

Document Number; PL-23-011

To whom it may concern

FUJIMORI KOGYO CO., LTD.

Certificate of Analysis

Product Code	Product Name	Lot Number	Expiration date
18002	PL chip for T-TAS 01	4115-PL11	2025/7/15

Data of Analysis

Test Item	Test Standards	Results
Exterior of PL chip	No abnormalities in appearance	PASS
Appearance of the chip at the time of measurement	No liquid leakage	PASS
Relative value with the standard product (AUC)	100±15% (85 - 115%)	99.8%
Reproducibility (n=10; AUC)	C. V. : within 15%	4.1%
Measured value when using a sample added with a designated drug (AUC)	AUC : ≤250	87.9

Check items

Check Item	Test Standards	Results
Packaging label	latest version	PASS
IFU	latest version	PASS
	Importer is correctly indicated on IFU	PASS
All products	checked that hard copy of the label is made (per lot)	PASS
	labeled correctly	PASS
	IFU is packed in all products	PASS

Every item above meets the criteria
Quality Assurance Section Manager

Approved By: G. Hinami

Date: 2024/01/31