

REQUEST FOR PROPOSAL
NO 1 OF 30.06.2017

Medicofarma Joint-Stock Company, in accordance with the principle of competitiveness currently in force, hereby invites Tenderers to submit tenders for the supply of equipment within the framework of the project entitled "Establishment of a Research and Development Laboratory of Medicofarma S.A.", in accordance with the terms and conditions defined in the present request for proposal

I. Details of the Contracting Authority

Medicofarma S.A.

ul. Sokołowska 9 lok. U19

01-142 Warsaw

NIP: 527-232-45-41

Statistical registration number (Regon): 012250271

National Court Register (KRS) number: 0000284694

Contact person authorized by the Contracting Authority as regards the request for proposal: Alicja Jabłońska, Tel. (+48) 609 781 781, a.jablonska@medicofarma.pl

II. Procedure for awarding the contract

The contract in excess of the net amount of PLN 50,000 will be awarded in accordance with the principle of competitiveness and the Guidelines on Eligibility of Expenditures within the Framework of the European Regional Fund, the European Social Fund and the Cohesion Fund for the Years 2014-2020.

III. Designation of the project under which this procurement is made

1. Project name: "Establishment of a Research and Development Laboratory of Medicofarma S.A."
2. Name of Operational Programme: Smart Growth Operational Programme
3. Name of priority axis: 2. Priority axis II – Support for the environment and capacity of enterprise for R&D&I activity

4. Name and number of measure: Measure 2.1 Support for investment in R&D infrastructure of enterprises
5. Project co-financed from the European Regional Development Fund and the government funds.

IV. Description of the subject of the contract

Subject of the contract in accordance with codes of the Common Procurement Vocabulary:

- 42000000-6 – industrial machinery
- 38432210-7 – gas chromatographs

1. Required delivery date of the contract: up to 10 months after conclusion of the contract
2. Place of delivery: Radom, ul. Tarnobrzaska 13.
3. Subject of the contract:

Part I

Delivery of a tablet coating machine with the following equipment: interchangeable drums, inlet air purification and heating system, discharge air purification and discharge system, CIP automatic washing system, mobile tank with a mixer arm. The machine is a process line machine to coat products;

Part II

Delivery of a capsule filling machine with the following equipment: capsule filling machine deduster, metal detector with the ejection system, empty capsule sorter, capsule polishing device, capsule deduster, system for powder/pellet and capsule loading, equipment to fill the capsules (also with pellets). The machine is a process line machine to manufacture products in the form of capsules.

Part III

Delivery of a gas chromatograph with the equipment that is a functional whole ready to operate. The subject of the contract shall comprise:

hydrogen generator and feeder gas installation (compressed air, helium, nitrogen), installations which ensure stable operation. The gas chromatograph will be used for pharmaceutical analyses, in particular VOC remains in substances and quantitative marking of certain active substances;

Part IV

Delivery of a tablet press line with the following equipment: two hoppers, tablet press line deduster, metal detector with the ejection system, tablet weight, hardness and height control system, tablet deduster, powder loading system. The machine is a process line machine to manufacture double-layered and traditional tablets.

Part V

Supply of a complete pellet production line, including the extruder and spheronizator. The machines are process line machines to manufacture products in the form of pellets.

4. The tablet coating machine, capsule filling machine, gas chromatograph and the tablet press line with equipment will be a subject of financial lease. The Contractor shall sell the machine to a reputable leasing company selected by the Contracting Authority.
5. The subject of the contract should come from current production – no demonstration or leased machines can be offered.
6. The subject of the contract includes picking up, packing and delivery – on the CIP Radom, INCOTERMS 2010 basis (carriage and insurance paid to the registered office of the Contracting Authority) – installation (assembly), commissioning, installation qualification, operational qualification, performance qualification (IQ/OQ), personnel training in the use and operation at the Contracting Authority's, delivery of the operating manual.
7. If any trademarks or origin designation is used in the description of the subject of the contract, the Contracting Authority allows the use of other devices, equipment, materials, components, etc., which must be technically and operationally equivalent. The Contractor must demonstrate that the technical parameters of the offered equivalent products and

devices comply with the requirements of the Contracting Authority. As proof of the equivalence of the offered items, the Contractor shall append data identifying the manufacturer to the tender, so as to confirm equivalence of the offered equipment with the Contracting Authority's requirements, including – as far as possible – indication of a customer for which the Contractor has previously implemented the same solutions.

8. The Contractor may hire subcontractors for the performance of the subject of the contract.
9. The Tenderer shall perform all the warranty and post-warranty repairs at the user's facility. For the equipment offered, the Tenderer shall be obliged to offer own maintenance service in the Republic of Poland or another Member State of the European Union, or co-operate with a company which provides such a service to the tenderer, in the territory of the Republic of Poland or another Member State of the European Union. The required service response time must not be longer than 48 hours of the report, excluding public holidays.
10. The Contracting Authority allows the manufacturer's own technical materials which confirm the offered technical properties to be appended to the tender documents regarding the offered machine (also in English).
11. The Contracting Authority shall accept partial tenders

V. Conditions for participation in the tender procedure

1. Award of the contract may be sought by natural persons who carry on economic activities or legal persons who meet the following criteria:
 - a) have qualifications necessary to carry out specific activities or actions if so required by the law,
 - b) have the respective expertise and experience,
 - c) have adequate technical potential and persons capable of fulfilling the contract,
 - d) their economic and financial standing is sufficient for the performance of the contract.
2. The Contracting Authority shall assess whether the aforesaid criteria are met on the basis of the documents and declarations attached to the tenders, on the basis of "meets" or "does not meet" criteria. Failure to

meet even one condition will result in excluding the contractor from the procedure and rejection of the contractor's tender.

3. When demonstrating fulfilment of conditions for participation, if the Contractor relies on knowledge and experience of other entities that will take part in contract performance, the Contractor shall present a written commitment of such entities to make necessary resources available to the Contractor for the duration of use of such resources in the performance of the contract.
4. The time limit for the tender: Contractors shall remain bound by their tender for 90 days from the time limit for submission of tenders.

VI. Description of the method of calculating the price

1. Settlements between the Contracting Authority and the Contractor shall be made in the Polish zlotys.
2. The Supplier (Contractor) shall calculate the tender price so that it includes all the costs to be incurred by the Contracting Authority in connection with performance of the contract including the costs of delivery, installation and commissioning and the costs of training selected members of the Contracting Authority's personnel in operation; it should also contain all the fees which the Contracting Authority shall have to pay - ex works the registered office of the Contracting Authority (equivalent of CIP Radom, INCOTERMS 2010) and other costs related to performance of this contract.
3. The price for the subject of the contract in accordance with the tender form must be stated as the net price, with the calculated VAT rate and the gross price. The tender price must be specified in the Polish zlotys or euros. For tenders submitted in euros, the average exchange rate of the NBP prevailing on the date of opening the tenders shall be applied.
4. The Contracting Authority shall evaluate each of the four components that make up the subject of the contract according to specified criteria, using for the assessment the net price in PLN given by the Contractors.
5. If the Contracting Authority needs to determine whether the tender contains a flagrantly low price for the subject of the contract, the Contracting Authority may ask the contractor for explanations regarding components of the tender affecting the price, by the specified deadline.

6. During review and evaluation of tenders, the Contracting Authority shall correct in the tender:
- 1) obvious typographical errors,
 - 2) obvious errors in calculations, considering computational consequences of the corrections made,
 - c) other errors resulting from non-compliance of the tender with the Terms of Reference, which do not considerably change the tender contents.

VII. Description of the criteria which the Beneficiary may apply to select the most favourable tender, complete with importance of the criteria

The criterion applied in the present procedure for the purposes of selecting the winning tender shall be the most advantageous balance of the criteria described below. Each of the four parts comprising the subject of the contract shall be evaluated separately.

Tenders shall be evaluated in terms of the most advantageous terms proposed by the tenderers under each criterion:

- a) Price (cost) - weighing factor 60 %,
- b) b) Technical evaluation – weighing factor 40 %

Score-based evaluation of individual criteria shall be carried out in accordance with the following principles:

Part I

Re a)

Each evaluated tender will be awarded the number of A_{on} points, calculated as follows:

$$A_{on} = \frac{\text{Lowest offered price}}{\text{Price of the tender under evaluation}} \times 100 \text{ points} \times 0.60$$

Re b)

The Contracting Authority shall evaluate the compliance of the machines offered with the requirements set out in the "Statement of parameters" Table below. Each evaluated tender will be awarded the number of B_{on} points, calculated based on the following principles:

- o the tender for the equipment which meets the minimum requirements defined in column 3 of the Table below will be awarded $B_1 = 0$ points,
- o tenders with desired higher parameters (above the required minimum), as defined below in column 4 of the Table, will be awarded a respective additional number of B_2 points (up to a maximum of 100 points). Column 5 defines the criteria for awarding points.
- o Each evaluated tender will be awarded the number of B_{on} points, calculated as follows:

$$B_{on} = B_1 + B_2 \times 0.40$$

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Table 1 Statement of parameters for tender evaluation

No.	Parameter under assessment	MINIMUM REQUIREMENTS	DESIRED VALUES	ADDITIONAL POINTS
1	2	3	4	5
A. Basic unit				
1	Tablet coating machine	a) dimensions – no more than: - height - 250 [cm] - width - 250 [cm] - depth -250 [cm]		
		b) weight no more than 3,000 kg		
		c) support for single coating by the batch volume: ≤ 30 [kg] ≥ 80 [kg]	120 kg	10 points per every 10 kg over and above 80 kg, no more than 40 point in total.
		d) the machine is to be used for product coating; no equipment for sugar coating is required,		
		e) the machine must be equipped with all the systems and devices required for operation,		
		f) design of the machine must ensure: - that the product being coated is mixed in the drum without damage to the product, - spraying with the aqueous solution of polymer (suspension) with quantity control and regulation, - batching the quantity of added solution with the built-in pump and mass meter, - batch drying, - automatic unloading feature, - simple sampling during the process, - sight glass and workspace lighting, - effective cleaning of the interior of the		

		<p>coating machine with the system of interior nozzles (CIP system),</p> <ul style="list-style-type: none"> - manual, automatic and mixed operation feature, next steps should be displayed on the control panel, - the process must be controlled and recorded by measuring at least the inlet and discharge air temperature, inlet air flow, drum rotational speed, spray pressure, sprayed solution quantity and discharge, 		
		g) temperature control sensor for the coated product bed	simple removal of the sensor, with such an option included in the control system	10 points for the easy removal of the bed temperature sensor
		h) safety button,		
		<p>i) finishing of:</p> <ul style="list-style-type: none"> ➤ elements in contact with the products: <ul style="list-style-type: none"> - made from materials approved to be in contact with food products – confirmed by the certificate, - AISI 316 L steel – Ra 0.4 mirror finish of surfaces to be in contact with the product (confirmed by the certificate of 		

		measurement); ➤ external elements of steel AISI 304, brushed external surfaces, Ra 0.8 roughness		
B. Other elements/equipment included in the price				
1.	Key components of the machine	a) if the design supports the use of interchangeable drums and such drums are necessary to fulfil the requirements of point A.1.c, they should be added and included in the tender with a one trolley to move the drums, b) spray guns in the quantity optimized to the drum and batch size.	Support for interchangeable drum operation spray guns - more than 3	20 points for the support for interchangeable drum operation 10 points for each additional spray gun over 3
2.	Machine peripherals	a) a portable tank with the rated capacity of 80-100l and a mechanical mixer with an anchor propeller to prepare coatings, with a controlled speed of the propeller. The tank must be equipped with: - a system which supports mixing 10 to 80l of the solution with the mixing speed control, - a system which ensures that the inside of the unit is cleaned, - a heating jacket – an electrical jacket isolated from the outside, the option to set the temperature within the range of up to 90°C, - a cover equipped with a feed hopper, sight glass, batch observation lamp, water supply stub pipe, - measurement elements - a thermometer to measure the solution temperature, - four wheels of dirt-proof plastic, including two steering wheels with brakes.		

		<p>b) an air treatment unit that ensures correct progress of the coating process, with air flow and air temperature control, equipped with:</p> <ul style="list-style-type: none"> - an anti-freeze system (for winter conditions), - inlet and outlet filter systems (at least H11 class), - a dedusting system, - an inlet air heating system. 		
3.	Qualification	FAT/SAT and IQ/OQ protocol templates in accordance with cGMP.		
4.	Documentation	<p>a) factory technical data including:</p> <ul style="list-style-type: none"> - real capacity for assumed operational parameters, - weight of the equipment (for transport, installation and during operation), - the list of required devices and accessories necessary to ensure proper operation of the tablet coating machine, - installation conditions for the tablet coating machine ensuring its safe installation on the site, and layout including connections to external systems, - demand for utilities, - total area of elements to be in contact with the product. <p>b) manufacturing quality certificate, in accordance with the cGMP</p> <p>c) the list of control and measurement equipment with criticality analysis and certificates for metrological activities required in the EU Member States.</p>		
C. Control system				

1.	System description	An HMI System meeting the requirements of 11 CFR 21 (PLC control, touch screen with colour display, menu available at least in Polish).		
2.	Type of controllers	Control based on Siemens controllers minimum S7.		
D. Other				
1.	Formal and legal requirements	Confirmations of manufacturing in accordance with the relevant legislation in force within the European Union – certificates and approvals (CE) for the machines offered		
2.	Warranty	Min. 12 months from the operational qualification completion date.	24 months after completion of operational qualification.	10 points per every additional <u>full 6 months</u> of warranty, no more than 20 point in total.
3.	Operating manual	Hardcopy and electronic version, both in Polish and English.		
4.	Personnel training	Personnel training in operation of the machine and software, as well as maintenance works at the Contracting Authority's plant.		
5.	Marking	a) Inscriptions on rating plate and descriptions of components/spare parts in Polish or English.		
		b) Inscriptions on information and warning labels in Polish		

Part II

Re a)

Each evaluated tender will be awarded the number of C_{on} points, calculated as follows:

$$C_{on} = \frac{\text{Lowest offered price}}{\text{Price of the tender under evaluation}} \times 100 \text{ points} \times 0.60$$

Re b)

The Contracting Authority shall evaluate the compliance of the machines offered with the requirements set out in the "Statement of parameters" Table below. Each evaluated tender will be awarded the number of D_{on} points, calculated based on the following principles:

- o the tender for the equipment which meets the minimum requirements defined in column 3 of the Table below will be awarded $D_1 = 0$ points,
- o tenders with desired higher parameters (above the required minimum), as defined below in column 4 of the Table, will be awarded a respective additional number of D_2 points (up to a maximum of 100 points). Column 5 defines the criteria for awarding points.
- o Each evaluated tender will be awarded the number of D_{on} points, calculated as follows:

$$D_{on} = D_1 + D_2 \times 0.40$$

Table 2 Statement of parameters for tender evaluation

No.	Parameter under assessment	MINIMUM REQUIREMENTS	DESIRED VALUES	ADDITIONAL POINTS
1	2	3	4	5
A. Basic unit				
1	Capsule filling machine	a) dimensions – no more than: - height (including the hopper) - 250 [cm] - width - 200 [cm] - depth -250 [cm]		
		b) weight no more than: - 3,000 kg		
		c) output no less than: - 20,000 [pcs./h]	120,000 [pcs./h]	10 points per every 20,000 [pcs./h] over and above 20,000 [pcs./h], no more than 50 points in total.
		d) capacity to fill capsules of the following sizes: - 000 - 00 - 0 - 1 - 2 - 3 - 4		
		d) can fill capsules with: - powders, - pellets		
		h) support for step-less discharge rate adjustment (from 20,000 pcs./h)		
		g) capsule filler deduster connection		

		h) capsule deduster connection		
		i) safety switch and limit switches for guards		
		j) dosage station for: - powders, - pellets		
		k) connection of a metal detector		
		i) finishing of: ➤ elements in contact with the products: - made from materials approved to be in contact with food products – confirmed by the certificate, - AISI 316 L steel – Ra 0.4 mirror finish of surfaces to be in contact with the product (confirmed by the certificate of measurement); ➤ external elements of steel AISI 304, brushed external surfaces, Ra 0.8 roughness		
B. Other elements/equipment included in the price				
1.	Complete format parts	a) equipment to fill the capsules of the following sizes: - 000 - 00 - 0 - 1 - 2		
		b) one dosing disc for each capsule size, a total of 5		
		a) equipment to fill the capsules with pellets		
2.	Machine peripherals	a) empty capsule sorter		
		b) capsule polishing device		
		c) capsule deduster		

		d) metal detector with the ejection system		
		e) equipment listed in items b through d: - may be provided as functionally interconnected - may be provided as independent devices - should be adapted to the maximum capacity of the capsule filling machine	2 functional interconnections	13 points per each option of the functional connection, no more than 26 points in total.
		f) system for powder loading, adapted to a room with the height of up to 350 cm: - vacuum operated and - tippler with a container system along with a 50-120 L container		
		g) capsule loading system		
		h) capsule deduster		
3.	Qualification	FAT/SAT and IQ/OQ protocol templates in accordance with cGMP.		
4.	Documentation	a) factory technical data including: - real capacity for assumed operational parameters, - weight of the equipment (for transport, installation and during operation), - the list of required devices and accessories necessary to ensure proper operation of the capsule filling machine, - installation conditions for the capsule filling machine ensuring its safe installation on the site, and layout including connections to external systems, - demand for utilities, - total area of elements to be in contact with the product.		

		b) manufacturing quality certificate, in accordance with the cGMP		
		c) the list of control and measurement equipment with criticality analysis and certificates for metrological activities required in the EU Member States.		
C. Control system				
1.	System description	An HMI System meeting the requirements of 11 CFR 21 (PLC control, touch screen with colour display, menu available at least in Polish).		
2.	Type of controllers	Control based on Siemens controllers minimum S7.		
E. Other				
1.	Formal and legal requirements	Confirmations of manufacturing in accordance with the relevant legislation in force within the European Union – certificates and approvals (CE) for the machines offered		
2.	Warranty	Min. 12 months from the operational qualification completion date.	24 months after completion of operational qualification.	12 points per every additional <u>full 6 months</u> of warranty, no more than 24 point in total.
3.	Operating manual	Hardcopy and electronic version, both in Polish and English.		
4.	Personnel training	Personnel training in operation of the machine and software, as well as maintenance works at the Contracting Authority's plant.		
5.	Marking	a) Inscriptions on rating plate and descriptions of components/spare parts		

		in Polish or English.		
		b) Inscriptions on information and warning labels in Polish		

Part III

Re a)

Each evaluated tender will be awarded the number of E_{on} points, calculated as follows:

$$E_{on} = \frac{\text{Lowest offered price}}{\text{Price of the tender under evaluation}} \times 100 \text{ points} \times 0.60$$

Re b)

The Contracting Authority shall evaluate the compliance of the machines offered with the requirements set out in the "Statement of parameters" Table below. Each evaluated tender will be awarded the number of F_{on} points, calculated based on the following principles:

- o the tender for the equipment which meets the minimum requirements defined in column 3 of the Table below will be awarded $F_1 = 0$ points,
- o tenders with desired higher parameters (above the required minimum), as defined below in column 4 of the Table, will be awarded a respective additional number of F_2 points (up to a maximum of 100 points). Column 5 defines the criteria for awarding points.
- o Each evaluated tender will be awarded the number of F_{on} points, calculated as follows:

$$F_{on} = F_1 + F_2 \times 0.40$$

Table 3 Statement of parameters for tender evaluation

No.	MACHINE PARAMETERS	MINIMUM VALUES REQUIRED	DESIRED VALUES	ADDITIONAL POINTS
1	2	3	4	5
A. Basic unit				
1	Gas chromatograph	a) Oven operating temperature +5 from ambient temp to + 400°C;	+4 - +450°C	4
		b) At least 10 programmable temperature ramps (including negative) and at least 10 plateaus	20 ramps and 20 plateaus	2
		c) maximum temperature ramp no less than 100°C/min	110°C, and more	3

No.	MACHINE PARAMETERS	MINIMUM VALUES REQUIRED	DESIRED VALUES	ADDITIONAL POINTS
1	2	3	4	5
		d) cooling from 450°C (or upper temp. range) to 50°C max 10 min.	Max 5 min	2
		e) electronic pneumatic control up to at least 50 psi kPa setpoint and control precision <0.004 psi	<0.002 psi	10
		f) selection and make up of the carrier gas He/ N ₂ / H ₂		
		g) Flow and pressure programming – at least 2 ramps	3 and more ramps	2
		h) Split/splitless inlet 1 unit – max. temp. 450°C Maximum split – at least 1:5000	1:6000 or better	2
		i) repeatability of retention times <0.1%	0.008%	5
		j) support for capillary columns with diameter from 100µm to 530 µm	range wider than required	10
2	Autosampler	To hold at least 16 vials,		
3	FID detector	a) Minimum detection level <2 pg C/s	<1.5 pg C/s	3
		b) linear dynamic range 10 ⁷		
		c) maximum data rates 200 Hz	7 for each 100 Hz in excess of 200, no more than 21	21
		d) Flameout detector and automatic reignition or an equivalent solution		
		e) Operating range up to 450°C		
4.	Head space	a) 80 samples capacity	100 samples and more	5
			The add-on should have at least two priority spaces for analysing additional samples without stopping the method sequence	10
		b) the maximum temperature of the thermostat, valve and injection loop and transfer line - 300°C temperature setpoint increment at least 1°C temperature resolution 0.5°C	temperature resolution 0.1°C and better °C	5
		c) additional HS functionality	shaking the samples for faster equilibration or an equivalent solution	2
		d) additional HS functionality	choice extraction mode: - single; - multiple; - multiple with concentration;	1

No.	MACHINE PARAMETERS	MINIMUM VALUES REQUIRED	DESIRED VALUES	ADDITIONAL POINTS
1	2	3	4	5
		e) electronic pneumatic control with compensation of barometric pressure and ambient temperature		
		f) HS functional connection to the GC	Connection of the transfer line and ALS to a single inlet or an equivalent solution	10
		g) flow and filling the loop at a controlled pressure and temperature		
		h) Oven capacity in the HS add-on not less than 5 vials	Min 10	3
5.	GC and Head Space qualification	Full IQ/OQ/PQ qualification according to GLP Performance qualification based on FP Monograph 0229 (magnesium stearate), p. stearic acid and palmitic acid. Acceptance criteria according to FP, current edition		
6	Gas cylinders (cylinder lease can be included), hydrogen generator, gas feeder installation for the chromatograph	a) Preparation of space for the cylinder		
		b) gas supply/ feeder lines		
		c) installation of pressure reducing units in the room		
		d) installation of hydrogen generator in the GC room hydrogen generator - 100 ml H ₂ /min or better		
		e) drainage of excess heat in the GC room (e.g. hood)		
B. Equipment and accessories				
1	Installation kit	Installation kit suitable for running the unit – ferules, seals, inlet liner, etc.		
2	10µl syringe	2 pcs.		
3	Septa	50 pcs.		
4	2 ml vials with septa, twisted	2,000 pcs.		
5	20 ml vials for head space, capped with septa	2,000 pcs.		
6	GC column	30 m x 0.25 mm stationary phase poly(dimethyl)siloxane d=0.25µm		
7	GC column	30 m x 0.32 mm stationary phase crosslinked polycyanopropylophenylsiloxane (6%) poly(dimethyl)siloxane (94%) d=1.8µm		
8	GC column	30 m x 0.32 mm stationary phase macrogol 20000 d=0.5µm		
9	GC column	30 m x 0.53 mm stationary phase		

No.	MACHINE PARAMETERS	MINIMUM VALUES REQUIRED	DESIRED VALUES	ADDITIONAL POINTS
1	2	3	4	5
		diphenyl polysiloxane (5%); dimethyl polysilokxane (95%) d=5 µm with a precolumn: 5 m x 0.53 mm stationary phenylmethylosiloxane		
C. Control computer				
	PC, laser printer, LCD 23" or larger display screen.	A full PC set with software required to control the parameters, collect and analyse the data, a laser printer		
D. Software				
	Operating programme Utilities OQ/PQ programme	Windows CFR 21 part 11 compliant		
E. Other				
1.	Manufacturer's ISO certificate	Yes		
2.	CE certificate for the equipment offered	Yes		
3.	Warranty	At least 36 months		
4.	Operating manual in the Polish/English language	Yes		
5.	Personnel training	At least 2 x 2-day training in equipment and software operation, spaced 3-6 weeks.		

Part IV

Re a)

Each evaluated tender will be awarded the number of G_{on} points, calculated as follows:

$$G_{on} = \frac{\text{Lowest offered price}}{\text{Price of the tender under evaluation}} \times 100 \text{ points} \times 0.60$$

Re b)

The Contracting Authority shall evaluate the compliance of the machines offered with the requirements set out in the "Statement of parameters" Table below. Each evaluated tender will be awarded the number of H_{on} points, calculated based on the following principles:

- o the tender for the equipment which meets the minimum requirements defined in column 3 of the Table below will be awarded $H_1 = 0$ points,

- o tenders with desired higher parameters (above the required minimum), as defined below in column 4 of the Table, will be awarded a respective additional number of H_2 points (up to a maximum of 100 points). Column 5 defines the criteria for awarding points.
- o Each evaluated tender will be awarded the number of H_{on} points, calculated as follows:

$$H_{on} = H_1 + H_2 \times 0.40$$

Table 4 Statement of parameters for tender evaluation

No.	Parameter under assessment	MINIMUM REQUIREMENTS	DESIRED VALUES	ADDITIONAL POINTS
1	2	3	4	5
A. Basic unit				
1	Tablet press line	a) dimensions – no more than: - height (including the hopper) - 250 [cm] - width - 200 [cm] - depth -250 [cm]		
		b) weight no more than 7,000 kg (design which supports seating the machine directly on the floor slab with load-bearing capacity of 10 tonnes/m ²)		
		c) discharge rate of bi-layer tablets no less than (can be higher): 40,000 [pcs./h]	80,000 [pcs./h]	10 points per every 20,000 over and above 40,000, no more than 20 points in total.
		d) support for of bi-layer tablets production		
		e) turret for EU-B dies and punches with the support for shape tablet production		
		f) pre-pressure no less than 10 kN and main pressure no less than 80 kN	pre-pressure no less than 30 kN and main pressure no less than 100 kN	9 points per every 10 kN over and above 10 kN, no more than 18 points in total. 9 points per every 10 kN over and above 80 kN, no more than 18 points in

				total.
		g) must support operation with part of sockets closed		
		h) support for step-less discharge rate adjustment (from 20,000/h)		
		i) safety switch and limit switches for guards		
		j) connection of a metal detector		
		k) finishing: ➤ elements in contact with the products: - made from materials approved to be in contact with food products – confirmed by the certificate, - AISI 316 L steel – Ra 0.4 mirror finish of surfaces to be in contact with the product (confirmed by the certificate of measurement); ➤ external elements of steel AISI 304, brushed external surfaces, Ra 0.8 roughness		
B. Other elements/equipment included in the price				
1.	Key components of the machine	a) interchangeable turret with an integrated or external arm for dismounting and trolley for turret transportation		
		b) set of punches and dies for round tablets.		
		c) device to provide a hopper with a certain amount of powder ensuring proper liquidity (constant amount/level feeder) and the system to control powder level in hoppers		
		d) two hoppers		

2.	Machine peripherals	a) tablet deduster		
		b) metal detector with the ejection system		
		c) system to measure a tablet's hardness, weight and height	possible modification of respective functional parameters of the tablet press line	8 additional points if it is possible to modify respective functional parameters of the tablet press line
		d) equipment listed in items a through c: - may be provided as functionally interconnected - may be provided as independent devices - should be adapted to the maximum capacity of the tablet press line	2 functional interconnections	8 points per each option of the functional connection, no more than 16 points in total.
		e) tablet press line deduster		
		f) system for powder loading to both feeders, adapted to a room with the height of up to 350 cm: - vacuum operated or - tippler with a container system with a 50-120 L container		
3.	Qualification	FAT/SAT and IQ/OQ protocol templates in accordance with cGMP.		
4.	Documentation	a) factory technical data including: - real capacity for assumed operational parameters, - weight of the equipment (for transport, installation and during operation), - the list of required devices and		

		<p>accessories necessary to ensure proper operation of the tablet press line,</p> <ul style="list-style-type: none"> - installation conditions for the tablet press line ensuring its safe installation on the site, and layout including connections to external systems, - demand for utilities, - total area of elements to be in contact with the product. 		
		b) manufacturing quality certificate, in accordance with the cGMP		
		c) the list of control and measurement equipment with criticality analysis and certificates for metrological activities required in the EU Member States.		
C. Control system				
1.	System description	An HMI System meeting the requirements of 11 CFR 21 (PLC control, touch screen with colour display, menu available at least in Polish).		
2.	Type of controllers	Control based on Siemens controllers minimum S7.		
D. Other				
1.	Formal and legal requirements	Confirmations of manufacturing in accordance with the relevant legislation in force within the European Union – certificates and approvals (CE) for the machines offered		
2.	Warranty	Min. 12 months from the operational qualification completion date.	24 months after completion of operational qualification.	10 points per every additional full <u>6 months</u> of warranty, no more than 20 point in total.
3.	Operating	Hardcopy and electronic version, both in		

	manual	Polish and English.		
4.	Personnel training	Personnel training in operation of the machine and software, as well as maintenance works at the Contracting Authority's plant.		
5.	Marking	a) Inscriptions on rating plate and descriptions of components/spare parts in Polish or English.		
		b) Inscriptions on information and warning labels in Polish		

If the Tenderer fails to provide the manufacturer's information materials confirming the desired parameter stated in the tender, the Contracting Authority shall not award additional points for this parameter.

Part V

Re a)

Each evaluated tender will be awarded the number of K_{on} points, calculated as follows:

$$K_{on} = \frac{\text{Lowest offered price}}{\text{Price of the tender under evaluation}} \times 100 \text{ points} \times 0.60$$

Re b)

The Contracting Authority shall evaluate the compliance of the machines offered with the requirements set out in the "Statement of parameters" Table below. Each evaluated tender will be awarded the number of L_{on} points, calculated based on the following principles:

- o the tender for the equipment which meets the minimum requirements defined in column 3 of the Table below will be awarded $L_1 = 0$ points,
- o tenders with desired higher parameters (above the required minimum), as defined below in column 4 of the Table, will be awarded a respective additional number

of L_2 points (up to a maximum of 100 points). Column 5 defines the criteria for awarding points.

- o Each evaluated tender will be awarded the number of L_{on} points, calculated as follows:

$$L_{on} = L_1 + L_2 \times 0.40$$

Table 5 Statement of parameters for tender evaluation

No	Parameter under assessment	MINIMUM REQUIREMENTS	DESIRED VALUES	ADDITIONAL POINTS
1	2	3	4	5
A. Basic unit				
1	Extruder	a) dimensions – no more than: - height - 250 [cm] - width - 280 [cm] - depth - 100 [cm]		
		b) weight no more than 1,000 kg		
		c) output at least 1 kg/hour	20 kg/hour	10 points per every 5 kg/hour, no more than 40 points in total.
		d) the machine must be equipped with all the supporting systems and devices required for operation,		
		e) design of the machine must ensure: - forming of product ribbons, - support for preparation and dosing of liquids during the process with an external dosing pump,		

		- temperature operating range 0 – 50°C		
		f) safety button,		
		i) finishing of: ➤ elements in contact with the products: - made from materials approved to be in contact with food products – confirmed by the certificate, - AISI 316 L steel – Ra 0.4 mirror finish of surfaces to be in contact with the product (confirmed by the certificate of measurement); ➤ external elements of steel AISI 304, brushed external surfaces, Ra 0.8 roughness		
2	Spheronizator	a) dimensions – no more than: - height - 120 [cm] - width - 120 [cm] - depth - 100 [cm]		
		b) weight no more than 300 kg		
		c) output at least 1 kg/hour	20 kg/hour	10 points per every 5 kg/hour, no more than 40 points in total.
		d) the machine must be equipped with all the systems and devices required for operation,		

		<p>e) design of the machine must ensure:</p> <ul style="list-style-type: none"> - conversion of product ribbons into pellets, 		
		<p>f) safety button,</p>		
		<p>i) finishing of:</p> <ul style="list-style-type: none"> ➤ elements in contact with the products: <ul style="list-style-type: none"> - made from materials approved to be in contact with food products – confirmed by the certificate, - AISI 316 L steel – Ra 0.4 mirror finish of surfaces to be in contact with the product (confirmed by the certificate of measurement); ➤ external elements of steel <ul style="list-style-type: none"> AISI 304, brushed external surfaces, Ra 0.8 roughness 		
B. Other elements/equipment included in the price				
1.	Qualification	FAT/SAT and IQ/OQ protocol templates in accordance with cGMP.		
2.	Documentation	<p>a) factory technical data including:</p> <ul style="list-style-type: none"> - real capacity for assumed operational parameters, - weight of the equipment (for transport, installation and during operation), - the list of required devices and accessories necessary to ensure proper operation of the extruder and spheronizator, - installation conditions for the extruder 		

		and spheronizator ensuring their safe installation on the site, and layout including connections to external systems, - demand for utilities, - total area of elements to be in contact with the product.		
		b) manufacturing quality certificate, in accordance with the cGMP		
		c) the list of control and measurement equipment with criticality analysis and certificates for metrological activities required in the EU Member States.		
C. Control system				
1.	System description	An HMI System meeting the requirements of 11 CFR 21 (PLC control, touch screen with colour display, menu available at least in Polish).		
2.	Type of controllers	Control based on Siemens controllers.		
D. Other				
1.	Formal and legal requirements	Confirmations of manufacturing in accordance with the relevant legislation in force within the European Union – certificates and approvals (CE) for the machines offered		
2.	Warranty	Min. 12 months from the operational qualification completion date.	24 months after completion of operational qualification.	10 points per every additional <u>full 6 months</u> of warranty, no more than 20 point in total.

3.	Operating manual	Hardcopy and electronic version, both in Polish and English.		
4.	Personnel training	Personnel training in operation of the machines and software, as well as maintenance works at the Contracting Authority's plant.		
5.	Marking	a) Inscriptions on rating plates and descriptions of components/spare parts in Polish or English.		
		b) Inscriptions on information and warning labels in Polish		

If the Tenderer fails to provide the manufacturer's information materials confirming the desired parameter stated in the tender, the Contracting Authority shall not award additional points for this parameter.

VIII. Selection of the winning tender

The winning tender will be selected with due diligence, in line with the principles of fair competition, impartiality, objectivity, effectiveness and transparency. Lack of reference in the tender to any of the points-awarding criteria, as listed in section VII, will result in 0 points being awarded for the given criterion.

The Contracting Authority will select the winning tender based on the criteria described in section VII, upon calculation of the assessment factor (W_i) according to the following formula:

Part I

$$W_1 = A_{on} + B_{on}$$

Part II

$$W_2 = C_{on} + D_{on}$$

Part III

$$W_3 = E_{on} + F_{on}$$

Part IV

$$W_4 = G_{on} + H_{on}$$

Part V

$$W_5 = K_{on} + L_{on}$$

If it is not possible to choose the best offer due to an equal result of their evaluation, the Ordering Party will conduct negotiations with the Bidders. If the Bidder whose offer has been chosen as the most beneficial one refuses to assume a legal obligation to implement the order, the Ordering Party reserves the right to choose the most beneficial offer from among the other offers.

If the price of the order implementation in the submitted offers exceeds the value of the financial means designated for the implementation of this aim, the choice of offers can be invalidated or additional price negotiations can be conducted with the Bidders whose offers have been evaluated.

If, when making the subject choice of the order, the Ordering Party will choose between offers that are the most beneficial economically, it undertakes to choose the offer that will be the most beneficial one in terms of the influence on

the environment and climate; the criterion: lower energy consumption at machine operation.

IX. Description of tender preparation

1. Each Tenderer may submit only one tender for each of the four parts of the subject of the contract (no variants allowed) under the pain of being excluded from the tender procedure.
2. The Tenderer shall bear all the costs related to preparation and submittal of the tender.
3. The tender should be signed by the persons authorised to represent the Contractor. If the tender is signed by a person(s) not authorized to represent the Contractor in accordance with the extract from the relevant register, the power of attorney granted to represent the Contractor in the procedure must be attached to the tender as the original or a copy certified by the Contractor, valid as on the day of tender submission.
4. The tender must be prepared in writing in the Polish or English language, and its form must ensure complete legibility thereof. All sheets/pages must be numbered.
5. All documents and declarations in a form other than the original (such as certified copies and photocopies of documents) must be authenticated in writing with an annotation stating "certified true copy" and a handwritten signature affixed by the Contractor or (a) person(s) authorized to represent the Contractor.
6. If any documents attached to the tender are prepared in a foreign language (which includes documents submitted by a foreign Contractor), a translation of the same is required, certified by the Contractor.
7. The tender price must be stated in a numerical form and in words.
8. Form of payment: irrevocable Letter of Credit issued by the lessor's bank or 100% payment prior to shipment.
9. All and any amendments made to the contents of the tender should be added in a legible form and additionally initialled by the persons signing the tender. The Contracting Authority may demand that the original or a copy certified by a notary

public be presented when the submitted photocopies of documents are illegible or rise doubts as to their authenticity.

10. The Contractor may change or withdraw the tender before the time limit for submission of tenders. Any amendment or withdrawal of a tender shall require a respective written declaration of the Contractor. Changes to the contents of the tender or documents attached to the tender should be prepared, packaged and addressed in the same way as the tender.

11. Documents, declarations and information should be arranged in the following order:

1. Declaration on appointment of an attorney – *if applicable*;
2. Tender form – *Appendix 1*
3. Statement about lack of personal and capital ties with Medicofarma S.A. – *Appendix 2*
4. A copy of a current excerpt from the respective register.

12. If the tender is submitted in a paper form, it should be packed into a sealed opaque envelope or a similar package and addressed to the Contracting Authority as demonstrated below:

<p>.....</p> <p><i>(Name and address of the Contractor, telephone number)</i></p> <p>Tender –</p> <p><i>(lot number(s))</i></p>
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X. Place and deadline of tender submittal and opening

1. Tenders (prepared in accordance with the template attached as Appendix 1) should be submitted in an electronic form to: a.jablonska@medicofarma.pl or in a hardcopy form at the registered office of the Contracting Authority at ul. Sokolowska 9 office U19, 01-142 Warsaw. If a tender is submitted in an electronic form by electronic mail as files attached to the communication, the files must be in a format which allows their contents to be read, e.g. PDF.
2. Tenders must be submitted no later than on 31.07.2017
3. No tender submitted past the aforesaid deadline shall be considered.
4. Tenders sent by post shall qualify for the procedure provided that they are delivered by the postal service to the registered office of the Contracting Authority no later than on the day and at the time stipulated in clause 2 above.
5. Notification on selection of the winning tender shall be published on www.bazakonkurencyjnosci.funduszeuropejskie.gov.pl website within 7 days of the time limit for submission of tenders.
6. Expected date of signing the contract: 10.08.2017