

114102

QUOTATION No ID 6886r4
Date: Aug. 21, 2019 ref. joci
Please mention in all correspondence
Rhodes_HW-6_QuoteNo. 6886r4
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CONFIDENTIAL

Rhodes Pharmaceuticals L.P.
498 Washington St.
Providence, RI 02846
Attn: Mr. John Ganley
Mr. Ganley is the contact person



Inquiry dated July 20, 2018 and follow up meetings.

Quotation No.: 6886r4

Local Frewitt representative: Ed King, www.process-info.com



MODULAR SYSTEM FREWITT
Hammer Mill model HammerWitt-6
With complete N2 purging and O2 control
Including PTS Conveying system. Designed for
OEB 4.

*Image at the right only for
reference, as its execution is
similar but not exactly as per
the present quotation.*



The HammerWitt-6 is a hammer mill that guarantees optimum milling results in the fine milling and pulverization of hard, crystalline, and fibrous products to fineness of up to 50 µm.

It is used for laboratory applications and small batch production. With its compact and modular design, it is easy to integrate in nearly any process flow. It is constructed to ensure optimum and reliable production in GMP and High Containment, even for very hard products.

Characteristics of the product to be milled:

Name	to be specified
Density	to be specified
Temperature of the local	to be specified
Size before milling	to be specified
Required final grain size	to be specified
Required output per hour	to be specified
Industry	<input checked="" type="checkbox"/> pharmaceutical <input type="checkbox"/> food <input type="checkbox"/> chemical

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Excellence in Milling and Handling of Powders

Frewitt USA Inc.
249 Homestead Road
Building 5, Unit 8
Hillsborough, NJ 08844

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www.frewitt-usa.com
Tel: +1.908.829.5245

TIN: 46-3540772
Santander Bank N.A.
Wyomissing, PA 19610
Acct No 7678513887 / ABA No 23-1372691 / SWIFT: SVRNUS33

1	1	Hammer Mill FREWITT type HammerWitt-6	
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General

Construction

according to the GMP-standard
required by the WHO

Product contact parts

stainless steel AISI-316/316L, polished
Ra ≤ 0.8 µm, polished welded seams
Ra ≤ 0.8 µm, seals made of PTFE,
EPDM and silicone (FDA conform)

Other parts

AISI-304, polished Ra 1.4 µm, brushed
and ground welding seams

Execution

The control panel and all electronics
are rated for NEMA 4X and suitable for
a Class I, Div. 1 Groups C & D and
Class II, Div. 2, Groups F & G area

Milling head

Fixing

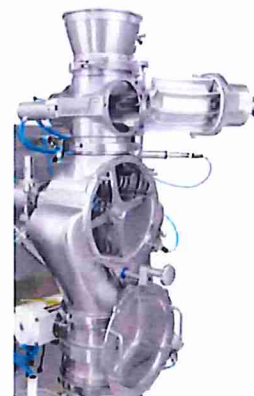
of the milling head to the drive unit by
means of a Tri-Clamp flange

Bearing

rotor drive housing cast in one piece
preventing any risk of leakage and
product contamination, **with air or gas
ventilation**, with control system. The
ventilation of the machine is controlled
with the starting and stopping of the
machine.

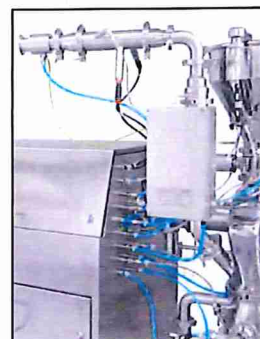
Feeding device

Type [ProFi-Valve 150](#) with pneumatic
drive, to guarantee a continuous
feeding of the machine. Includes valve
pocket purge option to help clean the
pockets of the valve when feeding
sticky materials.



**De-dusting filter with O2 control on milling chamber
and on inlet funnel**

Type [ProFi-Clean 90](#), allows the
filtering and separation of powder
particles in the extracted air. The de-
dusting filter is cleaned automatically
by pressure impulses. This guarantees
that the whole cartridge surface area
remains clog-free and the powder is
blown-back into the product, filter
cartridge made of Polyester-PTFE H13
(DIN EN 1822)



**Venturi system / time regulation for the blow back directly
integrated in the HMI**

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Position	Quantity	Description	USD/unit
Machine with drive unit model FreDrive in mobile execution, complete electrical control with HMI			
		Drive channel	designed for mounting the milling head by means of a Tri-Clamp flange
		Motor protection	the motor is installed under a special protection cover. handle to help to move the machine
		Milling chamber	with N2 connection
		Support	special stand, equipped with 4 adjustable height castors (four mobile, two with brake), in antistatic execution (grey – not marking)
		Motorization	motor 4.0 kW, with frequency converter for speed adjustment of rotor speed from 1000 – 6000 rpm. Speed measurement made on the drive shaft
		Electrical connection	3x460V, 60 Hz, 3Ph (other connections available) Remark: If the installation equipped with a frequency converter is connected to an electrical network including a residual current circuit-breaker (RCD), please clarify the exact type with us.
		Electrical parts:	mounted in an electrical cabinet

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Position	Quantity	Description	USD/unit
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Control system:

For direct use in Class I, Division 1 and Class II, Division 2 hazardous environments.

To be designed per US standards, UL and NEC.

All control components to be UL marked.

Panel to be UL marked.

A purge system will be provided to reduce the environment internal to the control enclosure to a non-hazardous level.

A 12" Allen-Bradley PanelView Plus 7 touch screen running FactoryTalk View ME will be mounted inside the main electrical enclosure and viewed through a window.

A keyboard with a pointing device will be located on a shelf below the touch screen in the hazardous area. The keyboard will be rated for direct use in the hazardous environment and run through intrinsically safe barrier. The keyboard will be manufactured from FDA approved silicone rubber.

The equipment will be portable with a flexible power cable.

An Allen-Bradley CompactLogix processor will be provided.

A 3 phase 460/230 VAC motor will be provided. The motor will be rated for direct use in CI,D1 and CII,D2 environments. Emergency stop and reset controls will be provided along with required safety relays.

The vacuum pump will be provided by Rhodes and installed by Rhodes. The vacuum pump is not part of the Frewitt scope of delivery. It must be installed before the Frewitt equipment arrives at Rhodes.

Pneumatic control components will be located within the purged main electrical enclosure. Any solenoid valves that are required to be external to the enclosure will be energized through intrinsically safe barriers, FM approved and rated for the hazardous environment.

Proportional valves will be provided for components requiring variable air flow/pressure.

All sensors and switches located in the hazardous area will be routed through intrinsically safe barriers suitable for the environment.

Nitrogen will be controlled within the main electrical enclosure for inerting. Software will be developed per US standards and to meet 21 CFR part 11 requirements.

PLC software to be developed using RSLogix 5000 using the latest available development environment.

HMI configuration will be developed using FactoryTalk View ME.

All software and configuration data will be provided for backup and maintenance purposes.

User access levels will be provided for operators, administrators and maintenance personnel.

Operating instructions will be provided with screen images.

Cabling machine supplied with 5 m main cable, without plug

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Intrinsically safe barrier for Ethernet connection: A printer is integrated into the application and process data will be transmitted from the HMI and PLC to an external computer or device. FM approved intrinsically safe barriers will be provided to reduce the power level for safe routing in the hazardous location. One barrier will be located in the purged main electrical panel and another will be in an enclosure in the non-hazardous area. Standard ethernet cabling is suitable for data transmission and will not require a hard piped connection. The non-hazardous area enclosure will have two ethernet ports. One port will be for communications through the hazardous area to the main electrical enclosure. The other will connect to the network where the printer or interfacing PC resides. The power supply, 110VAC plug, terminals, barriers will be included and installed. Print functionality will be included on the appropriate screens and the PLC tag database will be organized and tags will be named for easy access from an external computer.

1.1 TBD Additional HW-6 screen sizes.

TBD

Inlet:

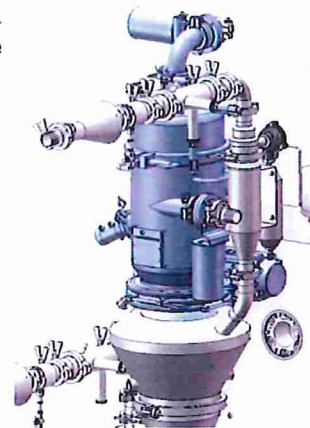
2 1 Inlet funnel DN 380 round, with level sensor, connection for ProFi-Clean de-dusting system, N2 injection, sight glass window, pressure sensor and security switch.

3 1 DEC PTS Pneumatic conveyor on inlet funnel
DEC PTS Pneumatic conveyor combine with N2 station to inert the incoming material.

Capacity at 5 meters	1200 dm ³ /h
Density	0.5 kg/dm ³
Material	Stainless Steel AISI 316/316L
Diameter of the Inlet piping	2"

Filter	Stainless Steel
Level of filtration	2 microns
Discharge Valve	Butterfly valve (AISI 316/316L)

Connection to Inlet funnel	Tri-clamp DN200 (ISO 2852) incl. seal and fixing clamps
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3.1 1 **Option: Ability for PTS system to be repurposed for alternate use** on customer supplied repacking station while still utilizing the HW-6 control panel. Vacuum not included (supplied by customer). Frewitt will deliver longer pneumatic tubing for PTS valve connections to our system (maximum distance not to exceed 2 meters!). A key switch will be included in the HW-6 machine controls so that Rhodes could switch from HW-6 operation to PTS only operation. The PTS system can be removed (via tri-clamp connection) from the inlet of the HW-6 system and then installed (via tri-clamp) in the inlet of the repacking station. Rhodes must insure safe distance on the discharge of the PTS system for butterfly valve to open up without interference.

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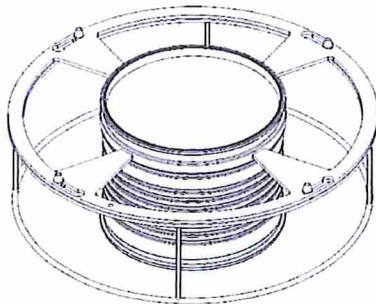
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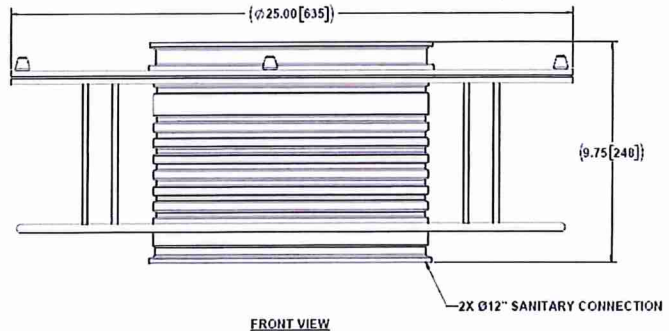
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Position	Quantity	Description	USD/unit
4	1	Outlet: Sampling device (designed for OEB4) Mounted on the HammerWitt-6 outlet with Tri-Clamp flange DN 200 (ISO 2852) Volume: 30 to 140 ml Actuator: pneumatic (4-6 barg) Connection: Tri-Clamp 2-1/2" (BS 4825)	
5	1	pressure sensor on outlet of milling chamber	
6	1	ILC Dover Continuous Liner canister (Rhodes scope of supply)	
Supplied by Rhodes. (to be shipped to Frewitt Switzerland during the assembly, Frewitt project manager will advise Rhodes of time requirement)			



HW12166-01: CANISTER, CONTINUOUS LINER W/ CAGE ASSEMBLY 75FT
MATERIAL: STAINLESS STEEL, TYPE 316L



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Outlet (continued):

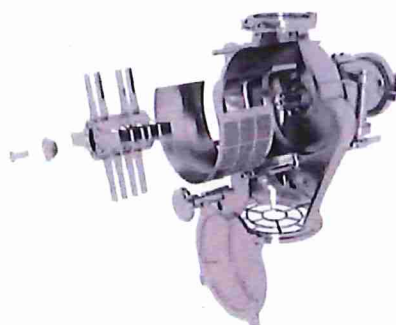
Safety		magnetic safety switch ELOBAU at inlet and at the front door to stop the machine if either the dosing device or the front door are not mounted	
Safety outlet		milling head fitted with a safety grid	

Tools

Screen		one (1) included – hole size to be specified when placing the order	
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Rotor		Pharma execution	
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Inerted milling zone with complete O2 control:

7 Gas inerted milling zone (pressure 5 bar – gas quantity, N₂ or CO₂, approx. 180-250 NI/min. for the HW-6), with control system. The machine is starting when the O₂ value is reached.

System includes:

- electropneumatic valve
- 3 inlet (1x inlet side , 1x milling head, 1x outlet side
- electropneumatic valves
- 2 Oxygen sensors on the 2 Profi-Clean (in total 4: 2x2)
- tubing
- pressure reducer for controlling the gas quantity

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Position	Quantity	Description	USD/unit
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O2 control system:

8

The control system measures the O2 concentration.

Two measuring cells are used to measure the O2 concentration on the outlet of the ProFi-Clean. (total 2x2)
The required O2-value can be adjusted acc. to the requirements.
The control system measures constantly the O2-concentration. In case that the value exceeds an alarm appears and the machine stops.

Function The required N2 pressure is 5 bar. The product is conveyed in the conveyor with N2 purging. The conveyor will then actuate as an inerting station. Product will be transferred on the inlet funnel that would be also inerted and controlled with the O2 sensors. Then will be dosed through the ProFi-Valve in the milling chamber that is also inerted and controlled with 2 x O2 sensors.

- First the O2-concentration value (e.g. 1.5%) needs to be reached in the complete installation.
- Machine will begin to dose, Production will begin.
- The dosing device will be stopped, if the O2 value is higher during production, and re-start if a certain value is again reached.
- The machine will be stopped, if the O2 value is higher during production

Notice: in the attached offer there is no control system of N2 foreseen for the room ambient. There are no room O2 monitoring systems included in our offer. The customer has the responsibility to assure that he will have a control system and that the room is sufficiently vented. All the exhaust of the filter systems need to be collected on the main ventilation.

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Position	Quantity	Description	USD/unit
9	1	Temperature measurement in the milling chamber PT-100 under the sieve for temperature measurement. Interface with electric to trigger alarm and stop the machine if temperature is reached Documentation:	
10	1	Standard operating instructions in English in PDF format on USB stick, adapted to the execution of the purchased machine, including the following chapters: <ul style="list-style-type: none"> - General documents (leaflet, machine assembly drawing) - Safety - Start-up - Operating instructions - Cleaning - Maintenance and support - Spare parts and tools - Electric/Drive/Pneumatic part - Certificates (EC declaration of conformity or EC declaration of incorporation, material certificate according to EN 10204-2.2, calibration certificates, oils and lubricants certificates, surface quality notification) - Protocols (quality certificate ISO 9001/ISO 14001, protocol of the electrical security) <p><i>Other documents not listed or further copies will be invoiced at costs</i></p>	
11	1	Set of NRTL certificates of the components (limited to the certificated supplied by the sub-supplier in original language)	
12	1	Export Packing:	

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13	1	Drum Containment System (DCS) from Dietrich Engineering Consultants (DEC) for powder emptying / transfer in a contained way from drums into HammerWitt-6.	
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To empty drums with :

- double liner (connection), full containment below 1 µg/m³,
- simple liner (connection) up to 10 µg/m³.

Drum(s) dimension:

Diameter : 380 - 600 mm (standard range)
320 - 680 mm (possible range)
Height : 650 - 900 mm

Suction lance:

Material : stainless steel 1.4404 (AISI 316L)
Diameter : 2"
Length : 1590 mm
Sealing : bellows in PUR L FDA
CIP connection : Stäubli

DCS head:

Consisting of:

- Top glass for a good visibility inside the glove box,
- Cylindrical glove box fixed on support frame,
- 1 filter tube for ventilation,
- 1 filter tube for extraction,
- 2 parallel openings with gloves,
- Bottom plate with flat gasket fixed under the DCS.

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Drum Containment System (DCS) continued:

13 1

Construction:

Window :	safety borosilicate glass, 10 mm (3 plies)
Contact parts :	stainless steel 1.4404 (AISI 316L)
Finish :	Ra0.8 µm
Coating :	none -
Filter tube :	stainless steel 1.4404 (AISI 316L)
Finish :	Ra0.8 µm
Coating :	none -
Gloves :	brombutyl, antistatic (Ø180, thk. 0.4mm)
Bottom plate :	stainless steel 1.4404 (AISI 316L)

Dimension:

Gloves box :	300 x 600 mm (height x diameter)
Glove ports :	200 mm (diameter)

Accessories:

Filter :	push-through, EPA E12, antistatisch
Waste port :	yes (bag, diameter 200 mm)
Waste port plug :	no
Air lock (with 2 covers):	no
Plate type :	with push ring, diameter 395 mm, external gasket glued
Closing plate :	no
Inerting :	none
Protection curtain :	no

Vent and pressure control:

- Connection for the extraction system (customer),
- Magnehelic differential pressure gauges to indicate pressure and filter blinding.

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Drum Containment System (DCS) continued:

13 1

Supporting frame:

Consisting of:

- Frame in solid square section bars (closed profile),
- Pneumatic lifting device to position the head on the drum,
- Safety blocking device,
- 2 pneumatic control boxes to lift and lower the head
- Adjustable support for suction lance,
- Weight equalizer (8-10 kg)

Construction:

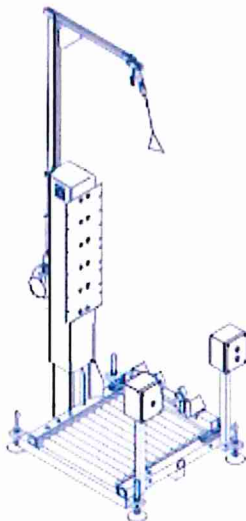
Material : stainless steel 1.4301 (AISI 304)
electro-polished

Dimension:

Length : 830 mm
Depth : 1280 mm
Height : 3250 mm

Accessories:

Frame : lifting device for head



Document title
Declaration of Conformity (or Incorporation) according to Machinery Directive 2006/42/EC (if applicable)
Declaration of Conformity (or Manufacturer) according to Pressure Equipment Directive 2014/68/EU (if applicable)
Declaration of Conformity (or Manufacturer) according to ATEX Directive 2014/34/EU (if applicable)
Installation, Operating & Maintenance Instructions
Components & Instruments Documentation
Equipment listing
Recommended commissioning spare parts list
Spare-parts list for two years operation
General arrangement drawing in 2D, including utilities requirement and battery limits
Panel layout drawings & control diagrams
Control diagrams
Available format :
- pneumatic : PDF/DXF/EMF/SVG/TIFF
- electric : DXF/DWG

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Not included in the present offer:

- Hastelloy material
- Metal detection.
- Grounding verification system
- Vacuum pump for DEC DCS PTS.

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