

E. Extended Quality Questionnaire		
Material Brand Name	Chemical Name (if applicable)	Product Code
1. General Information		
1.1.	Are customer audits and/or inspections by agencies permitted?	Yes <input type="checkbox"/> No <input type="checkbox"/>
1.2.	Is the decision to release or reject a product for sale independent from production?	Yes <input type="checkbox"/> No <input type="checkbox"/>
1.3.	Who is signing the Certificate of Analysis (Analytical Report)?	
1.4.	Who is responsible for the final product release?	
1.5.	Who is responsible for contacts with us concerning quality matters?	
1.6.	What kind of product do you manufacture <ul style="list-style-type: none"> ▪ Bulk raw materials? ▪ Bulk raw materials for pharmaceuticals? ▪ Active pharmaceutical ingredients? ▪ Technical products? ▪ Packaging material? ▪ Others? Please, specify:	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>
1.7.	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	Ref:

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2. Personnel, Training and Education				
2.1	Do you have written job descriptions for all personnel?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
2.2	Do you have procedures that document how you perform training?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
2.3	Do you maintain records of the training?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
2.4	Is your personnel aware that the products supplied are used for the manufacturing of active pharmaceutical ingredients?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
2.5	Does the Training Program in place have the following elements:			
2.5.1	Formal Introduction to Regulatory Guidance (GMP, ISO, etc.)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
2.5.2	New Hire Program	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
2.5.3	Specific training e.g. clean room or handling toxic, infectious or sensitising materials?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
2.5.4	Periodic assessment of practical effectiveness?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
2.5.5	Periodic refresher training programs for established employees?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
2.5.6	At the start of new product manufacturing?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
2.5.7	When new methods are used?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
2.5.8	Quality techniques for production people?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
2.6	Does your training program emphasise:			
2.6.1	Product integrity?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
2.6.2	Hygiene?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
2.6.3	Cleanliness?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
2.6.4	Other? Please specify:	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>

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3. Facility and Utilities		
3.1	Were the premises designed or adapted for the present use?	<input type="checkbox"/> designed <input type="checkbox"/> adapted
3.2	Are there separate areas for:	
3.2.1	▪ Handling of starting materials?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
3.2.2	▪ Manufacturing?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
3.2.3	▪ Quarantined finished products or are other control systems in place?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
3.2.4	▪ Approved finished products?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
3.2.5	▪ Packaging and dispatch?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
3.2.6	▪ Rest and eating?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
3.3	Does the present design prevent:	
3.3.1	▪ Chemical contamination?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
3.3.2	▪ Physical contamination?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
3.3.3	▪ Microbial contamination?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
3.4	Are your working-rooms:	
3.4.1	▪ Of proper size for the intended functions?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
3.4.2	▪ Satisfactorily lighted, air-conditioned?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
3.4.3	▪ Clean and cleaned-up?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
3.4.4	▪ Designed to avoid (cross-) contamination?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
3.4.5	▪ Supplied with security and fire protection measurements?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
3.5	Do you have written Good House Keeping Procedures?	
3.5.1	If yes, do you maintain follow- up records of these procedures?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
3.6	Do your manufacturing locations follow Good Manufacturing Practices?	
3.7	Are your sites inspected by the FDA or national (health) authorities?	
3.8	Are plant supply pipelines identified and labelled?	
3.9	Do you monitor the quality of the water used to prepare standards and reagents?	
3.10	Do you monitor the quality of the water used during the manufacturing process?	

4. Machines and Equipment			
4.1	Is the production line multi purpose or single purpose?	<input type="checkbox"/> multi	<input type="checkbox"/> single
4.1.1	If multi, what other products do you manufacture there?		
4.2	Is there a maintenance and preventative maintenance program for all pieces of equipment?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
4.3	Do you have written maintenance and calibration procedures for critical equipment?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
4.4	Can all critical apparatus and devices easily be recognised as such, e.g. by calibration stickers?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
4.5	Are these calibrations traceable back to national standards?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
4.6	Do you retain records of calibration as evidence of control?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
4.7	Is there a cleaning plan/procedure for production machines, equipment?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
4.8	Have the cleaning and sterilisation processes been validated?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
4.9	Is any manufacturing equipment software controlled?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
4.10	Do you have a documented procedure for the validation of all test and measuring equipment used to demonstrate the conformance of product to the specified requirements?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
4.11	Do you retain records of validation as evidence of control?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
4.11.1	If yes, <ul style="list-style-type: none"> ▪ Is the software validated? ▪ Are modifications of software (or its use) implemented by manufacturing personnel? ▪ Is there a procedure concerning change of software and its copying? ▪ Is the security of software controlled? 	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
4.12	Do you contract out any of the following services		
4.12.1	Instrument Calibration?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
4.12.2	Preventative / Breakdown Maintenance?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>

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5. Production and Process Control			
5.1	Is your manufacturing process validated?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
5.1.1	If not, do you have plans to do so?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
5.1.1.1	If you do: what is your target date for completion?		
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 <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
5.6	If, for capacity reasons, you combine material coming from more than one particular piece or part of process equipment into one lot/batch:		
5.6.1	Is the lot/batch being homogenised prior to packaging?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
5.6.2	Is the homogenisation operation validated?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
5.7	Do you manufacture according to a written procedure for each product supplied to the market?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
5.8	Are these procedures approved by QA?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
5.9	Do you have a batch record for each batch/lot manufactured?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
5.9.1	If yes, do the batch records detail the following:		
	▪ Description, Lot Number & Quantities of Material used?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
	▪ Processing Conditions (Temperature, Times etc)?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
	▪ The identification of the Person who performed the particular step?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
	▪ Results of any In-process tests?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
	▪ All deviations from standard conditions?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
	▪ All cleaning operations carried out before & after batch manufacture?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
5.9.2	If yes, for how long do you keep the batch records?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
5.9.3	If yes, are these records formally checked and approved by QA?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
5.10	Do you maintain lot separation during		
	▪ Manufacturing?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
	▪ Packaging?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>
	▪ Storage?	Yes <input type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>

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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 <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
5.12	Are computers used to store records of manufacture, testing, storage or distribution for the product you supply?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
5.13	Do all product containers bear identification labels, e.g. stating batch/lot number, product name etc.?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
5.14	Is there expiry or retest dates defined for all material?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
5.15	Is there storage conditions defined for all material?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
5.16	Is the product identifiable throughout the manufacturing process?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
5.17	Is traceability of all raw materials used, maintained throughout manufacture?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
5.18	Is there a procedure in place to prevent cross-contamination?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
5.20	Do you use dedicated equipment for the production of the product in question?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
5.22	Is testing or inspection performed on finished products?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
5.23	Are rejected lots identified as such and separated?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
5.24	Do you perform a failure investigation in case of a reject?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
5.25	Is reprocessing of rejected lots documented?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
5.26	Do you have a procedure covering rework/reprocessing or recovery of material?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
5.27	Is non-conforming final product ever blended with conforming product to bring it into specification?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>

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5.28	Is there a documented procedure that clearly defines when blending of non-conforming product is allowed?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
5.29	How long do you keep the analytical and production records (number of years)?	Years		
5.30	Do you have plant shutdowns (holidays, maintenance)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
5.30.1	If yes, which one(s)?	<input type="checkbox"/> main	<input type="checkbox"/> hol	
5.31	Do you have manufacturing alternatives/fall back?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
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?			

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6. Materials Control				
6.1	Do you have an approved supplier list?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
6.3	Do you have written specifications for all incoming raw material?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
6.6	Are Certificates of Analysis routinely compared against a written specification?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
6.7	Do you routinely test receipted materials to verify conformance with the supplier certification?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
6.8	Do you have procedures for the control of raw materials?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
6.9	Are records kept that show full traceability of raw materials?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
6.10	Do you maintain information records for raw materials which include the following:			
	▪ Your lot Identity?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	▪ Suppliers Lot No?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	▪ Date of Receipt?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	▪ Quantity?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	▪ Suppliers name?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	▪ Shelf Life?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	▪ Test Results?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	▪ Specification?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	▪ Accepted/Rejected?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	▪ Retained Sample?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
6.13	Are scheduled stock checks performed?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
6.14	Do you have a rework/reprocess policy?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>

7. Quality Control		
7.1	Is Quality Control (QC) independent of Production?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
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 <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
7.4	If so, do these records include the following: <ul style="list-style-type: none"> ▪ Date sample received? ▪ Identity of samples? ▪ Results of testing? ▪ Date sample taken? 	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
7.5	Are there formal written procedures for all performed tests?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
7.6	Are the analytical methods validated?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
7.7	Are control samples routinely run with assays?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
7.8	Are analytical calculations checked by a second person?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
7.9	Do you perform trend analysis on analytical results?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
7.10	Are the results of reference standard testing maintained on file?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
7.11	Is there a procedure for documenting and investigating out-of-specification results?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
7.12	Do you use any contract laboratories?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
7.13	Have you qualified/evaluated these contract laboratories?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
7.14	What types of testing is contracted out?	
7.15	Are quality standards or written control procedures available for: <ul style="list-style-type: none"> ▪ Starting materials? ▪ In-process control? ▪ Physical identification at all stages (e.g. labelling of semi-finished products)? ▪ Finished products? ▪ Microbiological control? 	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>

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7.16	Are records kept of all control results?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
7.16.1	If yes, for how long do you keep those records?	Years		
7.17	Is your critical analytical laboratory equipment fully qualified?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
7.18	Is there a maintenance plan/procedure for laboratory equipment?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
7.18.1	If yes:			
7.18.1.1	Do you have a calibration scheme?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
7.18.1.2	Do you have calibration instructions?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
7.18.1.3	Do you keep all records of calibration performances?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
7.19	Does any laboratory equipment have software control?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
7.19.1	If yes:			
7.19.1.1	Is the software validated?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
7.19.1.2	Are modifications of software (or its use) implemented by laboratory personnel?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
7.19.1.3	Is there a procedure concerning change of software and its copying?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
7.19.1.4	Is the security of software controlled?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
7.20	Are samples of end product taken by appropriate trained personnel?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
7.21	Which sampling plan do you use:			
7.21.1	▪ For starting materials?			
7.21.2	▪ For finished products?			
7.22	Do you analyse each sample?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
7.23	Do you keep retain samples of each lot?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
7.24	For how long do you keep retain samples?	Years		
7.25	Is there a procedure in place to establish and manage reference standards?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>

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8. Quality Assurance		
8.1	Is there an independent Quality Assurance (QA) department within the company?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
8.2	Who is responsible for evaluation and approval: <ul style="list-style-type: none"> ▪ of specifications of end products? ▪ of critical manufacturing process parameters? 	
8.3	Do you have procedures covering the release or rejection of material?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
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 <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
8.7	Are deviations and non-conformances investigated, documented and filed?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
8.8	Do you communicate doubts regarding the quality of the product to the customers?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
8.8.1	Even when the product is still within specification?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
8.9	Would you notify your Customer of any significant deviations that occur during manufacturing?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
8.10	Do you introduce changes according to a written procedure?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
8.11	Do you inform your customers about changes?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
8.11.1	If yes, how do you inform them?	
8.11.2	Do you wait for approval of customers on major changes?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
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 form animal, human or vegetable origin?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
8.11.4	Would you notify your Customer in writing prior to implementing major changes in plant, site of production or contract manufacturing?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
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 <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
8.13.1	If 'YES', will the Certificate of Analysis include actual analytical results?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
8.14	Will you supply a Certificate of Sterilization with each batch?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>

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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 <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.2	Are container labels reconciled and the number of labels printed, used and destroyed recorded?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.3	Is each bag/container labelled with the lot/batch no.?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.4	Will each bag/container on a pallet have the lot/batch no. and/or description clearly visible on it?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.5	Do you keep records of all shipments to customers, including batch number and quantity?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.6	Do you use your own transport for shipping to customers or do you use a contractor?	Supplier- Owned <input type="checkbox"/>	Contractor <input type="checkbox"/>	N/A <input type="checkbox"/>
9.7	If you use a contractor, Do you have an agreed contract between parties which specifies required shipping conditions for materials?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.7.1	If yes, have they been evaluated?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.8	Is the shipping temperature controlled?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.9	Have stability studies for temperature controlled shipments been performed?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.10	Are written instructions available for Packaging components? Packaging operation? Labels and labelling?	Yes <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/>	No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/>	N/A <input type="checkbox"/> N/A <input type="checkbox"/> N/A <input type="checkbox"/>
9.11	Does the labelling procedure emphasise special precautions to prevent unintentional mix-up or substitution?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.12	Do you maintain lot separation during packaging?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.13	Are you prepared to meet packaging and labelling requirements from your customers?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.14	Does your labelling indicate: <ul style="list-style-type: none"> ▪ Name and quality? ▪ The site of manufacturing? ▪ The lot number? ▪ Our order number? ▪ Our code number? 	Yes <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/>	No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/>	N/A <input type="checkbox"/> N/A <input type="checkbox"/> N/A <input type="checkbox"/> N/A <input type="checkbox"/> N/A <input type="checkbox"/>

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9.15	Do you use re-usable containers?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.15.1	If yes: Do you have procedures to take special precautions to avoid cross-contamination in this case?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.16	Do you have your own transportation system?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.16.1	If yes: Do you have a SQAS assessment report? Valid date of the SQAS report :	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
		--	--	
9.17	Do you have a Quality-/Safety selection system for contracting carriers	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.18	Do you have a regular carrier for your goods?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.18.1	If yes: What is the name of this company? Who is the carrier's agent?			
9.19	Do you contact your customer in case of delay?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.20	Does your transport system make use of a tracking report?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.21	Does your carrier have a Quality Manual?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.22	To which norm is this quality system related?			
9.23	Is this system certified by an accredited third party auditing body?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.23.1	If yes, which one(s)?			
9.24	Does your carrier have a SQAS assessment report?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.24.1	If yes, valid date of the SQAS report :	--	--	
9.25	Does your carrier provide documented evidence of proper storage conditions during transportation?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.26	Are transportations insured?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.27	Do you have one or more substitute carriers?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.27.1	If yes, which one(s)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.27.2	Does the substitute carrier(s) have a SQAS assessment report?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.27.2.1	Valid date of the SQAS report :	--	--	
9.27.3	Does your substitute carrier have a certified person: "Safety-advisor transport dangerous materials (road/rail)"?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.27.4	Please enclose a copy of the certificate:	Ref:		
9.28	Does the Safety-advisor make annually reports to the highest management about the transport- activities of the company with respect to dangerous materials?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>

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9.29	In case of liquid products	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.29.1	Do you use dedicated tankers?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.29.2	Do you require cleaning of road tankers after every use?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.29.3	Are cleaning certificates kept by the driver?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.29.4	Are cleaning certificates available for inspection by us?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>

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10. Safety, Health and Environment (SHE)		
10.1	Do you have an operational management system(s) for Safety, Health and Environment (SHE)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
10.1.1	If so, are these systems	
	a. based on an international standard (ISO 9001/14001/18001)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	b. certified by a accredited third party auditing body?	Yes <input type="checkbox"/> No <input type="checkbox"/>
10.2	Do you have a dedicated organisation for safety, health and environment?	Yes <input type="checkbox"/> No <input type="checkbox"/>
10.3	How many people are employed in this organisation?	
10.4	Have you identified all relevant SHE aspects of your activities and all relevant legal requirements you have to comply with?	Yes <input type="checkbox"/> No <input type="checkbox"/>
10.5	Do you have a structured SHE program, which is regularly monitored and updated?	Yes <input type="checkbox"/> No <input type="checkbox"/>
10.6	Does your site comply with all licenses under relevant laws (Nuisance Act, Environmental Protection Act, Integrated Pollution Prevention, Hazardous Waste, etc.)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
10.7	Are the following subjects regulated by law and/or specific standards:	
	▪ emissions to air	Yes <input type="checkbox"/> No <input type="checkbox"/>
	▪ discharge of waste water	Yes <input type="checkbox"/> No <input type="checkbox"/>
	▪ disposal of hazardous waste	Yes <input type="checkbox"/> No <input type="checkbox"/>
	▪ protection against/remediation of soil pollution	Yes <input type="checkbox"/> No <input type="checkbox"/>
	▪ risk control and reduction	Yes <input type="checkbox"/> No <input type="checkbox"/>
	▪ nuisance by noise/odour	Yes <input type="checkbox"/> No <input type="checkbox"/>
	▪ occupational safety	Yes <input type="checkbox"/> No <input type="checkbox"/>
10.8	Does your site operate its own wastewater treatment installation?	Yes <input type="checkbox"/> No <input type="checkbox"/>
10.9	Is your site controlled by regular inspections of authorities in the field of safety, health and environment?	Yes <input type="checkbox"/> No <input type="checkbox"/>
10.9.1	Please specify	
10.10	Is your personnel instructed on the handling of any kind of hazardous materials that you use and on how to act in case of unwanted events?	Yes <input type="checkbox"/> No <input type="checkbox"/>
10.11	Do you have an adequate emergency response plan and organisation?	Yes <input type="checkbox"/> No <input type="checkbox"/>
10.12	Do you run SHE (compliance/performance) audits?	Yes <input type="checkbox"/> No <input type="checkbox"/>
10.13	Do you have a certified person: "Safety-advisor transport dangerous materials (road/rail)"?	Yes <input type="checkbox"/> No <input type="checkbox"/>
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 about the transport activities of the company with respect to dangerous materials?	Yes <input type="checkbox"/> No <input type="checkbox"/>