

Technical Bulletin

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SURFACE DEFECTS IN FUNCTIONAL STAINLESS STEEL SURFACES IN PHARMACEUTICAL PLANT CONSTRUCTION Origin, Assessment and Elimination

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*The component's
value is assured
by its surface*



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Functional stainless steel surface in contact with the production medium have the task of being resistant to corrosion, hygienic, easy to clean and free of particles. These demands regarding sterile and neutral product integrity as well as cleaning reliability are true both for equipment and tubing made of stainless steel. Localised irregularities in the material especially in the weld beam may not safely be avoided due to the character of the material (material defects). Such irregularities may also be caused by technical manufacturing faults. In this case they are nearly impossible to detect via roughness specifications in routine controls.

In practice such defects, which are relatively simple to detect by specialised electrochemical polishing, show themselves in the following forms:

1. Faults attributable to material

- 1.1 Roller traces as rough, lamellar areas
- 1.2 Roller faults as folds or doublings
- 1.3 Islands of foreign matter as roller traces

2. Faults attributable to mechanical processes

- 2.1 Micro fissures due to deformation
- 2.2 Butts with singular surfaces

3. Faults attributable to welding

- 3.1 Hollows are result of inadequate weld penetration
- 3.2 Localised formation of pores in connection with 3.1
- 3.3 Localised burns as a result of localised crystallisation
- 3.4 Micro fissures as a result of localised crystallisation
- 3.5 Metal carbide impurities on the weld (overheating products)

This summary of the most frequently observed faults, which may be ascertained visually via elution with deionised water after electropolishing, allows the conclusion that a noticeable reduction of defects could be achieved through greater care in the manufacturing process.

The assessment of the defects is based, without exception, on the following criteria:

1. Deterioration of corrosion resistance
2. Impairment of the medium product due to the introduction of particles and/or pyrogenetics
3. Impairment of the sterilisation respectively the residue-free cleaning

Fundamentally, the formation of microscopic dead volume such as cracks, fissures, cavities etc. means an incalculable alteration of the essential characteristics of the surface quality, which means a hazard to the condition of production.

For these reasons the necessity is evident that for sensitive applications the faults mentioned above are to be avoided as these leads to the formation of dead volume.

Localised irregularities in the surface such as pores, grooves etc. which are accessible to the cleaning process can be accepted as long as they meet the roughness specification. These irregularities must be polished and longer or wider than they are deep.

Defects with inaccessible depths which cannot be seen into such as micro fissures, pores, doublings are inaccessible as they may cause uncontrollable exchange reactions as a result of localised diffusion effects. These may have an adverse effect on product quality.

The elimination of such defects is always to be preferred to their concealment and is usually carried out by localised grinding and/or localised welding and grinding with consequent electro-chemical polishing until the defects are removed as required for final inspection.

The care taken in the selection of material must be increased as well as the efforts taken to improve design and manufacturing technology. In this manner the resources needed for repairs necessary to achieve the surface quality generally recognised as suitable for pharmaceutical surface qualities may be minimised or, better still, avoided completely.

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- ▶ Electrochemical and chemical deburring
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- ▶ Chemical pickling
- ▶ Passivation
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