

PharmaNews



NEW 200 EVO COMPACT PARTS WASHER

#YourMachineForTheVaccine now
available with short lead times!

M-LINE HIGH PRESSURE WASHER

Cleaning evaluation tests
at client's sites: find out more

TAILORED BASKETS

Enjoy the fascinating journey behind
the production of your basket!

APPLICATION FOCUS

The rise of HPAPI

NEWS FROM THE MARKET

New IWT installations

UPCOMING EVENTS

WELCOME TO THE SECOND ISSUE!

Welcome to this new issue of IWT Pharma News – this issue focuses on the energetic restart after the tough 20 months of the pandemic and the dawn towards a new normal.

Our selection of articles aim to convey this - the ongoing renaissance, represented by new equipment, exciting applications and in-field activities, as well as growing trends in the industry.

The 200EVO, the latest addition to the IWT Parts Washer portfolio, is designed to grant quick turnaround times and fast track deliveries following the demand of a challenging and dynamic market

such as the Pharmaceuticals.

Custom racks represent the most critical component for any automatic cleaning processes - a short video will lead you through the main steps involved in the development of your needed solution, from requirements to validation.

Every single application created is different from the previous one, as dictated by the custom rack design, but the cleaning challenges are often similar, we are sure some of you will see yourself and your procedures in CIPLA's operations and might appreciate the huge improvements that an automatic cleaning process will offer.

Last but not least, we will chat about the fast-paced, and expanding, world of the High Potent Active Principle Ingredients. HPAPI is vital in a world where, despite the COVID pandemic, nobody can be left behind, and deserves the utmost dedication, competence and cutting-edge developments of pharmaceutical organizations.

We all hope you will enjoy this edition and we sincerely hope to see you soon at upcoming in-person events!



www.iwtpharma.com

NEW 200EVO COMPACT PARTS WASHER

now available with short lead times!

IWT Cleaning Excellence are adding to an already exceptional line-up of washing systems with a next generation cleaning system that will totally set new standards in the industry towards washing and decontamination.

Since the successful launch of the 200 series family of Part Washers, our partners in industry have benefited from a single minded focus on washing and the art around correct application placement through our award winning basket and racking design solutions. The steps we have taken through the years to constantly evolve and develop the 200 brings about our latest solution to the critical markets of the cGMP.

What is the 200EVO?

The 200EVO is, in simple terms, an evolution of the 200 series Part Washer. This latest member to the IWT family, the 200EVO offers users a system that will provide a totally repeatable cleaning process, which is fully validated and to the highest GMP standards.

Now fully equipped with the latest automation ancillaries from either Siemens or Allen Bradley (selection applicable to the needs of your business), the touch screen user interface will allow you total control over all process related parameters with a heightened level of finesse, and with security ensured via the multi-level password protection style.

The 200EVO will also support the next generation of customised load baskets which will continue to benefit from the proven concept of direct coupling to the washer via our patented Quick Couple Connector (QCC) system for an optimised and mapped cleaning process.

The art of designing a customised load basket is our passion and it helps ensure performance related results with utility

consumption kept to a minimum, cycle time reduced, enhanced flexibility and maximised up-time.

All this is packaged in system which can be manufactured, tested, delivered, installed, and fully validated within as short a time as most of the competition would take to develop a 1st stage submittal package!



- 200EVO MAIN FEATURES
- ▶ Engineered to clean product contact parts from solid, semi-solid, liquid and aseptic manufacturing sites, from tableting machines to sterile filling lines
 - ▶ Modular design to allow quick turnaround projects
 - ▶ Compact solution to simplify installations in existing productions minimizing any impact on operational flows
 - ▶ Multiple configurations available
 - ▶ Three different sizes: 600, 1000, 1400 liters (160, 265, 370 gal) to maximize and optimize cleaning batches
 - ▶ Up to 30 fully customizable washing programs from pre-washing to drying and cooling
 - ▶ PanelPC configuration for remote connectivity and INDUSTRY 4.0 integration
 - ▶ Cutting edge automation system GAMP5 compliant with ERES (21CFR Part11) and AUDIT TRAIL functions
 - ▶ HEPA filtered drying system for fast drying of parts, chamber and piping
 - ▶ Multiple water inlet and chemical dosing systems with flow meter and conductivity control
 - ▶ Single Pass Rinse feature via sterile compressed air booster with final conductivity control
 - ▶ Full in-house design and manufacturing of customized racks connected via automatic quick-lock patented system
 - ▶ Comprehensive set of handling solutions for manoeuvring, stocking and loading/unloading of custom racks



GAMP5	✓
cGMP	✓
ASME-BPE	✓
ISPE baseline	✓
FDA (including 21CFR part11)	✓
CE Marking	✓
UL Listing	✓

▶ Best-in-class ratio between chamber and total volumes in the smallest footprint for parts cleaning:

200 EVO MODEL	060
Chamber Nominal Volume [m3 – ft3]	> 0.6 – 21.2
Footprint [m² – ft²]	~ 1.2 – 12.9
Unit height [mm - ft]	2500 - 8.2
Unit total volume [m³ – ft³]	3 – 105.8
Ratio	20%

200 EVO MODEL	100
Chamber Nominal Volume [m3 – ft3]	> 1.00 – 35.3
Footprint [m² – ft²]	~ 1.8 – 19.4
Unit height [mm - ft]	2500 - 8.2
Unit total volume [m³ – ft³]	4.5 – 159.1
Ratio	22%

200 EVO MODEL	140
Chamber Nominal Volume [m3 – ft3]	> 1.4 – 49.4
Footprint [m² – ft²]	~ 2.5 – 26.9
Unit height [mm - ft]	2500 - 8.2
Unit total volume [m³ – ft³]	6.3 – 220.6
Ratio	22%

WHAT'S BEHIND YOUR TAILORED BASKET?

The manufacturing process behind the scenes!

Ensuring an effective clean of a wide range of machine parts and miscellaneous items is essential to prevent the cross-contamination between production batches. From drums to hoses, glasswares to plasticwares, filling needles to punch and dies - all components are meticulously studied to design and engineer the associated baskets and racks with the aim to achieve the optimal exposure and to optimize the load per cycle.

The drivers in developing our solutions are:

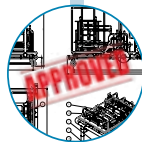
- ▶ **ERGONOMICS** – How easy is it to manage the loading/unloading of the parts for the skilled technicians involved with the cleaning (avoiding potential muscle straining and injury)
- ▶ **EFFICIENCY** - The parts need to be loaded into a basket quickly and efficiently to ensure quick turnaround times
- ▶ **GMP** - The need to ensure Good Manufacturing Practice throughout all stages in the production process is critical. GMP extends to the basket construction as well as the washer machine manufacture. IWT supports this demand by offering detailed documentation packages that cover design, material traceability, engineering standards, control of skill and training and more
- ▶ **OVERALL PERFORMANCE** - Modeling and simulation allow you to verify and proof that the basket final design the most stringent acceptance criteria before production begins.



3D SCANNING for custom parts and MEASUREMENTS CHECKS for standardized components



3D PARTS MODELING AND POSITIONING, BATCH OPTIMIZATION STUDIES AND FLUIDODYNAMIC COVERAGE SIMULATIONS



CUSTOMER'S APPROVAL of the detailed proposal design



SHOP-DRAWINGS ELABORATION AND RELATED MANUFACTURING STEPS inclusive of mandatory traceability and quality controls



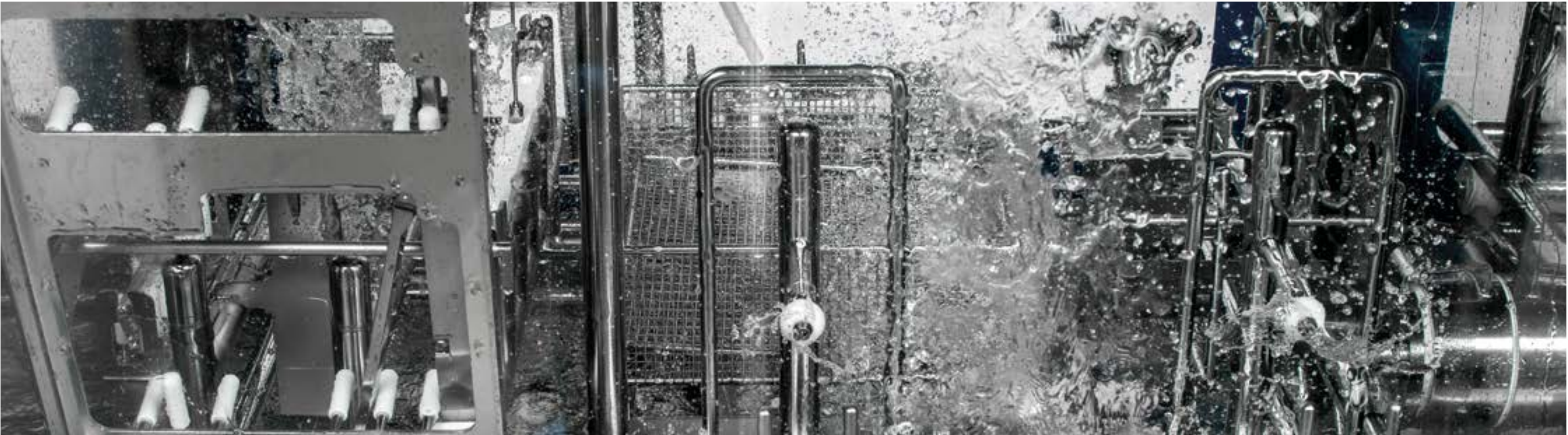
RACK INTERNAL COMMISSIONING AND CUSTOMER'S APPROVAL AT FAT



ON-SITE CLEANING VALIDATION with actual final load

...BUT WHAT'S BEHIND YOUR TAILORED BASKET?

Enjoy the short video below, to see an overview of the REAL process behind the manufacturing of your cleaning basket. With no 3D renders, no layouts and no animations, we let visual media speak for itself, to let you enjoy the passion, the commitment and the attention to detail that we put into everything we do.



M-LINE HIGH PRESSURE WASHER

DEMO at CIPLA Pharmaceuticals

ABOUT THE PRODUCT: IWT M-LINE

M-Line is IWT mobile high-pressure unit for the cleaning of product contact parts of any pharmaceutical IBC, drum, preparation tank and bulk container in general. Thanks to its innovative design and lightness, M-Line is highly ergonomic and user-friendly.

- Suitable for a wide range of applications (CIP and COP)
- Made of AISI316L, GMP and FDA compliant
- Up to 70 Bar (1015 PSI) for great water mechanical action and quick cycles
- Only 40 l/min (9 gal/min) water flow for reduced water and chemical consumptions
- Quick lock connections for hydrokinetic lances.



ABOUT THE CLIENT: CIPLA PHARMACEUTICALS

Cipla Pharmaceuticals, located in Hauppauge (New York) is a leading pharmaceutical company with a focus on a wide range of therapeutic areas including cardiovascular, anti-infective, CNS, anti-inflammatory, anti-diabetic, and anti-depressants.

Cipla is present in 80+ countries providing over 1,500 products across various therapeutic categories in 50+ dosage forms.

M-LINE SET UP

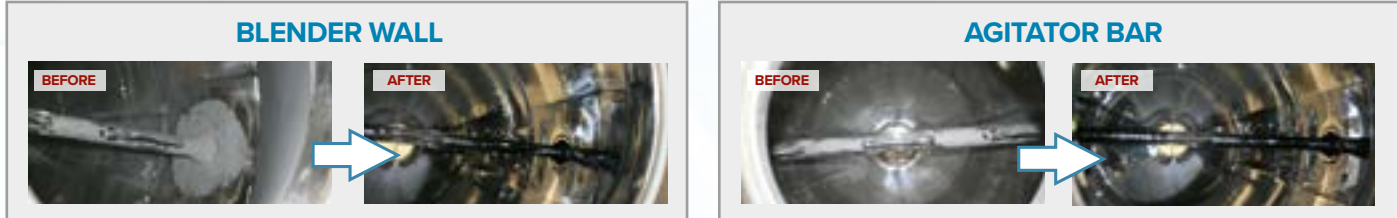


SCAN THE QR CODE
OR [CLICK HERE](#)
to see the
M-LINE SET UP VIDEO

Are you interested in finding out more about the M-LINE demo at Cipla, and receive the White Papers?

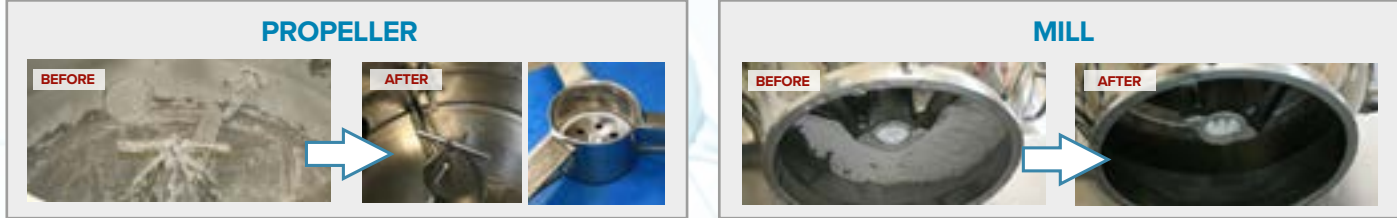
CONTACT US!
info@iwtpharma.com

DEMO #1 - DOUBLE CONE BLENDER CLEANING PROCESS



	CIPLA'S MANUAL CLEANING PROCESS	M-LINE CLEANING PROCESS	PERCENT CHANGE
Cleaning time	estimated 60 minutes	33 minutes	↓ 45% DECREASE
Water usage	estimated 2270 liters (600 gallons)	503 liters (133 gallons)	↓ 78% DECREASE
Quality	good	excellent	IMPROVED

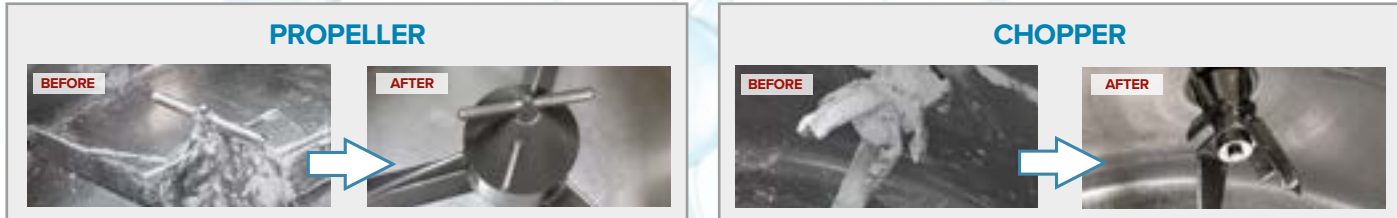
DEMO #2 - RAPID MIXER GRANULATOR CLEANING PROCESS



	CIPLA'S MANUAL CLEANING PROCESS	M-LINE CLEANING PROCESS	PERCENT CHANGE
Cleaning time	estimated 120 minutes	8 minutes 10 seconds	↓ 93% DECREASE
Water usage	estimated 340 liters (90 gallons)	223 liters (50 gallons)	↓ 44% DECREASE
Quality	acceptable	excellent	IMPROVED

DEMO #3 - RAPID MIXER GRANULATOR CLEANING PROCESS

Cipla USA Central Islip, NY manufacturing facility - Unit #1 in May 2021



	CIPLA'S MANUAL CLEANING PROCESS	M-LINE CLEANING PROCESS	PERCENT CHANGE
Cleaning time	estimated 180 minutes	7 minutes 45 seconds	↓ 95% DECREASE
Water usage	estimated 511 liters (135 gallons)	170 liters (45 gallons)	↓ 66% DECREASE
Quality	acceptable	excellent	IMPROVED

THE RISE OF THE HPAPI

With an ever increasing global population across all sectors and the ability to diagnose with increased accuracy diseases such as cancer, our society is looking to the pharmaceutical industry to develop and produce pharmaceutical's that can treat or cure these conditions.

They are also looking for a steady and robust supply network which can be made accessible to all markets.

Emerging markets such as India, China and Middle Eastern Regions are now accounting for the fastest growth rates in Cancer related diagnoses. According to WHO, developing regions accounted for over 66% of all cancer related deaths in 2014.

The rate of percentage growth around new cancer cases in Asia between 2012 to 2020 was up by 24% (6.8m to 8.4m). This trend is not slowing and will continue to increase as our ability and accessibility to current and future methods of diagnoses tools evolve.

If we specifically consider the HPAPI (High Potency Active

Pharmaceutical Ingredients) segment of the pharmaceutical manufacturing industry, this sector has continuously grown production yield about 7% per year since 2005 to 2019, HPAPIs are estimated to have an annual growth of 12% over the same period and this now accounts for about 12% of the total pharmaceutical market.

To support the fight against disease related threats, the utilisation of High Potency Active Pharmaceutical Ingredients (HPAPI) is vital.

As an ingredient for many drugs which are linked to cancer treatments, the methods utilised for the handling

of HPAPI's is tightly controlled and managed with specialised containment methods.

This is essential to shield workers and the surrounding areas from exposure related events, due to the hazardous nature of these API's. In most instances, specifically designed HPAPI manufacturing facilities are being built due to the unique and complex handling requirements.

This is the vital link for the Industry and IWT Cleaning Excellence, with the simple question of how to manage and maintain correct standards of cleaning that can be supported with a validated

system yet offer the user the required levels of safety to ensure a safe working environment?

As a globally recognised leader in the manufacture of cGMP related cleaning systems, IWT has developed, via close working partnerships, a system that can ensure correct worker shielding from accidental HPAPI exposure.

All this whilst offering a cleaning process which can be specifically tailored towards the needs of the application without size of part or design complexity being a limiting factor.

Solutions range from small component part washers which utilise pressurised seals and gaskets to limit any air exchange between environmental facility zones through to Large IBC/Bulk containment washing skids that can offer autonomy for works when manipulating parts to be made ready for washing.

An IWT cleaning system is more than a conventional component washing machine and the industry which we serve has facilitated this technical

evolution due to the unique demands of applications such as HPAPI's.

If we look specifically at the cleaning of IBC style mobile storage vessels, these containers are available in storage sizes ranging from 50 – 1000ltr and are commonly equipped with a containment valve system that demands a specific manipulation to actively open and close the valve.



WATCH THE C-LINE - HIGH POTENT API IBC CLEANING IN ACTION!

Our current range of IBC/Bin washing systems can now be equipped with a fully automatic solution which will ensure user safety during this critical phase of cleaning. Additionally, the IBC washer can also accommodate smaller component styled parts which would often demand a dedicated Part washer styled solution.

Our history and expertise of customised

basket solutions can ensure we are able to design and manufacture the basket in a manner that offers total critical surface area wash coverage and minimal part shadowing effects (part shadowing is the common effect that is created when a component supported in a customised basket is in direct surface contact with the application, resulting in areas being obscured from direct wash action).

As a basic conclusion, the development and manufacture of HPAPIs requires significant planning, extensive training, proper equipment, and facility design as well as implementation of the necessary procedures to safely handle the compounds. The investments are significant, and the knowledge gained through experience is invaluable. IWT Cleaning Excellence is best placed to support this evolving market. The experiences and successes we have created globally will continue to help support our partners in the industry.

IWT equipment for HPAPI applications:



200EVO PARTS WASHER



300 FLEXIBLE PARTS WASHER



2CLEAN IBCs AND CONTACT PARTS WASHER



C-LINE HIGH PRESSURE IBC WASHER



NEW IWT INSTALLATIONS



This project consisted of two 2Clean IBC/Part washers, two 200 GMP washers and a number of customised baskets.

This completed project will allow the client to improve their washing capabilities and increase throughput in their cleaning operations.

The IWT Cleaning Excellence team have project managed, installed, commission and provided in depth training for the client during the COVID-19 pandemic! The video features the washers in-situ and highlights the quality of the product and the installation.



A couple of weeks ago our technicians finished installing **the third 200 Contact Parts Washer** at one of our well known French pharma clients.

After months of working on this important project, the 3 machines are installed and the washing area is finally ready.



After a succesful FAT (Factory Acceptance Test) performed at IWT Headquarters in mid July, our **2CLEAN IBCs and Contact Parts Washer** has just reached the premises of our well renowned German client manufacturing food supplements.

Enjoy these pics portraying equipment transport and installation!



UPCOMING EVENTS

IWT Pharma are delighted to be attending our first face to face events! You will be able to join us on stand to see our latest product innovations and discuss your projects at...

INTERPHEX BOOTH #2968

Javits Center, NYC, USA
October 19-21

A3P INTERNATIONAL

Biarritz, France
November 23-25

CPHI WORLDWIDE BOOTH #10M61

Rho Fiera, Milan, Italy
November 9-11



09-11 November 2021

Fiera Milano, Milan, Italy