A. General Information on Company, Product and Quality Management

1. Company Information

1.1 Company Address Information	
Name of company:	
Address:	
Postcode:	
Country:	
Telephone number:	
Fax number:	
Web address:	

1.2 Is the address listed above the only site for production?	Yes ☐ No ☐	**If NO, please provide details below:**
Name of company(s):		
Address:		
Postcode:		
Telephone number:		
Fax number:		

1.3 Is your company a subsidiary?	Yes ☐ No ☐	**If Yes, please provide details below:**
Name of company:		
Address:		
Postcode:		
Telephone number:		
Fax number:		

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 (Quallity 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 ☐ Ref:	N/A ☐
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 ☐ Ref:	N/A ☐
1.5.6	Does your factory operate in a shift system?	Yes ☐	No ☐
	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 ☐	No ☐
1.6.4	Do you have an annual report available?	Yes ☐	No ☐
	If yes, please enclose the annual report	Ref:	

2. Product Information

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

2.5	Additives (if applicable)				Comments
2.5.1	Additive E Numbers	Yes ☐	No ☐	N/A ☐	
2.5.1	Other additives than colours and sweeteners (Dir. 95/2/EC* and subsequent amendments.)	Yes ☐	No ☐	N/A ☐	
2.5.1	Purity criteria (Dir. 96/77/EC* and subsequent amendments.)	Yes ☐	No ☐	N/A ☐	
2.5.1	Other relevant purity criteria applicable	Yes ☐	No ☐	N/A ☐	
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 ☐	Ref:	No ☐	N/A ☐
3.2	Do you hold accreditation, certification or registration by any regulatory agency or body? If yes, please provide a copy of documentation	Yes ☐	Ref:	No ☐	N/A ☐
3.3	Are any aspects of the process / service provided subcontracted?	Yes ☐		No ☐	N/A ☐
3.3.1	If so, please provide detail:				
3.3.2	Are there Quality / Technical Agreements held with subcontractors?	Yes ☐		No ☐	N/A ☐

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 ☐ No ☐ N/A ☐	
4.1.2	Equipment & Instrument Validation / Qualification Program	Yes ☐ No ☐ N/A ☐	
4.1.3	Internal Audit / Self-Inspection Program	Yes ☐ No ☐ N/A ☐	
4.1.4	Supplier Evaluation / Qualification Program	Yes ☐ No ☐ N/A ☐	
4.1.5	Does your company operate a supplier-auditing system?	Yes ☐ No ☐ N/A ☐	
4.1.6	Training Program	Yes ☐ No ☐ N/A ☐	
4.1.7	Change Control	Yes ☐ No ☐ N/A ☐	
4.1.8	Deviation / Investigation Reporting	Yes ☐ No ☐ N/A ☐	
4.1.9	Non-Conformance Reporting	Yes ☐ No ☐ N/A ☐	
4.1.10	Documentation Control	Yes ☐ No ☐ N/A ☐	
4.1.11	Do you have a recall system/procedure in place?	Yes ☐ No ☐ N/A ☐	
4.2	**PRODUCTION / OPERATIONS SYSTEM**		
4.2.1	Environmental Monitoring Program	Yes ☐ No ☐ N/A ☐	
4.2.2	Housekeeping Program	Yes ☐ No ☐ N/A ☐	
4.2.3	Gowning / Entry & Exit Procedure	Yes ☐ No ☐ N/A ☐	
4.2.4	Availability of Master Production Instructions and Batch production Records	Yes ☐ No ☐ N/A ☐	
4.2.5	Availability of Equipment Cleaning Procedures, Cleaning Records and Cleaning Verification	Yes ☐ No ☐ N/A ☐	
4.3	**PACKAGING / LABELLING SYSTEM**		
4.3.1	Labelling of Intermediate / Final Products	Yes ☐ No ☐ N/A ☐	
4.3.2	Storage of Intermediate / Final Products	Yes ☐ No ☐ N/A ☐	
4.3.3	Product / Sample Shipping Validation Program	Yes ☐ No ☐ N/A ☐	
4.4	**FACILITIES AND EQUIPMENT SYSTEM**		
4.4.1	Pest Control Program	Yes ☐ No ☐ N/A ☐	
4.4.2	Preventive Maintenance Program	Yes ☐ No ☐ N/A ☐	
4.4.3	Calibration Program	Yes ☐ No ☐ N/A ☐	
4.4.4	Facility Cleaning / Sanitization	Yes ☐ No ☐ N/A ☐	

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

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 ☐ No ☐ N/A ☐
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***

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

6. Industry History

6.1	Do you supply to any other customer in the Pharmaceutical / Health care industry?	Yes ☐ No ☐ N/A ☐
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 ☐ No ☐ N/A ☐

7. Comments

8. References - Appendices

Please, list all references and enclosures that you make to this questionnaire and specify the reference number given to each document. Use one list for all sections of the document and extend it if needed.

Ref #	Description/Name

9. Sections completed

Please, tick the boxes for the sections you have completed.

- ☐ **Sections A – General Company Information and Quality Management Questionnaire**
- ☐ **Sections B – BSE/BSE Risk Analysis Survey**
- ☐ **Sections C – GMO – Vegetable Origin**
- ☐ **Sections D – Allergen**
- ☐ **Sections E – Extended Quality Questionnaire for Critical Material**
- ☐ **Sections F – Packaging Material**

Completion Signatures

- Confirmation that enclosed information is correct and relevant to the product(s) in scope.
- You will inform us in case of any changes to the product status

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:	