



## RBS Detergents

Solutions for cleaning processes

Pharmaceutical industry



Controlling production environment by implementing adequate cleaning processes is critical at each step when manufacturing pharmaceuticals. RBS high performance cleaning agents have been providing solutions for decades in the pharmaceutical industry. RBS wide products range offers efficient solutions for cleaning all kind of mobile or fixed equipments and surfaces made of glass, plastic or stainless steel including tanks, pipes, blenders, reactors, tablet presses, valves, thermowells, transfer lines ...



## RBS detergents, a long experience to share with customers

Combining a strong theoretical knowledge with a large field experience, RBS engineers assist their customers by proposing solutions at each step of the cleaning process, from development to validation. Such solutions are implemented according to cGMP (FDA), GMP (EMA) requirements and other standards as being part of a quality assurance policy.

RBS products allows removal of residues resulting from complex formulations based on active substances, excipients and from external contamination sources like lubricants and residues from previous productions.

Because selecting a cleaning agent is a crucial step when manufacturing pharmaceutical products, RBS has developed a dedicated approach to cover its customer needs.

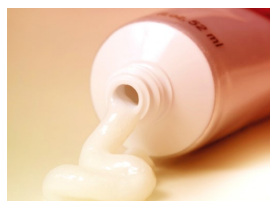


## Equipment and surface state

### Material to clean and contamination to remove

Although pharmaceutical process equipment and tools are typically made of fairly robust and cleanable material, assessing compatibility of such material with the proposed RBS detergent is decisive. Some surfaces might be intolerant to acidic or basic solutions. Surfaces finish and roughness impact significantly cleaning speed, and consequently its efficacy.

Defining the origin and the type of contamination is a determinant factor for selecting the right RBS detergent. On one hand, removing organic soils such as fatty residues, ointments, creams, oils and proteins should be performed with an alkaline detergent. On the other hand, inorganic residues such as mineral salts, scales, metal oxides (rust, rouge) should be removed with help of an acidic detergent. Neutral detergents are recommended for the removal of hydro-soluble soils and should definitely considered when cleaning sensitive materials. In any case, thanks to its enlarged product portfolio, RBS has a solution for its customers.



## Cleaning method

Adapted RBS solution whatever the selected cleaning method

When developing a cleaning procedure, cleaning method is a key element for selecting the right RBS detergent: lightly foaming and weakly alkaline detergents are used in manual cleaning application when non foaming and strongly alkaline detergent are recommended for automatic processes. High performance RBS formulations were designed for each cleaning method to offer synergic actions by using multiple cleaning mechanisms such as solubilisation, emulsification, wetting, chelating, hydrolysis and oxidation. In addition, defining optimal parameters such as detergent concentration, temperature, contact time, washing and rinsing cycles will allow to increase the cleaning efficiency.



RBS detergents are high quality reverse osmosis water based solutions which cover following cleaning methods:

- Manual cleaning by an operator (in place or in a wash room): direct cleaning of internal or external equipment surfaces using a power spray, rotary head, brushes ...
- Immersion Cleaning-in-Place CIP: cleaning small manufacturing tanks, blenders...
- Ultrasonic cleaning: cleaning tools and parts in ultrasonic bath.
- Low and high power spray Cleaning-In-Place (CIP) for fixed equipment: cleaning of equipment with large internal surfaces.
- Washing machine (automatic or semi-automatic cleaning): mobile units, tools and disassembled production equipment are cleaned in an Clean-out-of-Place (COP) procedure.



## Analytical method validation

A parameter required in the validation procedure

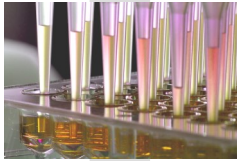
RBS detergent should be compatible with the selected analytical method for cleaning procedure validation. This means that cleaning agent should be measurable and detectable at low concentrations.

Method choice for detecting residues mainly depends on customers constraints, method practical aspects and availability of the related technology:

- *Specific analytical methods*: High Performance Liquid Chromatography HPLC, Ion chromatography, Thin-layer chromatography, spectrophotometry (UV), Enzyme-linked immunosorbent assay, Electrophoresis.
- *Non specific analytical methods*: visual analysis, pH value, conductivity, Total Organic Carbon (TOC) ...



## Cleaning tests & sampling



RBS, the key to success cleaning validation

As part of the cleaning validation procedure, effectiveness of selected RBS detergent can be confirmed by two sampling techniques :

- Direct method of sampling the surface of the equipment (swabbing, ...),
- Indirect method using the rinsing solution.

Our support team can help customers to determine relevant residues acceptance criteria and assist them by carrying worst case validation study in RBS laboratories before beginning real testing in production.

From defining customers needs to validating cleaning procedure, RBS team will closely collaborate with you to succeed in establishing efficient cleaning Standard Operating Procedure (SOP).

In this context, a documents set including Material safety Data Sheet, Technical Data Sheet, tests reports, Certificate of Analysis and brochures are available for the whole RBS range.

## What makes RBS detergents better solutions?



- Total rinse
- Safe-to-use
- Quality controlled products
- Cost effective
- Proven efficiency
- Reproducible process

For more information on products list  
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