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SUPPLIER QUESTIONNAIRE

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FROM: AL MOTAKADEMA PHARMACEUTICAL LTD. | QA DEPARTMENT

THIS QUESTIONNAIRE IS AN ESSENTIAL PART OF THE SUPPLIER QUALIFICATION PROGRAM AT AL MOTAKADEMA PHARMACEUTICAL LTD. ***PLEASE COMPLETE THIS QUESTIONNAIRE THOROUGHLY AND RETURN IT TO US.***

CONTACT DETAILS:

*Organization Name:

*Contact Person/Title

*Phone Number

*E-mail

*Manufacturing Site:

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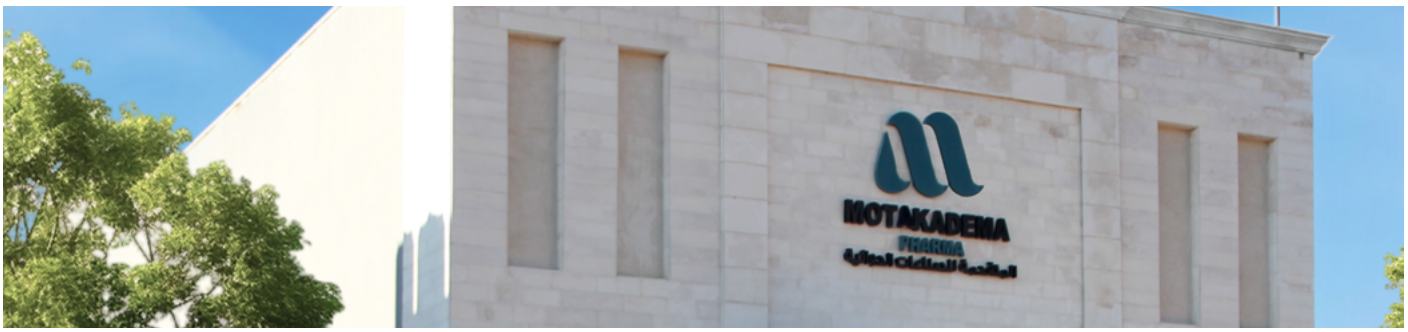

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1 General Information:

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1. GENERAL INFORMATION:

1.1 Are customer audits and/or inspections by agencies permitted? ◯ Yes ◯ No

1.2 Is the decision to release or reject a product for sale independent from production? ◯ Yes ◯ No

1.3 Who is responsible for the final product release?

1.4 Who is responsible for contacts with us concerning quality matters?

1.5 *WHAT KIND OF PRODUCT DO YOU MANUFACTURE

- ☐ Bulk raw materials?
- ☐ Bulk raw materials for pharmaceuticals?
- ☐ Active pharmaceutical ingredients?
- ☐ Technical products?
- ☐ Packaging material?
- ☐ Others? Please, specify:

1.6 PLEASE, GIVE A BRIEF FLOW DIAGRAM OF THE PROCESS, INCLUDING INFORMATION ABOUT WHERE IN-PROCESS CONTROLS ARE PERFORMED. SPECIAL ATTENTION MUST BE GIVEN TO THE LAST STEP IN THE PROCESS E.G. REAGENTS, PRECIPITATION AGENT AND SOLVENTS

2 Personnel, Training and Education

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2.PERSONNEL, TRAINING AND EDUCATION:

2.1	Do you have written job descriptions for all personnel?	Yes	No	N/A
2.2	Do you have procedures that document how you perform training?	Yes	No	N/A
2.3	Do you maintain records of the training?	Yes	No	N/A

2.4 DOES THE TRAINING PROGRAM IN PLACE HAVE THE FOLLOWING ELEMENTS:

2.4.1	Formal Introduction to Regulatory Guidance (GMP, ISO, etc.)	Yes	No	N/A
2.4.2	New Hire Program	Yes	No	N/A
2.4.3	Specific training e.g. clean room or handling toxic, infectious or sensitizing materials?	Yes	No	N/A
2.4.4	Periodic assessment of practical effectiveness?	Yes	No	N/A
2.4.5	Periodic refresher training programs for established employees?	Yes	No	N/A
2.4.6	At the start of new product manufacturing?	Yes	No	N/A
2.4.7	When new methods/Documents are used?	Yes	No	N/A
2.4.8	Quality techniques for production people?	Yes	No	N/A

2.5 DOES YOUR TRAINING PROGRAM EMPHASIZES:

2.5.1	Product integrity?	Yes	No	N/A
2.5.2	Hygiene?	Yes	No	N/A
2.5.3	Cleanliness?	Yes	No	N/A

☐ Others? Please, specify:

3 Facility and Utilities

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3. FACILITY AND UTILITIES

3.1	Were the premises designed or adapted for the present use?	◯ Designed	◯ Adapted	
3.2	**ARE THERE SEPARATE AREAS FOR:**			
3.2.1	Handling of starting materials?	◯ Yes	◯ No	◯ N/A
3.2.2	Manufacturing?	◯ Yes	◯ No	◯ N/A
3.2.3	Quarantined finished products or are other control systems in place?	◯ Yes	◯ No	◯ N/A
3.2.4	Approved finished products?	◯ Yes	◯ No	◯ N/A
3.2.5	Packaging and dispatch?	◯ Yes	◯ No	◯ N/A
3.2.6	Rest and eating?	◯ Yes	◯ No	◯ N/A
3.3	**DOES THE PRESENT DESIGN PREVENT:**			
3.3.1	Chemical contamination?	◯ Yes	◯ No	◯ N/A
3.3.2	Physical contamination?	◯ Yes	◯ No	◯ N/A
3.3.3	Microbial contamination?	◯ Yes	◯ No	◯ N/A
3.4	**ARE YOUR WORKING-ROOMS:**			
3.4.1	Of proper size for the intended functions?	◯ Yes	◯ No	◯ N/A
3.4.2	Satisfactorily lighted, air-conditioned?	◯ Yes	◯ No	◯ N/A
3.4.3	Clean and cleaned-up?	◯ Yes	◯ No	◯ N/A
3.4.4	Designed to avoid (cross-) contamination?	◯ Yes	◯ No	◯ N/A
3.4.5	Supplied with security and fire protection measurements?	◯ Yes	◯ No	◯ N/A
3.5	**DO YOU HAVE WRITTEN GOOD HOUSE KEEPING PROCEDURES?**	◯ Yes	◯ No	◯ N/A
3.5.1	If yes, do you maintain follow- up records of these procedures?	◯ Yes	◯ No	◯ N/A
3.6	Do your manufacturing locations follow Good Manufacturing Practices?	◯ Yes	◯ No	◯ N/A
3.7	Are your sites inspected by the FDA or national (health) authorities?	◯ Yes	◯ No	◯ N/A
3.8	Are plant supply pipelines identified and labelled?	◯ Yes	◯ No	◯ N/A
3.9	Do you monitor the quality of the water used to prepare standards and reagents?	◯ Yes	◯ No	◯ N/A
3.10	Do you monitor the quality of the water used during the manufacturing process?	◯ Yes	◯ No	◯ N/A

4 Machines and Equipment

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4. MACHINES AND EQUIPMENT

4.1 Is the production line multi-purpose or single purpose? ◯ multi ◯ Single

If multi, what other products do you manufacture there?

4.2	Is there a maintenance and preventative maintenance program pieces of equipment?	◯ Yes	◯ No ◯ N/A
4.3	Do you have written maintenance and calibration procedures for critical equipment?	◯ Yes	◯ No ◯ N/A
4.4	Can all critical apparatus and devices easily be recognized as such by calibration stickers?	◯ Yes	◯ No ◯ N/A
4.5	Are these calibrations traceable back to national standards?	◯ Yes	◯ No ◯ N/A
4.6	Do you retain records of calibration as evidence of control?	◯ Yes	◯ No ◯ N/A
4.7	Is there a cleaning plan/procedure for production machines, equipment?	◯ Yes	◯ No ◯ N/A
4.8	Have the cleaning and sterilization processes been validated?	◯ Yes	◯ No ◯ N/A
4.9	Is any manufacturing equipment software controlled?	◯ Yes	◯ No ◯ N/A
4.10	Do you have a documented procedure for the validation of all test and product measuring equipment used to demonstrate the conformance of to the specified requirements?	◯ Yes	◯ No ◯ N/A

4.11 DO YOU RETAIN RECORDS OF VALIDATION AS EVIDENCE OF CONTROL? ○ Yes ○ No ○ N/A

4.11.1 If yes,

4.11.1.1 Is the software validated? ○ Yes ○ No ○ N/A

4.11.1.2 Are modifications of software (or its use) implemented by manufacturing personnel? ○ Yes ○ No ○ N/A

4.11.1.3 Is there a procedure concerning change of software and its copying? ○ Yes ○ No ○ N/A

4.11.1.4 Is the security of software controlled? ○ Yes ○ No ○ N/A

4.12 DO YOU CONTRACT OUT ANY OF THE FOLLOWING SERVICES?

4.12.1 Instrument Calibration? ○ Yes ○ No ○ N/A

4.12.2 Preventative / Breakdown Maintenance? ○ Yes ○ No ○ N/A

5 Production and Process Control

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5. PRODUCTION AND PROCESS CONTROL

5.1 IS YOUR MANUFACTURING PROCESS VALIDATED? ◯ yes ◯ no

5.1.1 If not, do you have plans to do so? ◯ yes ◯ no

5.1.1.1 If you do, what is your target date for completion? ◯ yes ◯ no

5.2 How do you define your lot/batch?

5.3 How and by whom are lot/batch numbers assigned?

5.4 What is your normal lot/batch size?

5.5 Does each lot/batch have an identification number? ◯ Yes ◯ No ◯ N/A

5.6 IF, FOR CAPACITY REASONS, YOU COMBINE MATERIAL COMING FROM MORE THAN ONE EQUIPMENT INTO ONE LOT/BATCH: *PARTICULAR PIECE OR PART OF PROCESS?*

5.6.1	Is the lot/batch being homogenized prior to packaging?	Yes	No	N/A
5.6.2	Is the homogenization operation validated?	Yes	No	N/A
5.7	Do you manufacture according to a written procedure for each product supplied to the market?	Yes	No	N/A
5.8	Are these procedures approved by QA?	Yes	No	N/A

5.9 DO YOU HAVE A BATCH RECORD FOR EACH BATCH/ LOT MANUFACTURED?

Yes No N/A

5.9.1 If yes, do the batch records detail the following:

5.9.1.1	Description, Lot Number & Quantities of Material used?	Yes	No	N/A
5.9.1.2	Processing Conditions (Temperature, Times etc)?	Yes	No	N/A
5.9.1.3	The identification of the Person who performed the particular step?	Yes	No	N/A
5.9.1.4	Results of any In-process tests?	Yes	No	N/A
5.9.1.5	All deviations from standard conditions?	Yes	No	N/A
5.9.1.6	All cleaning operations carried out before & after batch manufacture?	Yes	No	N/A
5.9.2	If yes, for how long do you keep the batch records?	Yes	No	N/A
5.9.3	If yes, are these records formally checked and approved by QA?	Yes	No	N/A

5.10 DO YOU MAINTAIN LOT SEPARATION DURING:

5.10.1	Manufacturing?	Yes	No	N/A
5.10.2	Packaging?	Yes	No	N/A
5.10.3	Storage?	Yes	No	N/A

5.11 Do you maintain records of use, maintenance for process equipment, in order to demonstrate the traceability in batches, product processed and personnel? ◯ Yes ◯ No ◯ N/A

5.12 ARE COMPUTERS USED TO STORE RECORDS OF MANUFACTURE, TESTING, STORAGE OR DISTRIBUTION FOR THE PRODUCT YOU SUPPLY? ◯ Yes ◯ No ◯ N/A

5.12.1 If yes, have these computer systems been validated (i.e.. have the complete life cycles of the systems been assessed and documented including stages of planning, specifications, programming, testing, commissioning, documentation, operation, monitoring and modifying)? ◯ Yes ◯ No ◯ N/A

5.13 Do all product containers bear identification labels, e.g. stating batch/lot number, product name etc.? ◯ Yes ◯ No ◯ N/A

5.14 Is there expiry or retest dates defined for all material? ◯ Yes ◯ No ◯ N/A

5.15 Is there storage conditions defined for all material? ◯ Yes ◯ No ◯ N/A

5.16 Is the product identifiable throughout the manufacturing process? ◯ Yes ◯ No ◯ N/A

5.17 Is traceability of all raw materials used, maintained throughout manufacture? ◯ Yes ◯ No ◯ N/A

5.18 Is there a procedure in place to prevent cross-contamination? ◯ Yes ◯ No ◯ N/A

5.19 Are line clearances undertaken between product changes during manufacturing and labelling? (i.e. Where a variety of products are manufactured on one site, do you carry out an independent, recorded check, immediately prior to a production run to verify the areas are free from previous starting materials, products documentation and waste and that it is fit for use)? ◯ Yes ◯ No ◯ N/A

5.20 Do you use dedicated equipment for the production of the product in question? ◯ Yes ◯ No ◯ N/A

5.20.1 If no, please provide details of other product types manufactured using this equipment:

5.21 Is testing or inspection performed between processes or manufacturing stages? ◯ Yes ◯ No ◯ N/A

5.22 Is testing or inspection performed on finished products? ◯ Yes ◯ No ◯ N/A

5.23 Are rejected lots identified as such and separated? ◯ Yes ◯ No ◯ N/A

5.24 Do you perform a failure investigation in case of a reject? ◯ Yes ◯ No ◯ N/A

5.25 Is reprocessing of rejected lots documented? ◯ Yes ◯ No ◯ N/A

5.26 Do you have a procedure covering rework/ reprocessing or recovery of material? ◯ Yes ◯ No ◯ N/A

5.27 Is non-conforming final product ever blended with conforming product to bring it into specification? ◯ Yes ◯ No ◯ N/A

5.28 Is there a documented procedure that clearly defines when blending of non-conforming product is allowed? ◯ Yes ◯ No ◯ N/A

5.29 How long do you keep the analytical and production records (number of years)?

5.30 DO YOU HAVE PLANT SHUTDOWNS (HOLIDAYS, MAINTENANCE)? ◯ Yes ◯ No ◯ N/A

5.30.1 If no, which one(s)? ◯ maintenanc ◯ holidays

5.31 Do you have manufacturing alternatives/ fall back? ◯ Yes ◯ No ◯ N/A

5.32 HOW MANY WEEKS OF INVENTORY DO YOU HAVE FOR THE PRODUCT(S) INVOLVED:

5.32.1 Raw materials?

5.32.2 Semi-finished product?

5.32.3 Finished product?

6 Materials Control

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6. MATERIALS CONTROL

6.1	Do you have an approved supplier list?	Yes	No	N/A
6.2	Do you have agreements in place with all your suppliers that require them to notify you of any change in raw material or the manufacturing process of the product supplied?	Yes	No	N/A
6.3	Do you have written specifications for all incoming raw material?	Yes	No	N/A
6.4	Who is responsible for establishing and approving the specifications of raw materials?			
6.5	Do you require a manufacturer's certificate of analysis for all material received in the company?	Yes	No	N/A
6.6	Are Certificates of Analysis routinely compared against a written specification?	Yes	No	N/A
6.7	Do you routinely test receipted materials to verify conformance with the supplier certification?	Yes	No	N/A
6.8	Do you have procedures for the control of raw materials?	Yes	No	N/A
6.9	Are records kept that show full traceability of raw materials?	Yes	No	N/A

6.10 DO YOU MAINTAIN INFORMATION RECORDS FOR RAW MATERIALS WHICH INCLUDE THE FOLLOWING :

6.10.1	Your lot Identity?	Yes	No	N/A
6.10.2	Suppliers Lot No?	Yes	No	N/A
6.10.3	Date of Receipt?	Yes	No	N/A
6.10.4	Quantity?	Yes	No	N/A
6.10.5	Suppliers name?	Yes	No	N/A
6.10.6	Shelf Life?	Yes	No	N/A
6.10.7	Test Results?	Yes	No	N/A
6.10.8	Specification?	Yes	No	N/A
6.10.9	Accepted/Rejected?	Yes	No	N/A
6.10.10	Retained Sample?	Yes	No	N/A

6.11 Please describe how material is issued from stock:

6.12 Do you have defined areas for Receipt, Identification, Sampling and Quarantine of incoming materials? ◯ Yes ◯ No ◯ N/A

6.13 Are scheduled stock checks performed? ◯ Yes ◯ No ◯ N/A

6.14 Do you have a rework/reprocess policy? ◯ Yes ◯ No ◯ N/A

7 Quality Control

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7. QUALITY CONTROL

7.1 Is Quality Control (QC) independent of Production? ◯ Yes ◯ No ◯ N/A

7.2 Please describe the QC laboratory facilities and the tests these laboratories are capable of performing:

7.3 ARE RECORDS KEPT OF ALL SAMPLES THAT ARE SUBMITTED TO THE LABORATORIES? ◯ Yes ◯ No ◯ N/A

7.3.1 If so, do these records include the following:

7.3.1.1 Date sample received? ◯ Yes ◯ No ◯ N/A

7.3.1.2 Identity of samples? ◯ Yes ◯ No ◯ N/A

7.3.1.3 Results of testing? ◯ Yes ◯ No ◯ N/A

7.3.1.4 Date sample taken? ◯ Yes ◯ No ◯ N/A

7.4 Are there formal written procedures for all performed tests? ◯ Yes ◯ No ◯ N/A

7.5 Are the analytical methods validated? ◯ Yes ◯ No ◯ N/A

7.6 Are control samples routinely run with assays? ◯ Yes ◯ No ◯ N/A

7.7 Are analytical calculations checked by a second person? ◯ Yes ◯ No ◯ N/A

7.8 Do you perform trend analysis on analytical results? ◯ Yes ◯ No ◯ N/A

7.9 Are the results of reference standard testing maintained on file? ◯ Yes ◯ No ◯ N/A

7.10 Is there a procedure for documenting and investigating out-of- specification results? ◯ Yes ◯ No ◯ N/A

7.11 Do you use any contract laboratories? ◯ Yes ◯ No ◯ N/A

7.12 Have you qualified/evaluated these contract laboratories? ◯ Yes ◯ No ◯ N/A

7.13 What types of testing is contracted out?

7.14	**ARE QUALITY STANDARDS OR WRITTEN CONTROL PROCEDURES AVAILABLE FOR:**			
7.14.1	Starting materials?	Yes	No	N/A
7.14.2	In-process control?	Yes	No	N/A
7.14.3	Physical identification at all stages (e.g. labelling of semi-finished products)?	Yes	No	N/A
7.14.4	Finished products?	Yes	No	N/A
7.14.5	Microbiological control?	Yes	No	N/A
7.15	**ARE RECORDS KEPT OF ALL CONTROL RESULTS?**	Yes	No	N/A
7.15.1	If yes, for how long do you keep those records?	Yes	No	N/A
7.16	Is your critical analytical laboratory equipment fully qualified?	Yes	No	N/A
7.17	**IS THERE A MAINTENANCE PLAN/PROCEDURE FOR LABORATORY EQUIPMENT?**	Yes	No	N/A
7.17.1	If yes,			
7.17.1.1	Do you have a calibration scheme?	Yes	No	N/A
7.17.1.2	Do you have calibration instructions?	Yes	No	N/A
7.17.1.3	Do you keep all records of calibration performances?	Yes	No	N/A
7.18	**DOES ANY LABORATORY EQUIPMENT HAVE SOFTWARE CONTROL?**	Yes	No	N/A
7.18.1	If yes,			
7.18.1.1	Is the software validated?	Yes	No	N/A
7.18.1.2	Are modifications of software (or its use) implemented by laboratory personnel?	Yes	No	N/A
7.18.1.3	Is there a procedure concerning change of software and its copying?	Yes	No	N/A
7.18.1.4	Is the security of software controlled?	Yes	No	N/A

7.19 Are samples of end product taken by appropriate trained personnel? ◯ Yes ◯ No ◯ N/A

7.20 WHICH SAMPLING PLAN DO YOU USE:

7.20.1 For starting materials?

7.20.2 For finished products?

7.21 Do you analyze each sample? ◯ Yes ◯ No ◯ N/A

7.22 Do you keep retain samples of each lot? ◯ Yes ◯ No ◯ N/A

7.23 For how long do you keep retain samples? _____ Years

7.24 Is there a procedure in place to establish and manage reference standards? ◯ Yes ◯ No ◯ N/A

8 Quality Assurance

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8.1 Is there an independent Quality Assurance (QA) department within the company? ◯ Yes ◯ No ◯ N/A

8.2 WHO IS RESPONSIBLE FOR EVALUATION AND APPROVAL:

8.2.1 Of specifications of end products?

8.2.2 Of critical manufacturing process parameters?

8.3 Do you have procedures covering the release or rejection of material? ◯ Yes ◯ No ◯ N/A

8.4 Who is responsible for release and reject of your end product?

8.5 On which quality data do you base the release of the product?

8.6 Are batch records reviewed / approved before the batch is dispatched? ◯ Yes ◯ No ◯ N/A

8.7 Are deviations and non-conformances investigated, documented filed? ◯ Yes ◯ No ◯ N/A

8.8 DO YOU COMMUNICATE VENDORS REGARDING THE QUALITY OF THE PRODUCT TO THE CUSTOMERS? ◯ Yes ◯ No ◯ N/A

8.8.1 Even when the product is still within specification? ◯ Yes ◯ No ◯ N/A

8.9 Would you notify your Customer of any significant deviations that occur during manufacturing? ◯ Yes ◯ No ◯ N/A

8.10 Do you introduce changes according to a written procedure? ◯ Yes ◯ No ◯ N/A

8.11 DO YOU INFORM YOUR CUSTOMERS ABOUT CHANGES? ◯ Yes ◯ No ◯ N/A

8.11.1 If yes, how do you inform them?

8.11.2 Do you wait for approval of customers on major changes? ◯ Yes ◯ No ◯ N/A

8.11.3 Would you notify your Customer in writing prior to implementing significant changes in analytical test methods, specifications or manufacturing procedures/process, use of raw material source from animal, human or vegetable origin? ◯ Yes ◯ No ◯ N/A

8.11.4 Would you notify your Customer in writing prior to implementing major changes in plant, site of production or contract manufacturing? ◯ Yes ◯ No ◯ N/A

8.12 Describe how senior management is informed of quality related issues:

8.13 DO YOU SUPPLY A CERTIFICATE OF ANALYSIS WITH EACH BATCH? ◯ Yes ◯ No ◯ N/A

8.13.1 If yes, will the Certificate of Analysis include actual analytical results? ◯ Yes ◯ No ◯ N/A

8.14 Will you supply a Certificate of Sterilization with each batch? ◯ Yes ◯ No ◯ N/A

9 Packaging, Labelling and Shipping

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9. PACKAGING, LABELLING AND SHIPPING

9.1	If containers are reused, are they cleaned via validated cleaning procedures and inspected before use?	Yes	No	N/A
9.2	Are container labels reconciled and the number of labels printed, used and destroyed recorded?	Yes	No	N/A
9.3	Is each bag/container labelled with the lot/batch no.?	Yes	No	N/A
9.4	Will each bag/container on a pallet have the lot/batch no. and/or description clearly visible on it?	Yes	No	N/A
9.5	Do you keep records of all shipments to customers, including batch number and quantity?	Yes	No	N/A
9.6	Do you use your own transport for shipping to customers or do you use a contractor?	Contractor Supplier-Owned		N/A
9.6.1	If you use a contractor, Do you have an agreed contract between parties which specifies required shipping conditions for materials?	Yes	No	N/A
9.6.1.1	If yes, have they been evaluated?	Yes	No	N/A
9.7	Is the shipping temperature controlled?	Yes	No	N/A
9.8	Have stability studies for tempera-ture-controlled shipments been performed?	Yes	No	N/A

9.9 ARE WRITTEN INSTRUCTIONS AVAILABLE FOR:

9.9.1	Packaging components?	Yes	No	N/A
9.9.2	Packaging operation?	Yes	No	N/A
9.9.3	Labels and labelling?	Yes	No	N/A
9.10	Does the labelling procedure emphasize special precautions to prevent unintentional mix-up or substitution?	Yes	No	N/A

9.11 Do you maintain lot separation during packaging? ○ Yes ○ No ○ N/A

9.12 Are you prepared to meet packaging and labelling requirements from your customers? ○ Yes ○ No ○ N/A

9.13 DOES YOUR LABELLING INDICATE:

9.13.1 Name and quality? ○ Yes ○ No ○ N/A

9.13.2 The site of manufacturing? ○ Yes ○ No ○ N/A

9.13.3 The lot number? ○ Yes ○ No ○ N/A

9.13.4 Our order number? ○ Yes ○ No ○ N/A

9.13.5 Our code number? ○ Yes ○ No ○ N/A

9.14 DO YOU USE RE-USABLE CONTAINERS? ○ Yes ○ No ○ N/A

9.14.1 If yes, Do you have procedures to take special precautions to avoid cross contamination in this case? ○ Yes ○ No ○ N/A

9.15 DO YOU HAVE YOUR OWN TRANSPORTATION SYSTEM? ○ Yes ○ No ○ N/A

9.15.1 If yes, Do you have a

9.15.1.1 SQAS assessment report? ○ Yes ○ No ○ N/A

9.15.1.2 Valid date of the SQAS report : _____

9.16 Do you have a Quality-/Safety selection system for contracting carriers ○ Yes ○ No ○ N/A

9.17 DO YOU HAVE A REGULAR CARRIER FOR YOUR GOODS? ○ Yes ○ No ○ N/A

9.17.1 If yes:

9.17.1.1 What is the name of this company? _____

9.17.1.2 Who is the carrier's agent? _____

9.18 Do you contact your customer in case of delay? ◯ Yes ◯ No ◯ N/A

9.19 Does your transport system make use of a tracking report? ◯ Yes ◯ No ◯ N/A

9.20 Does your carrier have a Quality Manual? ◯ Yes ◯ No ◯ N/A

9.21 To which norm is this quality system related?

9.22 IS THIS SYSTEM CERTIFIED BY AN ACCREDITED THIRD PARTY AUDITING BODY? ◯ Yes ◯ No ◯ N/A

9.22.1 If yes, which one(s)?

9.23 DOES YOUR CARRIER HAVE A SQAS ASSESSMENT REPORT? ◯ Yes ◯ No ◯ N/A

9.23.1 If yes, valid date of the SQAS report :

9.24 Does your carrier provide documented evidence of proper storage conditions during transportation? ◯ Yes ◯ No ◯ N/A

9.25 Are transportations insured? ◯ Yes ◯ No ◯ N/A

9.26 DO YOU HAVE ONE OR MORE SUBSTITUTE CARRIERS? ◯ Yes ◯ No ◯ N/A

9.26.1 If yes, which one(s)?

9.26.2 Does the substitute carrier(s) have a SQAS assessment report? ◯ Yes ◯ No ◯ N/A

9.26.2.1 Valid date of the SQAS report :

9.26.3 Does your substitute carrier have a certified person: "Safety Advisor – Transport of Dangerous Goods (Road/ Rail)"?

Yes No N/A

9.26.4 Please enclose a copy of the certificate:

Ref.:

9.27 Does the Safety-advisor make annually reports to the highest management about the transport- activities of the company with respect to dangerous materials?

Yes No N/A

10 Health, Safety and Environment (HSE)

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10. HEALTH, SAFETY AND ENVIRONMENT (HSE)

10.1 Do you have an operational management system(s) for Health, Safety and Environment (HSE)? ◯ Yes ◯ No

10.1.1 If so, are these systems

10.1.1.1 a. based on an international standard (ISO 9001/14001/18001)? ◯ Yes ◯ No

10.1.1.2 b. certified by an accredited third party auditing body? ◯ Yes ◯ No

10.2 Do you have a dedicated organization for Health, Safety and Environment (HSE)? ◯ Yes ◯ No

10.3 How many people are employed in this organization? _____

10.4 Have you identified all relevant HSE aspects of your activities and all relevant legal requirements you have to comply with? ◯ Yes ◯ No

10.5 Do you have a structured HSE program, which is regularly monitored and updated? ◯ Yes ◯ No

10.6 Does your site comply with all licenses under relevant laws (Nuisance Act, Environmental Protection Act, Integrated Pollution Prevention, Hazardous etc.)? ◯ Yes ◯ No

10.7 ARE THE FOLLOWING SUBJECTS REGULATED BY LAW AND/OR SPECIFIC STANDARDS:

10.7.1 emissions to air ◯ Yes ◯ No

10.7.2 discharge of waste water ◯ Yes ◯ No

10.7.3 disposal of hazardous waste ◯ Yes ◯ No

10.7.4 protection against/remediation of soil pollution ◯ Yes ◯ No

10.7.5 risk control and reduction ◯ Yes ◯ No

10.7.6 occupational safety ◯ Yes ◯ No

10.8 Does your site operate its own wastewater treatment installation? ◯ Yes ◯ No

10.9 IS YOUR SITE CONTROLLED BY REGULAR INSPECTIONS OF AUTHORITIES IN THE FIELD OF HEALTH, SAFETY AND ENVIRONMENT (HSE)? ◯ Yes ◯ No

10.9.1 Please specify:

10.10 Is your personnel instructed on the handling of any kind of hazardous materials you use and on how to act in case of unwanted events? ◯ Yes ◯ No

10.11 Do you have an adequate emergency response plan and organization? ◯ Yes ◯ No

10.12 Do you run HSE (compliance/performance) audits? ◯ Yes ◯ No

10.13 DO YOU HAVE A CERTIFIED PERSON: "SAFETY-ADVISOR TRANSPORT DANGEROUS MATER (ROAD/RAIL)"? ◯ Yes ◯ No

10.13.1 Please enclose a copy of the certificate.

Ref.:

10.13.2 Does the Safety-advisor make annually reports to the highest management transport activities of the company with respect to dangerous materials? ◯ Yes ◯ No

CONTACT DETAILS:

*Authorized Representative Name:

*Title:

*E-Signature, Stamp, & Date:

*DECLARATION OF INFORMATION ACCURACY:

I, the undersigned, hereby confirm that I am an authorized representative of the supplier/company named in this questionnaire. I declare that all the information and data provided in this questionnaire are true, complete, and accurate.

I understand that providing any false, misleading, or incomplete information may result in rejection of the qualification request or in disqualification from the approved supplier list of Al Motakadema Pharmaceutical Ltd., and may lead to the termination of any existing qualification status.

I agree to provide Al Motakadema Pharmaceutical Ltd. with any additional information or documentation upon request and acknowledge that an audit visit by company representatives may be conducted as part of the supplier evaluation program if deemed necessary.

◯ Yes

*** ALL FIELDS MARKED WITH A (*) ARE MANDATORY.**

*** ONCE COMPLETED, CLICK THE "SUBMIT" BUTTON. IF THIS DOES NOT WORK ON YOUR DEVICE, PLEASE SAVE THE FILE AND EMAIL IT TO: PURCHASING@MOTAKADEMA.COM.**

SUBMIT

SCAN ME !

Al Motakadema Pharmaceutical Ltd.

CONTACT US:

Phone:
(962) 79 86 67 12 9

Email:
director@motakadema.com

Fax:
(962) 5 355 2534

WWW.MOTAKADEMA.COM

Jordan – Al Salt, Al Bohaira, Industrial Zone