



Site Quality Self-Assessment

based on

Rx-360 Supplier Assessment Questionnaire Module 2, Site Specific Information

Relevant for

Merck Life Science Technologies (Nantong) Co., Ltd
No.39, Jianggang Road, NETDA, Nantong, Jiangsu,
P.R. China

An affiliate of Merck KGaA, Darmstadt, Germany

The site self-assessment covers our quality management system for the following regulated applications:

- Manufacturing of pharma raw materials (Excipients, APIs) and food additives: summarized as PIS (Production Inorganic Salts)

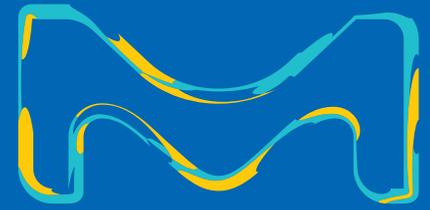
The site also processes products which do not fall under any of the above mentioned regulated areas. For these products, other quality standards apply. For details, please refer to Cell Culture Media (CCM) and Ready to use media (RTU) Site Self-Assessment.



As a trusted partner of our customers, we deliver quality
- always.

Merck KGaA
Corporation with General Partners
Frankfurter Str. 250
64293 Darmstadt, Germany

The life science business of Merck KGaA,
Darmstadt, Germany operates as
MilliporeSigma in the U.S. and Canada.



Information

This document is based on the Rx-360 Consortium's Supplier Assessment Questionnaire template, Module 2. The contents of this questionnaire are built on the Rx-360 questionnaire version 2.0 intact with no question added or deleted.

Rx-360's CEO/COO gave permission to Life Science to use the Rx-360 logo.



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Please check here if additional documents are attached.

SECTION 1. General Site Information

1.1	Site or Facility-Specific Name: Merck Life Science Technologies (Nantong) Co., Ltd An affiliate of Merck KGaA, Darmstadt, Germany
1.2	Address: No.39, Jianggang Road, NETDA, Nantong, Jiangsu, P.R. China GPS Coordinates: 31°50'36.79"N, 120°58'7.56"E
1.3	Phone: +86 513-69917000
1.4	Email: Please refer to your local Sales representative
1.5	Fax: +86 513-69917200
1.6	Website: http://www.emdmillipore.com

SECTION 2. General Site Operating Information

2.1	What year did the site start operating? 2020
2.2	What is the primary activity of the site? (e.g. manufacturing, distribution, etc.) Manufacturing of PIS(Inorganic Salt)products Manufacturing of CCM (Cell Culture Media) products- see CCM site Self-Assessment Manufacturing of RTU(Ready to Use Media) products- see RTU site Self-Assessment
2.3	To which, if any, subdivision of the parent company does the site belong? Life Science is a business of Merck KGaA, Darmstadt, Germany
2.4	Size of site (in sq. ft. or m.): 44,414 square meters
2.5	Please list or attach the normal hours/schedule of the facilities, including shutdown dates (if applicable): 5 days a week, 2 shifts, 12h per shift, shutdown date during public holiday
2.6	Total number of employees on site: 236
2.7	Total number of employees in Quality: 44
2.8	Total number of employees in Manufacturing: 62

2.9	<p>What quality management system is utilized on site?</p> <p><input checked="" type="checkbox"/> ISO 9001 <input type="checkbox"/> ISO 13485 <input type="checkbox"/> 21 CFR Part 210/211 <input type="checkbox"/> 21 CFR Part 820 <input type="checkbox"/> European GMP, Eudralex Volume 4 Part I <input type="checkbox"/> European GMP, Eudralex Volume 4 Part II <input checked="" type="checkbox"/> ICH Q7 <input checked="" type="checkbox"/> HACCP <input type="checkbox"/> ISO 22000 <input checked="" type="checkbox"/> Other</p> <p>Please describe: IPEC-PQG Joint GMP Guide for Pharmaceutical Excipients</p> <p>Which Regulatory initiatives does the site follow/comply with?</p> <p><input type="checkbox"/> REACH <input type="checkbox"/> RoHs <input type="checkbox"/> Ca Prop. 65 <input type="checkbox"/> WEEE</p>																														
2.10	<p>Does the company/site have an export license? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p>																														
2.11	<p>Is the site registered with any government regulatory agency (FDA registration, GMP certification, etc.)? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p> <p>If yes, please specify. Drug Manufacturing License for Active Pharmaceutical Ingredients (API) Drug Manufacturing License for Food Additive FDA registration</p>																														
2.12	<p>By whom is the site inspected (regulatory or third party) and list inspections within the last three years:</p> <table border="0"> <tr> <td>DQS: ISO 9001:2015</td> <td>2021.09.01 - 2021.09.03</td> <td></td> </tr> <tr> <td>EXCiPACT (SGS)</td> <td>2024.05.06-2024.05.08</td> <td></td> </tr> <tr> <td>RX 360</td> <td>2024.01.22-2024.01.23</td> <td></td> </tr> <tr> <td>Drug manafacuring license</td> <td>2020.11.20</td> <td></td> </tr> <tr> <td>Indonesia Halal</td> <td>2022.09.05</td> <td></td> </tr> <tr> <td>Malaysia Halal</td> <td>2023.05.18</td> <td></td> </tr> <tr> <td>OU Kosher</td> <td>2021.09.23</td> <td></td> </tr> <tr> <td>Written confirmation for Sodium acetate trihydrate</td> <td></td> <td>2021.12.22-2021.12.24</td> </tr> <tr> <td>Written confirmation for Zinc Chloride</td> <td></td> <td>2022.11.08-2022.11.10</td> </tr> <tr> <td>FDA Inspection</td> <td>2023.10.23-2023.10.27</td> <td></td> </tr> </table>	DQS: ISO 9001:2015	2021.09.01 - 2021.09.03		EXCiPACT (SGS)	2024.05.06-2024.05.08		RX 360	2024.01.22-2024.01.23		Drug manafacuring license	2020.11.20		Indonesia Halal	2022.09.05		Malaysia Halal	2023.05.18		OU Kosher	2021.09.23		Written confirmation for Sodium acetate trihydrate		2021.12.22-2021.12.24	Written confirmation for Zinc Chloride		2022.11.08-2022.11.10	FDA Inspection	2023.10.23-2023.10.27	
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2.13	<p>How often, as an annual average, is the site audited by customers or third parties? 40</p>																														
2.14	<p>Has an Rx-360 audit been performed at this site? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Please also state the date of the audit if applicable. 2024.01.22-2024.01.23</p> <p>Learn more about the Rx-360 Joint Audit Program@ here.</p>																														
2.15	<p>Are you willing to have Rx-360 conduct an audit on behalf of your customers according to the Rx-360 audit programs on your site? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>																														

2.16	Are you willing to have your customers conduct audits on your site? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
2.17	Please list regulatory sanctions impacting the site within the last five years (i.e. warning letters, CEP suspension, import alerts, etc.): None
2.18	Does the site outsource any quality-related activity? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A If answering yes, please specify the activities: NA
2.19	Please check the supplier controls in place for this facility:
2.19a	Quality Agreements with Suppliers <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.19b	Subcontractor Qualification/Audit Program <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
2.19c	Periodic Review of Supplier Performance <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.19d	Supplier Feedback Program <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.19e	Approved Material Supplier List <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.19f	Approved Service Supplier List <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

Additional comments:

The service supplier list combines material supplier list together.

SECTION 3. Objectionable Materials On Site

3.1	Does the site or production plant produce, process or store any of the following?	Yes	No	Not Applicable
3.1a	Beta-Lactam Antibiotics	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1b	Steroids and/or hormones	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1c	High potency compounds	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1d	Materials of animal origin/Biologics	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1e	Live virus or micro-organism	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1f	Allergens	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1g	Genetically Modified Organisms (GMO)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1h	Agrochemicals (Pesticides, Herbicides, Fungicides, etc.)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3.1i	Other (Please specify): 3.1h The sporicide is used in production area cleaning
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SECTION 4. Cross-Contamination Control

4.1	Are any of the following cross-contamination controls in place?	Yes	No	Not Applicable
4.1a	Dedicated Facilities	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4.1b	Access Controls	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1c	Dedicated Personnel	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1d	Dedicated Gowning	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1e	Procedural Controls	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1f	Other (Please specify): NA			

Additional Comments:

NA

SECTION 5. Site Operating Policies

5.1	Does the site utilize the following written policies, programs or procedures?	Yes	No	Not Applicable
Site Specific:				
5.1a	Environmental, Health and Safety	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1b	Facility Environmental Control Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1c	General Facility Cleaning Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1d	Hygiene and Sterilization Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1e	Validated Equipment Cleaning Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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5.1f	Preventative Maintenance Program/Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1g	Pest Control Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1h	Master Production Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Quality:				
5.1i	Quality Control/Quality Management Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1j	Quality Manual	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1k	Periodic Product Quality Review	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1l	Master Validation Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1m	Risk Assessment Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1n	Supplier Approval Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1o	Monitoring and Review of Approved Suppliers	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1p	Mechanism to Reduce Testing	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5.1q	Receiving Incoming Inspection	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1r	Change Control Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1s	Document Management Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1t	Document Retention Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1u	Change Notification Procedures for Clients	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1v	Control of Nonconforming Material	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1w	Deviation/Investigation Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1x	Out of Specification Policy and Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1y	Sampling Procedure/Sampling Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1z	Raw Material Retention Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1aa	CAPA Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1bb	Label Control and Accountability	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1cc	Product Release Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1dd	Employee Training Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ee	Stability, Expiration, and Shelf-Life Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ff	Product Retention Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1gg	Recall Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1hh	Customer Complaint Handling	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ii	Equipment validation/qualification procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1jj	Internal audit/self-inspection program procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1kk	Site Security/Site Access Control Policies	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ll	New Hire Program/Induction Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Business Continuity/Contingency Plan:				
5.1mm	Disaster Recovery Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5.1nn	Pandemic Preparedness Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1oo	Supply Chain Emergency Preparedness Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1pp	Business Continuity/Contingency Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1qq	Can the company provide a plan upon request? OR provide a short description below: Can be requested during site audit			

SECTION 6. Quality Assurance and Production

		Yes	No	Not Applicable
6.1	Does the site have an independent and defined Quality Assurance/Quality Management Division?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.2	Does QA/QM have authority over the following:			
6.2a	Policies and procedures?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.2b	Review of documentation for release?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.2c	Release or rejection of incoming materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.3	Does QA/QM investigate and resolve quality complaints?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.4	Does QA/QM investigate and resolve internal deviations?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.5	Does QA/QM have the authority to assign a disposition to materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.6	Does QA/QM review manufacturing and testing records prior to release?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.7	Does the facility utilize computerized systems for managing GxP activities and data?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.8	Are relevant computerized systems 21 CFR part 11 and EU GMP annex 11 compliant?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.9	Does the site use statistical methods for consistency and uniformity?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.10	Does the site use controlled documents for following and recording manufacturing instructions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.11	Does the company qualify and/or validate manufacturing procedures?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.12	Is any environmental monitoring conducted in production/finishing areas?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.13	Does the site supply BSE/TSE declarations?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.14	Does the site supply a declaration of Elemental Impurities?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.15	Are ICH Q3C solvents used in the manufacturing process of supplied materials?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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6.15a	If Yes, what class of solvent is used? NA			
6.16	Are stability studies carried our according to ICH guidance?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.17	Are solvents and mother liquor reused/recycled?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.18	Does the site have a process water treatment system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.18a	Please check all that apply to the system: <input checked="" type="checkbox"/> City/potable water <input type="checkbox"/> Distilled water <input type="checkbox"/> Dionized water <input type="checkbox"/> Water for injection (WFI) <input checked="" type="checkbox"/> Reverse Osmosis <input checked="" type="checkbox"/> Clean steam <input checked="" type="checkbox"/> Ultra-filtrated water (purified water) <input type="checkbox"/> Other:			
6.19	Does the plant have a batch/lot system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.19a	Is the system traceable?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.19b	Is it unique?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.19c	Is batch/lot manufacturing continuous?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.19d	Is manufacturing batch by batch?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.20	Does the site perform on-plant audits prior to approving critical GxP suppliers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.21	Does the site audit critical GxP suppliers after initial approval?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.22	Does the site inspect incoming materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.23	Does the site test incoming materials to defined specifications?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.24	Does the site establish purchase specifications for raw materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.25	Is the equipment multi-use?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.26	Does the site qualify equipment installation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.27	Does the site qualify equipment operation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.28	Does the site qualify equipment performance?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.29	Are production critical use instruments calibrated regularly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.30	Is rework allowed?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.31	Is reprocessing allowed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.32	Are manufacturing and packaging activities traceable to the equipment, areas, and materials used?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.33	Are production materials handled and stored in a manner to prevent degradation, contamination and cross-contamination?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.34	If answering 'not applicable' for any of the above, please elaborate: NA			

Additional Comments:

NA

SECTION 7. Laboratory Procedures		<input type="checkbox"/> N/A for this Site		
		Yes	No	Not Applicable
7.1	Does the site have standard procedures for sample handling/tracking?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1a	Does the site have standard procedures for retaining samples?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1b	Does the site have standard procedures for retesting samples?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2	Does the site have written and approved specifications and test methods?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.3	Are laboratory instruments calibrated regularly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.4	Is there a standard procedure in place for analytical method development?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.5	Does the site qualify and/or validate analytical test procedures?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.6	Does the site perform stability testing on materials and/or products?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.7	Are retention samples of key raw materials maintained?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.8	Are standards traceable to their preparation and reagents used?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.9	Are retention samples of finished products maintained?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.10	Are shelf life/retest/expiration dates available and standardized?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.11	Does the company provide a certificate of analysis (CoA) and/or a Certificate of Conformation/Compliance (CoC) for each lot or batch?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.12	Does the CoA/CoC contain the manufacture name and location?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.13	Is the CoA/CoC signed/e-signed by a Quality representative?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7.14	If a repacker performs analyses, will the CoA reflect both the original manufacturing site data as well as the repacking site data?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.15	If answering 'not applicable' for any of the above, please elaborate: 7.4 no analytical method development activities in site 7.14 Products are manufactured, tested, released, packed and labelled at Nantong site and not repacked externally.			

Additional Comments:

7.11:CoC is not applicable and not available

SECTION 8. Packaging, Storage and Transport		<input type="checkbox"/> N/A for this Site		
		Yes	No	Not Applicable
8.1	Does the site have a validated or qualified labeling system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.2	Are batch production records retained and available?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.3	Are packaging and labeling areas separate from production?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.4	Are barcode readers in use and challenged regularly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.5	Are vision systems in use?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.6	Is product ever packaged without a label being initially applied (i.e. bright stocking)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.7	Do labels include shelf life/expiration dates?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.8	Do labels include lot/batch number?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.9	Do labels include requirements for storage conditions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.10	Is tamper evident seal used for each container of supplied materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.11	Does the company use a First-In-First-Out or First-Expiration-First-Out system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.12	Does the company maintain appropriate storage conditions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8.12a	Are those storage conditions monitored and documented?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.13	Does the site make available a description of storage and/or warehouse conditions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.14	Does the site distribute products via a third party?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.15	Are good distribution policies implemented?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.16	Are transport mechanisms dedicated?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.17	Does the company validate shipping method?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.18	Does the company validate packaging methods?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Additional Comments:

8.4 Barcode was used in site. but challenge test not performed, due to this function was validated in system validation.

I (Supplier) confirm that the information provided in this questionnaire is correct and can be verified.

Title: Quality Manager

Date: 23rd September 2024

Additional Site-Specific Information

(not based on Rx 360 Supplier Assessment Questionnaire)

9. Additional information for cleanrooms		Yes	No
9.1	Are different cleanliness classes installed in the manufacturing-and Laboratory building/area installed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.2	Are the different cleaning classes zones monitored according to SOPs?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.2.1	Are maximum airborne particles defined for the different Cleanliness classes in release and operation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.2.2	Are maximum levels of Airborne Microbe defined for the different Cleanliness classes?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.2.3	Are maximum settling Microbe levels defined for the different Cleanliness classes?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.2.4	Are maximum surface Microbe monitoring defined for the different Cleanliness classes?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.3	Is there a monitoring frequency for the cleaning class zones defined in SOPs?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

10. Warehousing		Yes	No
10.1	Are warehouse rooms with different temperature conditions in place?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
10.2	Is the temperature monitored	<input checked="" type="checkbox"/>	<input type="checkbox"/>
10.2.1	What kind of storage temperatures are in place?		
	For the storage on general conditions?	15~25°C	
	For cool storage?	2~8°C	
10.3.	Are dangerous goods stored separately	<input checked="" type="checkbox"/>	<input type="checkbox"/>
10.3.1	Describe dangerous goods storage Different rooms for alkali materials, for precursor chemicals, for explosive chemicals, for metallic materials, for Toxic material(Cl2)		

11. Lot Numbering Information

Example lot number	1234567890
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1234567890: Processing 10 digits number generated automatically by ERP System, unique per batch.

12. Batch homogeneity

Homogeneity of pharmaceutical grade material is a GMP requirement. Our materials are homogeneous within the specified parameters. In compliance with applicable guidelines, the following definition of homogeneity for release of such materials is applicable:

A lot is defined as a product volume produced during a fixed period of time or a quantity dependent upon the equipment used, respectively.

Batch homogeneity test has been performed during process validation.