

This material is an English translation of the press release announced on August 12, 2021 in Japanese, and the Japanese release is given priority about the content and the interpretation.

August 12, 2021

Notification of Hisamitsu Pharmaceutical Co., Inc. receiving Administrative Disposition from Saga Prefecture

Hisamitsu Pharmaceutical, Co., Inc. (President and CEO: Kazuhide Nakatomi, Head office: Tosu City, Saga Prefecture; hereinafter referred to as "Hisamitsu") would like to hereby announce that we received administrative disposition today from Saga Prefecture for violating "the Law for Securing the Quality, Efficacy, and Safety of Pharmaceuticals and Medical Devices" (hereinafter referred to as "the Pharmaceutical Affairs Law"); the violation was related to the manufacturing and marketing of "SALONPAS HOT ®," an OTC pain relieving patch manufactured at Hisamitsu Tosu Factory (hereinafter, "the Product"), specifically for the use of a colorant that doesn't comply with the specification.

We sincerely accept this administrative disposition and deeply apologize to all of our stakeholders, including our customers.

< Overview of the Disposition >

1. Pharmaceutical Manufacturing License of the Tosu Factory

Subject entity: Hisamitsu Pharmaceutical, Co., Inc., Tosu Factory

Address: 408 Tashiro Daikan-machi, Tosu-shi, Saga Prefecture, Japan

Scope: Pharmaceutical Manufacturing License

**The administrative disposition does not apply to the following operations:

- Modification, maintenance, and inspection of the facilities;
- Use of office buildings unrelated to manufacturing (including import) or shipment; and
- Research and development with no direct use of the manufacturing facilities.

(1) Description of Disposition

1) Suspension of business with Pharmaceutical Manufacturing License at Tosu Factory: 8 days

From Friday, August 13, 2021 to Friday, August 20, 2021

2) Reasons for Disposition

[1] SALONPAS HOT was manufactured by using tar pigments that do not comply with the standards specified by the Ministerial Ordinance (August 31, 1966, Ministry of Health and Welfare Ordinance No. 30) that defines tar pigments that can be used in pharmaceutical drug.

(Violation of the Pharmaceutical Affairs Law, Article 56, Clause 9)

[2] Tosu Factory failed to appropriately perform the quality control of SALONPAS HOT manufactured at its facilities; its quality control staff violated the standard procedures for the raw material acceptance testing, engaging in an inappropriate processing so that the material would appear to meet the specifications.

[Violation of Article 96 of the Law for Ensuring the Quality, Efficacy, and Safety of Drugs and

Medical Devices, Enforcement Regulations (MHW Ordinance No. 1 of 1961; hereinafter referred to as "Regulation") pertinent to the Pharmaceutical Affairs Law, Article 18, Paragraph 3, and violation of the Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Drugs and Quasi-drugs (MHLW Ordinance No. 179 of 2004), Article 3, Paragraph 2; Article 5, Paragraph 1, Clause 1; Article 6, Paragraphs 1 and 3; Article 11, Paragraph 1, Clause 4; and Article 15, Paragraph 1]

2. Pharmaceutical Marketing License of Hisamitsu Pharmaceutical Co., Inc.

Subject entity: Hisamitsu Pharmaceutical, Co., Inc.

Address: 408 Tashiro Daikan-machi, Tosu-shi, Saga Prefecture, Japan

Scope: Class 2 Pharmaceuticals Manufacturing and Marketing Business License

- * The administrative disposition does not apply to the following operations:
 - Use of office buildings unrelated to manufacturing, marketing, or shipment; and
 - Post-marketing pharmacovigilance, and handling of complaints and returned products.

(1) Description of Disposition

1) A Suspension of Class 2 Pharmaceuticals Manufacturing and Marketing Business License: 4 days

From Friday, August 13, 2021 to Monday, August 16, 2021

2) Reason for Disposition

[1] Hisamitsu marketed SALONPAS HOT manufactured at Tosu Factory, which used a tar pigments that did not meet the specifications set out by the Ministerial Ordinance on Tar Pigments Usable for Pharmaceutical Products (MHW Ordinance No. 30 of 1966).

(Violation of the Pharmaceutical Affairs Law, Article 56, Clause 9)

[2] Hisamitsu failed to supervise Tosu Factory to appropriately perform the quality control of Salonpas Hot manufactured at Tosu Factory and marketed by Hisamitsu; Tosu Factory's quality control staff violated the standard procedures for the raw material acceptance testing, engaging in an inappropriate processing so that the material would appear to meet the specifications.

[Violation of the Regulation, Article 92, Clauses 1 and 2 pertinent to the Pharmaceutical Affairs Law, Article 18, Paragraph 1, and violation of the MHLW Ordinance on Standards for Quality Control of Pharmaceuticals, Quasi Drugs, Cosmetics, and Cellular and Tissue-based Products (MHLW Ordinance No. 136 of 2004), Article 4, Paragraph 1; and Article 8, Clauses 1 and 2]

<Background Leading to Disposition>

In May 2020, an in-house inspection confirmed that the colorant used in the Product did not meet the specification, but was manufactured and marketed as conforming to the specification. Upon such discovery, Hisamitsu reported it immediately to Saga Prefecture, and started voluntarily recalling the Product from July 2020. Thereafter, Hisamitsu complied with a series of inspections and guidance provided by Saga Prefecture, and made its utmost efforts to improve its quality and manufacturing control; after which, Saga Prefecture has now made the decision to enforce the aforementioned administrative disposition.

Meanwhile, Saga Prefecture has confirmed the full compliance of Hisamitsu's GMP scheme with no GMP control-related violation other than this particular matter.

< Possible Health Hazards Related to this Product>

The amount of the colorant used for this Product was very little, and has been confirmed to cause no serious health hazards. Presently, there have been no reports of adverse events resulting from this matter..

< Disposition of Directors >

We would like to hereby announce that, as a voluntary punitive action in the face of this administrative disposition, Hisamitsu has decided, at the board meeting held on August 10, 2021, to reduce compensation of all directors as follows.

- President and Representative Director: 20% reduction of 1-month compensation from August 2021
- Executive directors: 10% reduction of 1-month compensation from August 2021
- Directors: 5% reduction of 1-month compensation from August 2021

(Outside directors excluded)

<Future plan>

While this event is expected to cause very little impact on the consolidated financial results for the fiscal year ending February 28, 2022, we will timely and promptly disclose any information as required by the disclosure rules if situations change in the future.

Since this event was discovered, Hisamitsu voluntarily suspended manufacturing of pharmaceutical products at and shipment thereof from Tosu Factory to improve its operations, and has been thoroughly self-inspecting all activities related to quality and manufacturing control to seek for the root cause of the problem, and based on which, setting out and executing appropriate strategies.

Hisamitsu takes this administrative disposition very seriously, and is committed to render its full capacity to further its efforts to make improvements, ensuring full observance of the Pharmaceutical Affairs Law and other regulations as a responsible pharmaceutical company, and that the management team and each employee will make their utmost efforts to prevent the recurrence of such failure and work sincerely to restore trust from the society.