1.4462 AISI 318 LN	0.03	1.00	2.00	0.015	21.0 - 23.0	4.5 - 6.5	2.5 - 3.5	0.5x% C	0.035	0.10	

At customer requests the material charactersitics can be certified by the test certificate 3.1 DIN EN 10204.

3. Sealing materials

In the selction of static and dynamic seals the requirement is matched to the FDA compliance. This will ensure that only materials are used which have no negative impact on the liquid. In addition in the choice of the sealing aterial the resistance, the sterilizability and the abrasion resistance will be considered.

Static sealings (gasket) – FDA compliant elastomers

+ EPDM
+ PTFE
+ FEP
+ FFKM (e.g. Kalrez) / FPM / FKM
+ according customer specifications

Dynamic seals (mechanical seals):

The choice of the mechanical seals is made on the liquid or on the customer's specifications for e.g. SiC/SiC, Coal/SiC, Hm/SiC, Hm/Hm, etc.

+ Single mechanical seal (see illustration 3)
+ Double-acting mechanical seal
+ Flushing
+ With static overlay
+ Material pairing
+ Ferrite content < 1 %
+ Surface roughness < 0.8 µm

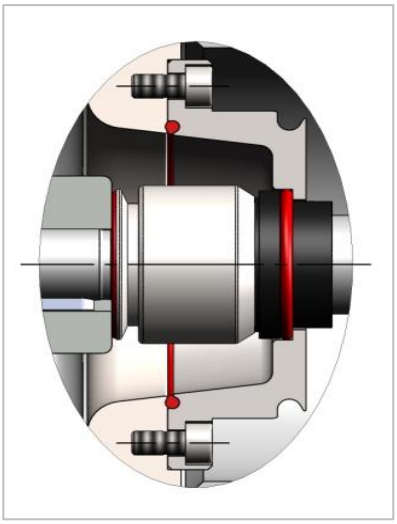

Illustration 3 – Sterile mechnical seal

4. Surface roughness

The surfaces of the SAWA stainless steel pumps for the pharmaceutical and sterile technology are treated to customer, so that the parts which are in contact with the product can have a surface roughness of up to Ra < 0.4 µm. SAWA stainless steel pumps for the pharmaceutical and sterile technology have standard a surface roughness of Ra < 0.8 µm.

Optionally, the surface roughness can be attested by a measurement protocol.

To achieve the required surface roughness, the pump parts are treated according to:

Illustration 4 – Measurement of the surface roughness

1. Machine processing as turning and milling
2. Mechanical processing as sanding and polishing – Avoid errors such as cracks and scratches.
3. Irrespective of the requirement of the Ra-value, the pump parts in the finishing are standard electropolished.

5. Dead space / Gap-free design

SAWA pumps are designed that no dead spaces in the pump inerior are available:

+ Dead space free design in the mechanical seal area
+ Gap-free design including the impeller seal, cover gasket etc.

6. Flow optimization

The aerodynamically optimized design results in an efficient and quiet liquid in the required application and a gentle pumping. The design ensures hygienic operation and a quick cleaning of the pump. The conical seal housing is generous in size and meets optimum flushing of the CIP-capable and sterilizable mechanical seal. In addition, the ideal flow conditions ensure a Anspülung of the O-rings.

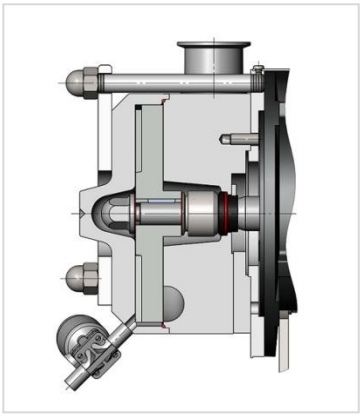

Illustration 5 – Centrifugal pump HDP with complete draining velve

7. Complete draining

The design is easy to clean and guarantees a complete draining of the pump. The liquid flows to the lowest point of the pump and can be emptied there through a valve (see illustration 5). The connections for the complete draining are selected according to customer require, e.g. tri-clamp or diaphragm valve (manually or automatically)

Vertical installation (see illustration):
In the vertical installation, the internal circulation acts to the sliding surfaces on the mechanical seal in the magnetic coupling, the SiC bearings and the can chamber. This achieves a proper CIP and SIP cleaning. The pump in vertical installation can be drained down through the suction branch.

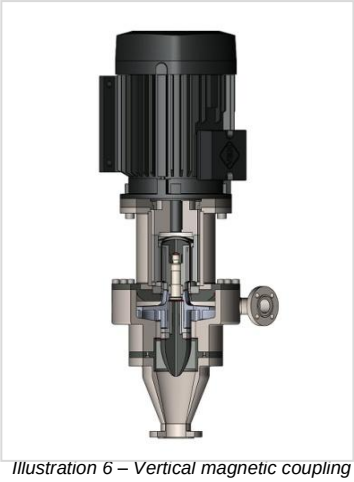

Illustration 6 – Vertical magnetic coupling pump ZAMPv14 in pharmaceutical design

Magnetic coupling:
In addition to the shaft sealing by mechanical seal SAWA manufactures also pharmaceutical pumps with magnetic coupling (horizontal and vertical installation) The inner roter of the magnetic coupling and the can are made of 1.4571 or 2.4610 „Hastelloy“. The inner rotor is completely encapsulated (laser welded). The parts which are in contact with the product met the requirements of hygiene (dead space, surface roughness etc.). The internal circulation flow allows optimal flushing of the slide bearings. The generously sized and pressurized slide barings made of SSiC is designed for process operation.

8. Cleanability

SAWA pharmaceutical and sterile pumps are easy and fast to clean due to the excellent CIP and SIP.

Illustration 7 – Aseptic clamp

9. Aseptic pipe connection

The sterlie connections are chosen according to customer, e.g.:

+ DIN 11864-1: Aseptic screw connection
+ DIN 11864-2: Aseptic flange
+ DIN 11864-3: Aseptic clamp (see Illustration)
+ Customized connections

10. Documentations, Certificates

Damit eine Pharmaanlage zur Zulassung validiert werden kann, ist eine vollständige Dokumentation unabdingbar.

The following documents are components of the scope of delivery:

+ Operating and maintenance manual
+ SAWA test certificate
+ FDA certificate of conformity of the elastomers
+ Test report 2.2 DIN EN 10204

Illustration 8 – Comprehensive documentation

The following documents are as an option available:

+ Acceptance test certificate 3.1 DIN EN 10204
+ Measurement report for surface roughness
+ δ-ferrite measurement report
+ USP Cl VI confirmation
+ Fusion protocol
+ customer specific reuirements to the documentation
+ Protocol „Electropolishing“

In SAWA each pump passed a function control test run before leaving the work. The dates are recorded in the database and including to the operating manual.