

<b>A. General Information on Company, Product and Quality Management</b>			
<b>1. Company Information</b>			
<b>1.1 Company Address Information</b>			
Name of company:			
Address:			
Postcode:			
Country:			
Telephone number:			
Fax number:			
Web address:			
<b>1.2 Is the address listed above the only site for production?</b>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	<b>If NO, please provide details below:</b>
Name of company(s):			
Address:			
Postcode:			
Telephone number:			
Fax number:			
<b>1.3 Is your company a subsidiary?</b>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	<b>If Yes, please provide details below:</b>
Name of company:			
Address:			
Postcode:			
Telephone number:			
Fax number:			

## Supplier Quality Questionnaire

### Supplier Questionnaire - Section A General Info\_modified

Page 2 of 10

1.4 Contact Information (Please provide details of an available contact)			
Name:			
Position:			
Telephone number:			
Fax number:			
Email address:			
1.5 Site Personnel Information			
1.5.1	Approximate total number of employees at facility of interest:		
1.5.2	Approximate number of employees in the Quality Unit (Quality Assurance/Quality Control)		
1.5.3	Approximate number of employees in Production/Operations Unit		
1.5.4	If available, please enclose a copy of your Organisational chart indicating key personnel.	Enclosed <input type="checkbox"/> Ref:	N/A <input type="checkbox"/>
1.5.5	If available, could you please supply copies of any sales information for the products listed on the front of this form?	Enclosed <input type="checkbox"/> Ref:	N/A <input type="checkbox"/>
1.5.6	Does your factory operate in a shift system?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	How many?		
	How many days a week?		
1.6 Company structure			
1.6.1	What is the legal ownership structure of your company?		
1.6.2	Please give a brief structure-diagram	Ref:	
1.6.3	Do you expect a change of the legal status and/or ownership of your company in the near future?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
1.6.4	Do you have an annual report available?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	If yes, please enclose the annual report	Ref:	

**Supplier Quality Questionnaire**

2. Product Information					
2.3	Origin of the main ingredients				Comments
2.3.1	Synthetic	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
2.3.2	Fermentation	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
2.3.3	Vegetable	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
2.3.4	Mineral	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
2.3.5	Animal (if YES, please complete section B as well)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
2.3.5	Bovine (or by-products)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
2.3.5	Porcine (or by-products)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
2.3.5	Poultry (or by-products)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
2.3.5	Fish (or by-products)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
2.3.5	Human (or by-products)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
2.4	Origin of the carrier components and/or any material used in the manufacture				Comments
2.4.1	Synthetic	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
2.4.2	Fermentation	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
2.4.3	Vegetable	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
2.4.4	Mineral	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
2.4.5	Animal (if YES, please complete section B as well)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
2.4.5	Bovine (or by-products)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
2.4.5	Porcine (or by-products)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
2.4.5	Poultry (or by-products)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
2.4.5	Fish (or by-products)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
2.4.5	Human (or by-products)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	

## Supplier Quality Questionnaire

2.5	Additives (if applicable)				Comments
2.5.1	Additive E Numbers	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
2.5.1	Other additives than colours and sweeteners (Dir. 95/2/EC* and subsequent amendments.)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
2.5.1	Purity criteria (Dir. 96/77/EC* and subsequent amendments.)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
2.5.1	Other relevant purity criteria applicable	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
2.6	Other products supplied to us:				

3. Quality Standards and Certifications							
3.1	Do you hold certification(s) against any recognized quality standards by a accredited third party body e.g. ISO 9001, 14001 or 22000? If yes, please provide a copy of certificate(s).			Yes <input type="checkbox"/>	Ref:	No <input type="checkbox"/>	N/A <input type="checkbox"/>
3.2	Do you hold accreditation, certification or registration by any regulatory agency or body? If yes, please provide a copy of documentation			Yes <input type="checkbox"/>	Ref:	No <input type="checkbox"/>	N/A <input type="checkbox"/>
3.3	Are any aspects of the process / service provided subcontracted?			Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
3.3.1	If so, please provide detail:						
3.3.2	Are there Quality / Technical Agreements held with subcontractors?			Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	

4. Quality Management Documentation					
Do you have procedures that document how you perform the following activities: If 'YES' please provide the document reference number / identification. In case you are certified towards ISO9001, only 4.1.2, 4.1.7, 4.1.11, 4.2.1, 4.2.2, 4.4.1, 4.4.4 and 4.5.2 are mandatory.					
4.1	QUALITY SYSTEM				Comment
4.1.1	Quality Policy / Manual	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
4.1.2	Equipment & Instrument Validation / Qualification Program	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
4.1.3	Internal Audit / Self-Inspection Program	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
4.1.4	Supplier Evaluation / Qualification Program	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
4.1.5	Does your company operate a supplier-auditing system?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
4.1.6	Training Program	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
4.1.7	Change Control	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
4.1.8	Deviation / Investigation Reporting	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
4.1.9	Non-Conformance Reporting	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
4.1.10	Documentation Control	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
4.1.11	Do you have a recall system/procedure in place?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
4.2	PRODUCTION / OPERATIONS SYSTEM				
4.2.1	Environmental Monitoring Program	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
4.2.2	Housekeeping Program	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
4.2.3	Gowning / Entry & Exit Procedure	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
4.2.4	Availability of Master Production Instructions and Batch production Records	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
4.2.5	Availability of Equipment Cleaning Procedures, Cleaning Records and Cleaning Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
4.3	PACKAGING / LABELLING SYSTEM				
4.3.1	Labelling of Intermediate / Final Products	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
4.3.2	Storage of Intermediate / Final Products	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
4.3.3	Product / Sample Shipping Validation Program	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
4.4	FACILITIES AND EQUIPMENT SYSTEM				
4.4.1	Pest Control Program	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
4.4.2	Preventive Maintenance Program	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
4.4.3	Calibration Program	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	
4.4.4	Facility Cleaning / Sanitization	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	

**Supplier Quality Questionnaire**

4.5 LABORATORY CONTROL SYSTEM			Comment
4.5.1	Method Qualification for all assays used in Testing of Samples	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	
4.5.2	Testing Reagents and Standards Controls Policy / Procedure	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	
4.5.3	Sample Retention Program	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	
4.5.4	Out of Specification (OOS) / Retest Procedures	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	
4.5.5	Availability of Analytical Raw Data Documentation	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	
4.6 MATERIALS CONTROL SYSTEM			
4.6.1	Materials Movement into the Facility	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	
4.6.2	Inventory Management System	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	
4.6.3	Warehouse System and Storage	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	
4.6.4	Inspection and Testing of Incoming Materials	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	
4.7 OTHER			
4.7.1	Contract Review	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	
4.7.2	Supply Chain Requirements	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	
4.7.3	Product Identification / Traceability	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	

5. Regulatory Compliance and History		
5.1	Has the company been subject to periodic audit by competent authorities e.g. MHRA, FDA, ISO inspection body etc?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
5.1.1	If 'YES' please provide details below for the past 2 years and attach supporting documents (e.g. ISO certificate, GMP certificate, EIR cover letter)	
Authority	Date	Result

## Supplier Quality Questionnaire

### Supplier Questionnaire - Section A General Info\_modified

Page 7 of 10

5.2	Regulatory Compliance (If YES is applicable, please specify the legislation the material is compliant with)	Comment
	<u>Remark:</u> If YES, please specify the legislation you are compliant to	
5.2.1	Mycotoxin (Regulation 1881/2006/EC and subsequent amendments)	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
5.2.2	Dioxin (Regulation 1881/2006/EC and subsequent amendments)	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
5.2.3	Ionisation	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
5.2.4	Pesticide Residues	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
5.2.5	Heavy Metals Specified	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
5.2.6	Polycyclic Aromatic Hydrocarbons (PAH)	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
5.2.7	Polychlorinated Biphenyls (PCBs)	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
5.2.8	Nitrate	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
5.2.9	BSE / TSE	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
5.2.10	Product Data Sheet	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
5.2.11	Safety Data Sheet	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>

6. Industry History		
6.1	Do you supply to any other customer in the Pharmaceutical / Health care industry?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
6.1.1	If 'YES', Please specify the approximate % of your business that this relates to:	
6.2	Have you been audited by any Pharmaceutical / Health care companies within the last two years?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>

## 7. Comments





<b>9. Sections completed</b>	
<b>Please, tick the boxes for the sections you have completed.</b>	
<input type="checkbox"/>	Sections A – General Company Information and Quality Management Questionnaire
<input type="checkbox"/>	Sections B – BSE/BSE Risk Analysis Survey
<input type="checkbox"/>	Sections C – GMO – Vegetable Origin
<input type="checkbox"/>	Sections D – Allergen
<input type="checkbox"/>	Sections E – Extended Quality Questionnaire for Critical Material
<input type="checkbox"/>	Sections F – Packaging Material

<b>Completion Signatures</b>	
<ul style="list-style-type: none"> <li>▪ Confirmation that enclosed information is correct and relevant to the product(s) in scope.</li> <li>▪ You will inform us in case of any changes to the product status</li> </ul>	
Site Operations Lead Representative:	
Name (Print):	
Position:	
Signature:	
Date:	
Head of Quality Assurance or representative; person who completed the questionnaire:	
Name (Print):	
Position:	
Signature:	
Date:	