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 ☐ No ☐
1.2	Is the decision to release or reject a product for sale independent from production?	Yes ☐ No ☐
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 ▪ Bulk raw materials? ▪ Bulk raw materials for pharmaceuticals? ▪ Active pharmaceutical ingredients? ▪ Technical products? ▪ Packaging material? ▪ Others? Please, specify:	 Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐
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:

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	Is your personnel aware that the products supplied are used for the manufacturing of active pharmaceutical ingredients?	Yes ☐	No ☐	N/A ☐
2.5	Does the Training Program in place have the following elements:			
2.5.1	Formal Introduction to Regulatory Guidance (GMP, ISO, etc.)	Yes ☐	No ☐	N/A ☐
2.5.2	New Hire Program	Yes ☐	No ☐	N/A ☐
2.5.3	Specific training e.g. clean room or handling toxic, infectious or sensitising materials?	Yes ☐	No ☐	N/A ☐
2.5.4	Periodic assessment of practical effectiveness?	Yes ☐	No ☐	N/A ☐
2.5.5	Periodic refresher training programs for established employees?	Yes ☐	No ☐	N/A ☐
2.5.6	At the start of new product manufacturing?	Yes ☐	No ☐	N/A ☐
2.5.7	When new methods are used?	Yes ☐	No ☐	N/A ☐
2.5.8	Quality techniques for production people?	Yes ☐	No ☐	N/A ☐
2.6	Does your training program emphasise:			
2.6.1	Product integrity?	Yes ☐	No ☐	N/A ☐
2.6.2	Hygiene?	Yes ☐	No ☐	N/A ☐
2.6.3	Cleanliness?	Yes ☐	No ☐	N/A ☐
2.6.4	Other? Please specify:	Yes ☐	No ☐	N/A ☐

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				
4.1	Is the production line multi purpose or single purpose?	☐ multi	☐ 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 ☐	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 recognised as such, e.g. 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 sterilisation 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 measuring equipment used to demonstrate the conformance of product 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, ▪ 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 ☐ Yes ☐ Yes ☐ Yes ☐	 No ☐ No ☐ No ☐ No ☐	 N/A ☐ N/A ☐ N/A ☐ 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				
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?			
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 particular piece or part of process equipment into one lot/batch:			
5.6.1	Is the lot/batch being homogenised prior to packaging?	Yes ☐	No ☐	N/A ☐
5.6.2	Is the homogenisation 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:			
	▪ Description, Lot Number & Quantities of Material used?	Yes ☐	No ☐	N/A ☐
	▪ Processing Conditions (Temperature, Times etc)?	Yes ☐	No ☐	N/A ☐
	▪ The identification of the Person who performed the particular step?	Yes ☐	No ☐	N/A ☐
	▪ Results of any In-process tests?	Yes ☐	No ☐	N/A ☐
	▪ All deviations from standard conditions?	Yes ☐	No ☐	N/A ☐
	▪ 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			
	▪ Manufacturing?	Yes ☐	No ☐	N/A ☐
	▪ Packaging?	Yes ☐	No ☐	N/A ☐
	▪ 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)?	Years
5.30	Do you have plant shutdowns (holidays, maintenance)?	Yes ☐ No ☐ N/A ☐
5.30.1	If yes, which one(s)?	☐ main ☐ hol
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

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:			
	▪ Your lot Identity?	Yes ☐	No ☐	N/A ☐
	▪ Suppliers Lot No?	Yes ☐	No ☐	N/A ☐
	▪ Date of Receipt?	Yes ☐	No ☐	N/A ☐
	▪ Quantity?	Yes ☐	No ☐	N/A ☐
	▪ Suppliers name?	Yes ☐	No ☐	N/A ☐
	▪ Shelf Life?	Yes ☐	No ☐	N/A ☐
	▪ Test Results?	Yes ☐	No ☐	N/A ☐
	▪ Specification?	Yes ☐	No ☐	N/A ☐
	▪ Accepted/Rejected?	Yes ☐	No ☐	N/A ☐
	▪ 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				
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 ☐
7.4	If so, do these records include the following:			
	▪ Date sample received?	Yes ☐	No ☐	N/A ☐
	▪ Identity of samples?	Yes ☐	No ☐	N/A ☐
	▪ Results of testing?	Yes ☐	No ☐	N/A ☐
	▪ Date sample taken?	Yes ☐	No ☐	N/A ☐
7.5	Are there formal written procedures for all performed tests?	Yes ☐	No ☐	N/A ☐
7.6	Are the analytical methods validated?	Yes ☐	No ☐	N/A ☐
7.7	Are control samples routinely run with assays?	Yes ☐	No ☐	N/A ☐
7.8	Are analytical calculations checked by a second person?	Yes ☐	No ☐	N/A ☐
7.9	Do you perform trend analysis on analytical results?	Yes ☐	No ☐	N/A ☐
7.10	Are the results of reference standard testing maintained on file?	Yes ☐	No ☐	N/A ☐
7.11	Is there a procedure for documenting and investigating out-of-specification results?	Yes ☐	No ☐	N/A ☐
7.12	Do you use any contract laboratories?	Yes ☐	No ☐	N/A ☐
7.13	Have you qualified/evaluated these contract laboratories?	Yes ☐	No ☐	N/A ☐
7.14	What types of testing is contracted out?			
7.15	Are quality standards or written control procedures available for:			
	▪ Starting materials?	Yes ☐	No ☐	N/A ☐
	▪ In-process control?	Yes ☐	No ☐	N/A ☐
	▪ Physical identification at all stages (e.g. labelling of semi-finished products)?	Yes ☐	No ☐	N/A ☐
	▪ Finished products?	Yes ☐	No ☐	N/A ☐
	▪ Microbiological control?	Yes ☐	No ☐	N/A ☐

7.16	Are records kept of all control results?	Yes ☐	No ☐	N/A ☐
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 ☐	No ☐	N/A ☐
7.18	Is there a maintenance plan/procedure for laboratory equipment?	Yes ☐	No ☐	N/A ☐
7.18.1	If yes:			
7.18.1.1	Do you have a calibration scheme?	Yes ☐	No ☐	N/A ☐
7.18.1.2	Do you have calibration instructions?	Yes ☐	No ☐	N/A ☐
7.18.1.3	Do you keep all records of calibration performances?	Yes ☐	No ☐	N/A ☐
7.19	Does any laboratory equipment have software control?	Yes ☐	No ☐	N/A ☐
7.19.1	If yes:			
7.19.1.1	Is the software validated?	Yes ☐	No ☐	N/A ☐
7.19.1.2	Are modifications of software (or its use) implemented by laboratory personnel?	Yes ☐	No ☐	N/A ☐
7.19.1.3	Is there a procedure concerning change of software and its copying?	Yes ☐	No ☐	N/A ☐
7.19.1.4	Is the security of software controlled?	Yes ☐	No ☐	N/A ☐
7.20	Are samples of end product taken by appropriate trained personnel?	Yes ☐	No ☐	N/A ☐
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 ☐	No ☐	N/A ☐
7.23	Do you keep retain samples of each lot?	Yes ☐	No ☐	N/A ☐
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 ☐	No ☐	N/A ☐

8. Quality Assurance				
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: ▪ of specifications of end products? ▪ 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 and filed?	Yes ☐	No ☐	N/A ☐
8.8	Do you communicate doubts 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 form 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				
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?	Supplier- Owned ☐	Contractor ☐	N/A ☐
9.7	If you use a contractor, Do you have an agreed contract between parties which specifies required shipping conditions for materials?	Yes ☐	No ☐	N/A ☐
9.7.1	If yes, have they been evaluated?	Yes ☐	No ☐	N/A ☐
9.8	Is the shipping temperature controlled?	Yes ☐	No ☐	N/A ☐
9.9	Have stability studies for temperature controlled shipments been performed?	Yes ☐	No ☐	N/A ☐
9.10	Are written instructions available for			
	Packaging components?	Yes ☐	No ☐	N/A ☐
	Packaging operation?	Yes ☐	No ☐	N/A ☐
	Labels and labelling?	Yes ☐	No ☐	N/A ☐
9.11	Does the labelling procedure emphasise special precautions to prevent unintentional mix-up or substitution?	Yes ☐	No ☐	N/A ☐
9.12	Do you maintain lot separation during packaging?	Yes ☐	No ☐	N/A ☐
9.13	Are you prepared to meet packaging and labelling requirements from your customers?	Yes ☐	No ☐	N/A ☐
9.14	Does your labelling indicate:			
	▪ Name and quality?	Yes ☐	No ☐	N/A ☐
	▪ The site of manufacturing?	Yes ☐	No ☐	N/A ☐
	▪ The lot number?	Yes ☐	No ☐	N/A ☐
	▪ Our order number?	Yes ☐	No ☐	N/A ☐
	▪ Our code number?	Yes ☐	No ☐	N/A ☐

9.15	Do you use re-usable containers?	Yes ☐	No ☐	N/A ☐
9.15.1	If yes: Do you have procedures to take special precautions to avoid cross-contamination in this case?	Yes ☐	No ☐	N/A ☐
9.16	Do you have your own transportation system?	Yes ☐	No ☐	N/A ☐
9.16.1	If yes: Do you have a SQAS assessment report? Valid date of the SQAS report :	Yes ☐ --	No ☐ --	N/A ☐
9.17	Do you have a Quality-/Safety selection system for contracting carriers	Yes ☐	No ☐	N/A ☐
9.18	Do you have a regular carrier for your goods?	Yes ☐	No ☐	N/A ☐
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 ☐	No ☐	N/A ☐
9.20	Does your transport system make use of a tracking report?	Yes ☐	No ☐	N/A ☐
9.21	Does your carrier have a Quality Manual?	Yes ☐	No ☐	N/A ☐
9.22	To which norm is this quality system related?			
9.23	Is this system certified by an accredited third party auditing body?	Yes ☐	No ☐	N/A ☐
9.23.1	If yes, which one(s)?			
9.24	Does your carrier have a SQAS assessment report?	Yes ☐	No ☐	N/A ☐
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 ☐	No ☐	N/A ☐
9.26	Are transportations insured?	Yes ☐	No ☐	N/A ☐
9.27	Do you have one or more substitute carriers?	Yes ☐	No ☐	N/A ☐
9.27.1	If yes, which one(s)?	Yes ☐	No ☐	N/A ☐
9.27.2	Does the substitute carrier(s) have a SQAS assessment report?	Yes ☐	No ☐	N/A ☐
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 ☐	No ☐	N/A ☐
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 ☐	No ☐	N/A ☐

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

10. Safety, Health and Environment (SHE)			
10.1	Do you have an operational management system(s) for Safety, Health and Environment (SHE)?	Yes ☐	No ☐
10.1.1	If so, are these systems		
	a. based on an international standard (ISO 9001/14001/18001)?	Yes ☐	No ☐
	b. certified by a accredited third party auditing body?	Yes ☐	No ☐
10.2	Do you have a dedicated organisation for safety, health and environment?	Yes ☐	No ☐
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 ☐	No ☐
10.5	Do you have a structured SHE 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 Waste, etc.)?	Yes ☐	No ☐
10.7	Are the following subjects regulated by law and/or specific standards:		
	▪ emissions to air	Yes ☐	No ☐
	▪ discharge of waste water	Yes ☐	No ☐
	▪ disposal of hazardous waste	Yes ☐	No ☐
	▪ protection against/remediation of soil pollution	Yes ☐	No ☐
	▪ risk control and reduction	Yes ☐	No ☐
	▪ nuisance by noise/odour	Yes ☐	No ☐
	▪ 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 safety, health and environment?	Yes ☐	No ☐
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 ☐	No ☐
10.11	Do you have an adequate emergency response plan and organisation?	Yes ☐	No ☐
10.12	Do you run SHE (compliance/performance) audits?	Yes ☐	No ☐
10.13	Do you have a certified person: “Safety-advisor transport dangerous materials (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 about the transport activities of the company with respect to dangerous materials?	Yes ☐	No ☐