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QUALITY AGREEMENT
API SUPPLIER QUALIFICATION
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QUALITY AGREEMENT

Between

BIOPHARMA INDUSTRIES LIMITED ("Buyer")
and
[API SUPPLIER NAME] ("Supplier")

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This Quality Agreement ("Agreement") is made and entered into on this [DATE]
day of [MONTH], [YEAR]

BETWEEN

BIOPHARMA INDUSTRIES LIMITED, a company incorporated under the Companies Act,
having its registered office at Plot No. 234-235, MIDC Industrial Area,
Thane-Belapur Road, Rabale, Thane - 400701, Maharashtra, India (hereinafter
referred to as the "Buyer" or "BioPharma")

AND

[SUPPLIER NAME], a company incorporated under [JURISDICTION], having its
registered office at [ADDRESS] (hereinafter referred to as the "Supplier")

RECITALS

A. The Buyer is engaged in the manufacture of pharmaceutical formulations and is licensed under the Drugs and Cosmetics Act, 1940.

B. The Supplier is engaged in the manufacture of Active Pharmaceutical Ingredients (APIs) and excipients.

C. The Buyer wishes to purchase API/excipients from the Supplier for use in its pharmaceutical manufacturing operations.

D. The parties wish to establish quality responsibilities and communication channels to ensure the quality of supplied materials meets regulatory and pharmacopeial standards.

NOW THEREFORE, in consideration of the mutual covenants contained herein, the parties agree as follows:

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ARTICLE 1: PURPOSE AND SCOPE

1.1 PURPOSE

The purpose of this Agreement is to define the quality responsibilities of each party to ensure that materials supplied by the Supplier meet the quality requirements of the Buyer and comply with applicable regulatory standards including:

- Indian Pharmacopoeia (IP)
- United States Pharmacopeia (USP)
- British Pharmacopoeia (BP)
- European Pharmacopoeia (Ph. Eur.)
- ICH Guidelines

- Schedule M of Drugs and Cosmetics Rules (India)
- WHO-GMP requirements

1.2 SCOPE

This Agreement covers the following material(s) supplied by the Supplier:

Material Name: [API/EXCIPIENT NAME]
CAS Number: [CAS NUMBER]
Grade: [Pharmacopeial grade - IP/USP/BP/Ph.Eur.]
Intended Use: Active Pharmaceutical Ingredient for oral solid dosage forms
DMF Reference: [DMF Number, if applicable]

1.3 RELATIONSHIP TO COMMERCIAL AGREEMENT

This Quality Agreement supplements but does not supersede the commercial supply agreement between the parties. In case of conflict, the terms more favorable to product quality shall prevail.

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ARTICLE 2: REGULATORY REQUIREMENTS

2.1 SUPPLIER CERTIFICATIONS

The Supplier represents and warrants that it holds the following certifications:

(a) Drug Manufacturing License: [License Number]
(b) WHO-GMP Certificate: [Certificate Number]
(c) US FDA Registration (if applicable): FEI [Number]

(d) CEP (Certificate of Suitability) - for EU markets
(e) ISO Certification: [If applicable]

2.2 DRUG MASTER FILE (DMF)

The Supplier has filed a Drug Master File with:
- CDSCO India: DMF Number [Number]
- US FDA: DMF Number [Number]
- [Other authorities as applicable]

The Supplier authorizes the Buyer to reference the DMF for regulatory filings.

2.3 REGULATORY INSPECTIONS

The Supplier shall:
(a) Notify the Buyer of any regulatory inspection within 48 hours
(b) Provide copies of inspection reports and observations
(c) Inform the Buyer of any adverse regulatory action
(d) Permit the Buyer to accompany during inspections if requested by regulatory authorities

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ARTICLE 3: SPECIFICATIONS AND TESTING

3.1 SPECIFICATIONS

The material shall comply with the specifications set out in Annexure A.

The specifications include:
- Identity tests

- Assay limits
- Related substances / impurity profile
- Residual solvents
- Heavy metals
- Microbial limits
- Physical characteristics (particle size, bulk density, etc.)

3.2 CERTIFICATE OF ANALYSIS (CoA)

The Supplier shall provide a Certificate of Analysis with each batch:

CoA Requirements:
(a) Batch number and manufacturing date
(b) Expiry/Retest date
(c) Test results for all specification parameters
(d) Pharmacopeial reference (IP/USP/BP)
(e) Analyst signature and date
(f) QA approval signature

3.3 TESTING RESPONSIBILITIES

Testing Party	Supplier	Buyer
Identity	Yes	Yes
Assay	Yes	Yes
Related Substances	Yes	Yes
Residual Solvents	Yes	No*
Heavy Metals	Yes	No*
Microbial Limits	Yes	Yes
Physical Tests	Yes	Yes

* Buyer may test periodically or when concerns arise

3.4 REFERENCE STANDARDS

The Supplier shall use pharmacopeial reference standards or qualified working standards traceable to pharmacopeial standards.

3.5 TEST METHODS

The Supplier shall use validated analytical methods as per ICH Q2(R1). Method validation reports shall be available for audit.

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ARTICLE 4: MANUFACTURING AND PROCESS CONTROLS

4.1 MANUFACTURING SITE

The material shall be manufactured at:
[Site Name and Address]

Manufacturing shall not be transferred to another site without prior written approval from the Buyer.

4.2 GMP COMPLIANCE

The Supplier shall manufacture the material in compliance with:
(a) Current Good Manufacturing Practices (cGMP)
(b) ICH Q7 - GMP for APIs
(c) Applicable pharmacopeial requirements
(d) Supplier's registered manufacturing process

4.3 PROCESS VALIDATION

The Supplier shall:
(a) Validate all critical manufacturing processes
(b) Maintain validation status through ongoing verification
(c) Revalidate upon significant process changes
(d) Provide validation summaries upon request

4.4 CLEANING VALIDATION

The Supplier shall:
(a) Validate cleaning procedures for equipment
(b) Establish and justify residue limits
(c) Prevent cross-contamination

4.5 CHANGE CONTROL

The Supplier shall not make any of the following changes without prior written approval from the Buyer (minimum 60 days advance notice):

(a) Change in manufacturing site
(b) Change in synthesis route or process
(c) Change in critical raw material source
(d) Change in specifications
(e) Change in packaging
(f) Change in testing methods (if affecting results)
(g) Change in equipment affecting product quality

Change notification shall include impact assessment and supporting data.

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ARTICLE 5: DOCUMENTATION AND RECORDS

5.1 BATCH RECORDS

The Supplier shall:
(a) Maintain complete batch manufacturing records
(b) Retain records for minimum 1 year after expiry or 5 years from manufacture, whichever is longer
(c) Provide copies upon request (within 5 business days)

5.2 TRACEABILITY

The Supplier shall maintain traceability of:
(a) All raw materials used
(b) Manufacturing equipment
(c) Personnel involved
(d) Environmental conditions
(e) Distribution to customers

5.3 STABILITY DATA

The Supplier shall:
(a) Conduct stability studies per ICH guidelines
(b) Establish and justify shelf life / retest period
(c) Provide stability data upon request
(d) Notify of any stability failure

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ARTICLE 6: PACKAGING AND LABELING

6.1 PACKAGING REQUIREMENTS

The material shall be packaged in:

- Container: [HDPE drums / Fiber drums with PE liner]
- Closure: [Tamper-evident seal]
- Pack size: [25 kg / 50 kg]

Packaging shall protect the material from moisture, light, and contamination during storage and transportation.

6.2 LABELING REQUIREMENTS

Each container shall be labeled with:
(a) Material name and grade
(b) Batch number
(c) Manufacturing date
(d) Expiry/Retest date
(e) Net weight
(f) Storage conditions
(g) Manufacturer name and address
(h) "For pharmaceutical use" or equivalent
(i) Safety/handling precautions

6.3 SHIPPING DOCUMENTATION

Each shipment shall include:
(a) Certificate of Analysis
(b) Packing list
(c) Safety Data Sheet (SDS)
(d) Country of origin certificate (if required)

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ARTICLE 7: SUPPLIER QUALIFICATION AND AUDITS

7.1 INITIAL QUALIFICATION

Prior to first supply, the Supplier has been qualified through:
(a) Questionnaire review
(b) Document review (licenses, certificates, DMF)
(c) On-site GMP audit
(d) Sample testing and qualification

Initial Audit Date: [DATE]
Audit Outcome: [Approved / Approved with conditions]

7.2 PERIODIC AUDITS

The Buyer reserves the right to conduct periodic audits:
(a) Regular audits: Every 2-3 years
(b) For-cause audits: At any time if quality concerns arise

The Supplier shall provide reasonable access to facilities, records, and personnel during audits.

7.3 AUDIT FINDINGS AND CAPA

The Supplier shall:
(a) Respond to audit findings within 30 days
(b) Implement corrective and preventive actions
(c) Provide evidence of CAPA effectiveness

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ARTICLE 8: QUALITY ISSUES AND COMPLAINTS

8.1 NON-CONFORMING MATERIAL

If the Buyer finds material non-conforming to specifications:
(a) Buyer shall notify Supplier within 15 days of receipt
(b) Supplier shall investigate and respond within 15 days
(c) Supplier shall replace non-conforming material at no cost
(d) Supplier shall conduct root cause analysis and implement CAPA

8.2 CUSTOMER COMPLAINTS

If the Buyer receives complaints related to Supplier's material:
(a) Buyer shall notify Supplier within 5 business days
(b) Supplier shall investigate and respond within 15 days
(c) Supplier shall provide investigation report
(d) Both parties shall collaborate on CAPA if required

8.3 FIELD ALERTS AND RECALLS

If a quality issue requires field action:
(a) Supplier shall notify Buyer immediately
(b) Both parties shall cooperate in investigation
(c) Supplier shall support any recall with documentation and resources
(d) Supplier shall bear costs if recall is due to Supplier's fault

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ARTICLE 9: CONFIDENTIALITY

9.1 CONFIDENTIAL INFORMATION

Each party shall keep confidential all information received from the
other party including:
(a) Technical information and know-how

(b) Manufacturing processes
(c) Specifications and test methods
(d) Business information
(e) Regulatory filings

9.2 EXCEPTIONS

Confidentiality obligations do not apply to information:
(a) Already in public domain
(b) Required to be disclosed to regulatory authorities
(c) Required by law

9.3 SURVIVAL

Confidentiality obligations survive termination for 5 years.

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ARTICLE 10: COMMUNICATION AND CONTACTS

10.1 QUALITY CONTACTS

For BioPharma (Buyer):
Name: Mrs. Deepika Sunil Jain
Title: Head of Quality Assurance
Email: qa.head@biopharma.com
Phone: +91-22-2568-XXXX

For [Supplier]:
Name: [Name]
Title: [Title]
Email: [Email]

Phone: [Phone]

10.2 EMERGENCY CONTACTS

For urgent quality matters (recalls, safety issues):
BioPharma: +91-98XXX-XXXXX (24/7)
Supplier: [24/7 Emergency Number]

10.3 REGULAR COMMUNICATION

The parties shall hold quality review meetings:
- Frequency: Quarterly (or as needed)
- Topics: Quality metrics, complaints, changes, audits

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ARTICLE 11: TERM AND TERMINATION

11.1 TERM

This Agreement shall be effective from [DATE] and shall continue for
a period of 3 (three) years unless terminated earlier.

11.2 RENEWAL

This Agreement shall automatically renew for successive 1-year periods
unless either party provides 90 days' written notice of non-renewal.

11.3 TERMINATION FOR CAUSE

Either party may terminate this Agreement immediately if:
(a) The other party materially breaches this Agreement and fails to

cure within 30 days of notice
(b) The other party's manufacturing license is suspended or cancelled
(c) The other party becomes insolvent or bankrupt

11.4 CONSEQUENCES OF TERMINATION

Upon termination:
(a) Supplier shall complete pending orders unless otherwise agreed
(b) Confidentiality and records retention obligations survive
(c) Pending quality investigations shall be completed

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ARTICLE 12: GENERAL PROVISIONS

12.1 GOVERNING LAW

This Agreement shall be governed by the laws of India.

12.2 DISPUTE RESOLUTION

Disputes shall be resolved through good faith negotiations. If unresolved, disputes shall be subject to arbitration in Mumbai under the Arbitration and Conciliation Act, 1996.

12.3 AMENDMENT

This Agreement may only be amended by written instrument signed by both parties.

12.4 ENTIRE AGREEMENT

This Agreement, together with its Annexures, constitutes the entire agreement between the parties regarding quality matters.

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IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

FOR BIOPHARMA INDUSTRIES LIMITED:

Signature: _____
Name: Mrs. Deepika Sunil Jain
Title: Head of Quality Assurance
Date: [DATE]

Signature: _____
Name: Dr. Ramesh Narayan Kulkarni
Title: Managing Director
Date: [DATE]

FOR [SUPPLIER NAME]:

Signature: _____
Name: [Name]
Title: [Title]
Date: [DATE]

Signature: _____
Name: [Name]
Title: [Title]
Date: [DATE]

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ANNEXURE A: SPECIFICATIONS

Material: [API NAME]
Grade: [IP/USP/BP/Ph.Eur.]

Parameter	Specification	Test Method
Description	[White crystalline powder]	Visual
Identification A (IR)	Matches reference	IP/USP
Identification B (HPLC)	RT matches reference	In-house
Assay	98.0 - 102.0%	HPLC (IP/USP)
Related Substances		
- Any individual impurity	NMT 0.2%	HPLC
- Total impurities	NMT 1.0%	HPLC
Residual Solvents	Per ICH Q3C	GC
Heavy Metals	NMT 20 ppm	ICP-OES
Sulphated Ash	NMT 0.1%	IP/USP
Loss on Drying	NMT 0.5%	IP/USP
Microbial Limits		
- TAMC	NMT 1000 CFU/g	IP/USP
- TYMC	NMT 100 CFU/g	IP/USP
- E. coli	Absent/g	IP/USP
- Salmonella	Absent/10g	IP/USP
Particle Size (D90)	NMT 100 microns	Laser diffraction

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ANNEXURE B: LIST OF CRITICAL RAW MATERIALS

[List of starting materials and key intermediates for the API]

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ANNEXURE C: APPROVED SUBCONTRACTORS

[List of approved contract testing labs, packaging vendors, etc.]

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END OF QUALITY AGREEMENT
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