

### JCM Validation Report Form

#### A. Summary of validation

##### A.1. General Information

Title of the project	Energy Saving by Introducing High Efficiency Autoclave to Infusion Manufacturing Factory
Reference number	ID029
Third-party entity (TPE)	PT Mutuagung Lestari (TPE-ID-011)
Project participant contracting the TPE	PT. Otsuka Indonesia
Date of completion of this report	14 March 2022

##### A.2 Conclusion of validation

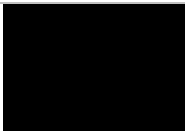
Overall validation opinion	<input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative
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##### A.3. Overview of final validation conclusion

*Only when all of the checkboxes are checked, overall validation opinion is positive.*

Item	Validation requirements	No CAR or CL remaining
Project design document form	The TPE determines whether the PDD was completed using the latest version of the PDD forms appropriate to the type of project and drafted in line with the Guidelines for Developing the Joint Crediting Mechanism (JCM) Project Design Document, Monitoring Plan and Monitoring Report.	<input checked="" type="checkbox"/>
Project description	The description of the proposed JCM project in the PDD is accurate, complete, and provides comprehension of the proposed JCM project.	<input checked="" type="checkbox"/>
Application of approved JCM methodology (ies)	The project is eligible for applying applied methodology and that the applied version is valid at the time of submission of the proposed JCM project for validation.	<input checked="" type="checkbox"/>
Emission sources and calculation of emission reductions	All relevant GHG emission sources covered in the methodology are addressed for the purpose of calculating project emissions and reference emissions for the proposed JCM project.	<input checked="" type="checkbox"/>
	The values for project specific parameters to be fixed <i>ex ante</i> listed in the Monitoring Plan Sheet are appropriate, if applicable.	<input checked="" type="checkbox"/>
Environmental impact assessment	The project participants conducted an environmental impact assessment, if required by the Republic of Indonesia, in line with Indonesia's procedures.	<input checked="" type="checkbox"/>
Local stakeholder consultation	The project participants have completed a local stakeholder consultation process and that due steps were taken to engage stakeholders and solicit comments for the proposed project unless a local stakeholder consultation has been conducted	<input checked="" type="checkbox"/>

Item	Validation requirements	No CAR or CL remaining
	under an environmental impact assessment.	
Monitoring	The description of the Monitoring Plan (Monitoring Plan Sheet and Monitoring Structure Sheet) is based on the approved methodology and/or Guidelines for Developing the Joint Crediting Mechanism (JCM) Project Design Document, Monitoring Plan, and Monitoring Report. The monitoring points for measurement are appropriate, as well as whether the types of equipment to be installed are appropriate if necessary.	<input checked="" type="checkbox"/>
Public inputs	All inputs on the PDD of the proposed JCM project submitted in line with the Project Cycle Procedure are taken into due account by the project participants.	<input checked="" type="checkbox"/>
Modalities of communications	The corporate identity of all project participants and a focal point, as well as the personal identities, including specimen signatures and employment status, of their authorized signatories are included in the MoC.	<input checked="" type="checkbox"/>
	The MoC has been correctly completed and duly authorized.	<input checked="" type="checkbox"/>
Avoidance of double registration	The proposed JCM project is not registered under other international climate mitigation mechanisms.	<input checked="" type="checkbox"/>
Start of operation	The start of the operating date of the proposed JCM project does not predate January 1, 2013.	<input checked="" type="checkbox"/>

Authorised signatory:	Mr. <input type="checkbox"/> Ms. <input checked="" type="checkbox"/>
Last name: Mitikauji	First name: Yuniar
Title: Manager Operational	
Specimen signature: 	Date: 16/03/2022

## B. Validation team and other experts

	Name	Company	Function*	Scheme competence*	Technical competence*	On-site visit
Mr. <input checked="" type="checkbox"/> Ms. <input type="checkbox"/>	Dwi Kus Pardianto	PT Mutuagung Lestari	Validator	<input checked="" type="checkbox"/>		<input type="checkbox"/>
Mr. <input checked="" type="checkbox"/> Ms. <input type="checkbox"/>	Irhan Febijanto	PT Mutuagung Lestari	Technical Expert	<input checked="" type="checkbox"/>	Authorized	<input type="checkbox"/>
Mr. <input type="checkbox"/> Ms. <input checked="" type="checkbox"/>	Yuniar Mitikauji	PT Mutuagung Lestari	Internal Reviewer	<input checked="" type="checkbox"/>		<input type="checkbox"/>
Mr. <input type="checkbox"/> Ms. <input type="checkbox"/>				<input type="checkbox"/>		<input type="checkbox"/>

Please specify the following for each item.

- \* *Function: Indicate the role of the personnel in the validation activity such as team leader, team member, technical expert, or internal reviewer.*
- \* *Scheme competence: Check the boxes if the personnel have sufficient knowledge on the JCM.*
- \* *Technical competence: Indicate if the personnel have sufficient technical competence related to the project under validation.*

## C. Means of validation, findings, and conclusion based on reporting requirements

### C.1. Project design document form

#### <Means of validation>

The Project Design Document (PDD) form used by Project Participants (PPs) through desk review was checked and confirmed as complete using the latest version of the PDD form, JCM\_ID\_F\_PDD\_ver02.0 and in accordance with the JCM Guidelines for Developing Project Design Document and Monitoring Report (JCM\_ID\_GL\_PDD\_MR\_ver03.0). The first version 1.0 of PDD dated 22/February/2022 was used for validation activity.

#### <Findings>

*Please state if CARs, CLs, or FARs are raised, and how they are resolved.*

No issue was raised to the requirement.

#### <Conclusion based on reporting requirements>

*Please state conclusion based on reporting requirements.*

The validators conclude that the PDD was completed and in line with the latest version of the PDD form and JCM Guidelines for Developing Project Design Document and Monitoring Report.

## C.2. Project description

**<Means of validation>**

The proposed JCM project aims to reduce emissions of greenhouse gas (GHG) by introducing a new type of high efficiency autoclave and a waste hot water recovery system in the Infusion Manufacturing Factory of PT. Otsuka Indonesia.

The installation of waste hot water recovery system to an IMP line reduces the amount of steam supplied by a boiler for heating water. It leads to reduction of fuel consumed by the boiler for generating steam, which consequently leads to GHG emission reductions.

The expected emission reductions that would be achieved by the proposed JCM project in its operation are estimated to be 207 tCO<sub>2</sub>e annually. The emission reductions of period from 2019 through 2027 are estimated to be 1,823 tCO<sub>2</sub>e in the PDD. The expected operational lifetime of the project is 8 years, which is based on the legal durable years for the manufacturing facilities of electronic parts, device and/or circuit issued by Ministry of Finance, Japan.

The validation are not conduct on-site assessment. However, the validation was conducted through interview by web conference and document review to validate the requirements about accuracy and completeness of the project description.

Regarding the coordinates of the project site in A.3, the validator raised CL-01 and these issue was resolved as explained in "Findings".

**<Findings>**

*Please state if CARs, CLs, or FARs are raised, and how they are resolved.*

**<CL-01>**

PPs are requested to provide more precise coordinates of the project site in A.3 of the project design document (PDD).

**<Comments from the PPs>**

Revise the PDD A.3. with more precise coordinate of machines location.

**<Assessment by the TPE>**

It is confirmed through the review of the revised PDD that the coordinates of the project site are correctly provided in section A.3 of the revised PDD. Thus, CL-01 is closed.

**<Conclusion based on reporting requirements>**

*Please state conclusion based on reporting requirements.*

The validator concludes that the description of the proposed project in the PDD complies with the supporting documents and information obtained through the desk review and the interview with the PPs, and the information description is complete and accurate.

### C.3. Application of approved methodology(ies)

#### **<Means of validation>**

The proposed project was used approved methodology ID\_AM028 "Energy saving by introducing waste hot water recovery system to autoclave in infusion manufacturing process line Ver 01.0" JCM\_ID\_AM028\_ver01.0 sectoral scope: 03. The methodology was approved by the Joint Committee on 17 February 2021 as an initial approval.

The validator was checked project applicability against one eligibility criteria as mentioned in the approved methodology. The project information for eligibility criterion and the conclusion about its applicability to the proposed project are summarized as follow:

Criterion 1: Waste hot water recovery system is newly installed to an autoclave(s) in an infusion manufacturing process line (IMP line). Based on interview with relevant persons through teleconference the machine namely Water shower sterilizer and a waste hot water recovery system. The manufacture is Shandong Xinhua Medical Instrument Co., LTD. Machine type PSMDP-DC-6 which replacing previous machine type PSMD6240.

#### **<Findings>**

*Please state if CARs, CLs, or FARs are raised, and how they are resolved.*

No issue was raised to the requirement.

#### **<Conclusion based on reporting requirements>**

*Please state conclusion based on reporting requirements.*

The validator concludes that the proposed project is eligible for applying the valid version of the approved methodologies JCM\_ID\_AM028\_ver01.0 and all eligibility criteria have been met by the proposed project.

### C.4. Emission sources and calculation of emission reductions

#### **<Means of validation>**

The proposed project aims to reduce emissions carbon dioxide by introducing new type of high efficiency autoclave and a waste hot water recovery system in the infusion manufacturing factory of PT Otsuka Indonesia.

Reference emissions (REs) are sourced from fuel consumption by reference boiler and project emissions (PEs) are sourced from electricity consumption by recovery pump to recover waste hot water system.

Reference emissions are calculated based on: the quantity of steam supplied to the heat exchanger; the ratio of heat quantity required under the project condition and the reference condition; the ratio of temperature difference under the project condition and the reference condition; fuel consumption by the boiler; net calorific value of fuel consumed by the boiler; total quantity of steam generated by the boiler supplying steam to the heat exchanger in the project IMP line; CO2 emission factor for fuel consumed by boiler to supply steam to the heat exchanger in the project IMP line.

It is confirmed through the review of relevant documents, interview by web conference, and tracing data activity and reperforming by the PPs that all GHG emission sources specified by the applied methodologies are identified, and the reference emissions, project emissions and emission reductions in the PDD and Monitoring Plan Sheet are correctly calculated, in accordance with the approved methodologies

Regarding the identification of emission source, the validator raised CAR-01 for the identification emission source in the PDD and these issue was resolved as explained in "Findings".

#### **<Findings>**

*Please state if CARs, CLs, or FARs are raised, and how they are resolved.*

#### **<CAR-01>**

CO2 emission source from fuel consumption by the reference boiler and electricity consumption by recovery pump to recover waste hot water at factory in PT Otsuka Indonesia is not appropriately illustrated in C.2 of PDD

#### **<Comments from the PPs>**

Revise the PDD C.2. by adding CO2 emission sources.

#### **<Assessment by the TPE>**

It is confirmed through the review of the revised PDD that CO2 emission from the fuel consumption and electricity is appropriately added in C.2 of the PDD. Thus. CAR-01 is closed.

#### **<Conclusion based on reporting requirements>**

*Please state conclusion based on reporting requirements.*

The validator concludes that the project information and description is complete.

#### C.5. Environmental impact assessment

##### **<Means of validation>**

The purpose of the proposed project is to reduce carbon dioxide emission through the installation of new type of high efficiency autoclave and a waste hot water recovery system. The PDD states that an environmental impact assessment (EIA) related the project activity is not required. Hence, there is no stipulation which requires EIA for the implementation of autoclave and a waste hot water recovery system.

##### **<Findings>**

*Please state if CARs, CLs, or FARs are raised, and how they are resolved.*

No issue was raised to the requirement.

##### **<Conclusion based on reporting requirements>**

*Please state conclusion based on reporting requirements.*

The validator through assessing the relevant documents conclude that the proposed project does not require the EIA for the implementation JCM project.

#### C.6. Local stakeholder consultation

##### **<Means of validation>**

The PPs conducted a local stakeholder consultation by web conference on September 17, 2021.

The participants (local stakeholder) invited by PPs as follow:

- Ministry of industry, Republic Indonesia
- Ministry of Energy and Mineral Resources, Republic Indonesia
- Indonesia JCM Secretariat
- Center of Farming Research - Batu
- PT Jaya Obayashi
- PT Taikisha Indonesia Engineering
- PT Widatra Bhakti

The participants from PPs are PT Otsuka Indonesia and Otsuka Pharmaceutical Factory, Inc.

There is no negative issue that require action to be taken by the PPs. It is confirmed through the review of the relevant documents and the interview with the PPs during the web conference assessment that the stakeholder consultation process was appropriately conducted to collect

stakeholder's opinion

**<Findings>**

*Please state if CARs, CLs, or FARs are raised, and how they are resolved.*

No issue was raised to the requirement.

**<Conclusion based on reporting requirements>**

*Please state conclusion based on reporting requirements.*

The validator concludes that the PPs have appropriately completed a local stakeholder consultation process and invited comments from the stakeholders relevant to the project. The minutes of meeting of the comments received is provided in the PDD in a complete manner.

**C.7. Monitoring**

**<Means of validation>**

The monitoring plan consist of the Monitoring Plan Sheet (MPS) and Monitoring Structure Sheet (MSS) provided by the methodology. There are six monitoring parameter, i.e

1. Total number of batch processess
2. Total number of hot water drainage from the project IMP line
3. Total quantity of steam supplied to the heat exchanger
4. Total quantity of steam generated by the boiler supplying steam to the hear exchanger in the project IMP line
5. Fuel consupion by the boiler supplying steam to the heat exchanger in the project IMP line
6. Electricity consumption of the recovery pump for the project waste hot water recovery system.

Through reperforming activity by web conference, data for monitoring was collected and input from measuring equipments in each monitoring points by responsible personnel. Review and approval the data monitoring by personnel following the MSS to make sure the data was correct and accurate. The roles and responsibilities of the personnel are described in the MSS showing that Plant Director, Engineering Dept. Manager, Engineering Dept. Section Chief, and Production 2 manager. They are compile the measured data and prepare a monitoring report.

By document review and interview with relevant personnels, the monitoring plan complies with the requirements of the approved methodology and the PPs are able to implement the monitoring activity appropriately according to the monitoring plan.

Regarding data management and monitoring frequency, the validator raised CL-02 and CL-03

and these issued were resolved as explained in "Findings".

**<Findings>**

*Please state if CARs, CLs, or FARs are raised, and how they are resolved.*

**<CL-02>**

The description on the archiving of data management and QA/QC is not provide in section (h) Measurement methods and procedures in Table 1 of the MPS.

**<Comments from the PPs>**

Revise the MPS Table 1 section (h) by adding archiving data plan.

**<Assessment by the TPE>**

It is confirmed through the reviewd of the revised MPS that the description on the archiving of data is appropriately provided in section (h) with description a record will achive electronically for 8 years since issuance of the credits. Thus, CL-02 is closed.

**<CL-03>**

PPs are requested to provide more measurable description on monitoring frequency in section (i) Monitoring frequency in Table 1 of the MPS.

**<Comments from the PPs>**

Revise the MPS Table 1 section (i) by adding more measurable time frame.

**<Assessment by the TPE>**

It is confirmed through the review of the revised MPS that the monitoring frequency is more measureable. Thus, CL-03 is closed

**<Conclusion based on reporting requirements>**

*Please state conclusion based on reporting requirements.*

The validator concludes that the description of monitoring plan is based on the approved methodology and JCM Guidelines for developing project design document and monitoring report, and the monitoring point as well as monitoring equipment for measurement are also appropriate.

**C.8. Modalities of Communication**

**<Means of validation>**

The MoC was provided to TPE and it was used valid form JCM\_ID\_F\_MoC\_ver01.0. The focal point entity is Otsuka Pharmaceutical Factory, Inc and project participants entity is PT Otsuka Indonesia. The MoC was signed by the authorized representative of focal point and PPs.

Through web conference assessment and interview with PPs. It is confirmed that all information in the MoC is correctly completed and duly authorized. Moreover, all corporate and personal details described in the MoC are valid and accurate.

**<Findings>**

*Please state if CARs, CLs, or FARs are raised, and how they are resolved.*

No issue was raised to the requirement.

**<Conclusion based on reporting requirements>**

*Please state conclusion based on reporting requirements.*

The validator concludes that the MoC complies with all relevant forms and requirements. The information and the specimen signature of the PPs provided in the MoC are correct and sufficient.

**C.9. Avoidance of double registration**

**<Means of validation>**

The representative of focal point entity in the MoC, Senior Manager Otsuka Pharmaceutical Factory, Inc. declares that the proposed project is not registered under any other international climate mitigation mechanism other than the JCM. It is confirmed through the check of publicly available information that the proposed project is not registered under any other international greenhouse gases (GHG) program in terms of the name of entity, applied technology, and location. Therefore, it can be concluded that the proposed project will not result in double counting of GHG emission reduction.

**<Findings>**

*Please state if CARs, CLs, or FARs are raised, and how they are resolved.*

No issue was raised to the requirement.

**<Conclusion based on reporting requirements>**

*Please state conclusion based on reporting requirements.*

The validator concludes that the proposed project was not registered under any other international GHG program and will not result in double counting of GHG emission reduction.

## C.10. Start of operation

**<Means of validation>**

The installation of autoclave and a waste hot water system were completed at the project site start from November 10, 2018 until Desember 23, 2018.

By reviewing the relevant documents and interview with PPs, the project operation start from March 13, 2019 as mentioned in the PDD.

**<Findings>**

*Please state if CARs, CLs, or FARs are raised, and how they are resolved.*

No issue was raised to the requirement.

**<Conclusion based on reporting requirements>**

*Please state conclusion based on reporting requirements.*

The validator concludes that the starating date is March 13, 2019, which does not predate January 1, 2013.

## C.11. Other issues

**<Means of validation>**

No more issued are raised in the validation of the project

**<Findings>**

*Please state if CARs, CLs, or FARs are raised, and how they are resolved.*

Not applicable

**<Conclusion based on reporting requirements>**

*Please state conclusion based on reporting requirements.*

Not applicable

**D. Information on public inputs**

## D.1. Summary of public inputs

In line with the JCM Project Cycle Procedure, the PDD was made publicly available for 30 days from December 24, 2021 to January 22, 2022 to invte public comments on the following JCM website <https://www.jcm.go.jp/id-jp/projects/99>

As a results, no public comments were received.

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#### D.2. Summary of how inputs received have been taken into account by the project participants

Not applicable.

### E. List of interviewees and documents received

#### E.1. List of interviewees

- Tatik Istiqamah (Plant Director, PT. Otsuka Indonesia)
- Emoto Yasutaka (Deputy Plant Director, PT. Otsuka Indonesia)
- M. Faizal Akbar (Head of Non Parenteral Prod. Dept., PT. Otsuka Indonesia)
- Mohammad (Utility Section, PT. Otsuka Indonesia)

#### E.2. List of documents received

1. PDD first version 22/02/2022
2. PDD second version 27/02/2022
3. JCM Modalities of Communication Statement Form (JCM\_ID\_F\_MoC\_ver01.0)
4. JCM approved Methodology ID\_AM028 (JCM\_ID\_AM028\_ver01.0)
5. Monitoring Spreadsheet (MPS and MSS) JCM\_ID\_AM028\_ver01.0
6. JCM Sustainable Development Implementation Plan Form (JCM\_ID\_F\_SDIP\_ver01.0)
7. Specification of machine water shower sterilizer type PSMDP-DC-6
8. Test certificate autoclave
9. Company profile of PT. Otsuka Indonesia
10. Layout of monitoring equipments
11. Specification of the steam flowmeter
12. Presentation file for local stakeholder consultation.
13. Participants list of local stakeholder consultation
14. Minutes of meeting local stakeholder consultation
15. Training record
16. SOP Process sterilization product 121 15 minute (SOP/C-1/LVP/027)
17. SOP Process sterilization product 121 8 minute (SOP/C-1/LVP/028)
18. SOP Operating Deaerator tank and boiler machine (SOP/C-2/ENG.U/029)

19. Log book sterilization
20. Photograph of converter, kWh meter,
21. Layout and photograph of installation autoclave and waste hot water recovery system.
22. Data monitoring 2019-2021
23. JCM Project cycle procedure (JCM\_ID\_PCP\_ver05.1)
24. JCM Guidelines for developing proposed methodology (JCM\_ID\_GL\_PM\_ver02.0)
25. JCM Guidelines for developing project design document and monitoring report (JCM\_ID\_GL\_PDD\_MR\_ver03.0)
26. JCM Guidelines for developing sustainable development implementation plan and report (JCM\_ID\_GL\_SDIP\_IR\_ver01.0)
27. JCM Guidelines for validation and verification (JCM\_ID\_GL\_VV\_ver01.0)
28. JCM Validation report form (JCM\_ID\_F\_Val\_Rep\_ver01.0)
29. JCM Glossary of Terms (JCM\_ID\_Glossary\_ver02.0)

**Annex Certificates or curricula vitae of TPE's validation team members, technical experts and internal technical reviewers**

*Please attach certificates or curricula vitae of TPE's validation team members, technical experts and internal technical reviewers.*

Dwi Kus Pardianto

Work Experience

1. Assistant professor in Marine Biology Department, Pukyong Nat'l Univ. Republic of Korea. 2015 - 2017
2. Manager Subdivision Quality Assurance PT Mutuagung Lestari, 2019 - present

Training

1. Workshop training on GHG Management and verification by ALSI, November 2017
2. Life Cycle Assessment on July 2018
3. CORSIA Verifier by Indonesia DGCA on July - August 2019
4. JCM-TPE Training by JCM Indonesia Secretariat and IGES on September 2019
5. ISCC Basic training on December 2019
6. GHG Management Training (New standards) by ALSI on March 2021

Auditing Experience

- Observer in JCM validation on August 2018
- Validation and verification for others GHG Program on September 2019
- ISCC audit since 2020

Irhan Febijanto

Work Experience

1. Japan Quality Assurance, JCM/CDM as auditor-now
2. PT CDM Indonesia Jaya, 2002-now
3. Technical advisor on Boiler/Turbine Maintenance in PT Indonesia Power (Indonesian Power Generation Company), 2002-2006
4. Staff in Boiler Maintenance Department and in Engineering Centre of Tokyo Electric Power Company (TEPCO Co.), 1999-2001
5. GHG Management Training (New standards) on 2021

#### Training

JCM Training by JQA on 21 August 2017

#### Auditing Experience

More than 3 times experiences working as validator and verifier since 2017

Yuniar Mitikauji

#### Work Experience

1. Research assistant in Forest Faculty, Gadjah Mada University, 2003-2005
2. Program Manager of Lan Rehabilitation Project in Samboja Lestari Project, East Kalimantan, 2005-2008
3. Coordinator of Roundtable Sustainable Palm Oil (RSPO) certification scheme at PT Mutuagung Lestari.
4. Auditor of Indonesia Sustainable Palm Oil (ISPO), RSPO, International Sustainability and Carbon Certification (ISCC) and Validator-verifier ISO 14064, JCM and verifier ICAO CORSIA.
5. Manager operational of Energy and Industry, 2018 - present

#### Training

- ISPO and RSPO on 2014
- ISO 14064 on June 2015
- ISO 50001, on April 2018
- SA 8000 on May 2018
- Life Cycle Assessment (LCA) on February 2019
- CORSIA Training by Joint Authorities Training Organisation (JAA) on May 2019
- ISCC Basic Training on May 2019
- GHG Management Training (New standards) by ALSI on March 2021

#### Auditing Experience

- ISPO and RSPO auditing since 2014 - 2019
- ISCC auditing since 2018 - present
- Validation and verification GHG Program, including JCM since 2018 - present.