CERTIFICATE OF ANALYSIS
ARTICLE :lidocaine 5% medicated plaster

Lot No.	30132	Expire	February 2023
Date of manufacture	March 13, 2020		
Date of Testing	March 17, 2020 — March 26, 2020		

Test Item	Standard	Result
Description	White to pale yellow polymeric adhesive material with a faint characteristic odor, spread on one side of non-woven fabric, and covered with a plastic film. The non-woven fabric is embossed "LIDOCAINE 5%" .	Conforming
pH	6.0 to 7.5	6.91 6.94 6.85 $\bar{X}$ 6.90
Identification Lidocaine (for shelf-life:tested at beginning of stability studies)		
①Precipitation	A fine, bluish green precipitate is formed.	Conforming
②HPLC Method	The retention time corresponds to the retention time of the standard solution.	Conforming
Methyl parahydroxybenzoate (tested at beginning of stability study)		
①HPLC Method	The retention time corresponds to the retention time of the standard solution.	Conforming
Propyl parahydroxybenzoate (tested at beginning of stability study)		
①HPLC Method	The retention time corresponds to the retention time of the standard solution.	Conforming

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Test Item	Standard	Result
Dimension	length : 14±0.7 cm width : 10±0.5 cm	14.05 cm 14.06 cm 14.02 cm $\overline{X}$ 14.04 cm 10.04 cm 10.02 cm 10.02 cm $\overline{X}$ 10.02 cm
Weight Variation test	Deviation not more than 10% (n=20)	Conforming
Average weight	15.2 - 17.8g (n=20)	$\overline{X}$ 16.5g
Adhesive strength test	Lower limit: Steel ball (7.9mm in diameter, 2.0g in weight) stops more than 5 seconds on the adhesive surface. Upper limit: Steel ball (38.1mm in diameter, 226g in weight) does not stop more than 5 seconds on the adhesive surface.	Conforming
Assay (Lidocaine)	700 ± 70 mg／patch	710.7 mg 697.1 mg 695.9 mg $\overline{X}$ 701.2 mg/patch
Methyl Parahydroxy-benzoate	14 ± 1.4 mg／patch	14.45 mg 14.05 mg 13.95 mg $\overline{X}$ 14.15 mg/patch
Propyl Parahydroxy-benzoate	7 ± 0.7 mg／patch	7.23 mg 7.02 mg 6.93 mg $\overline{X}$ 7.06 mg/patch

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Test Item	Standard	Result
Related compounds to lidocaine base	Single known: not more than 0.1% w/w (2.6-Dimethylaniline) (DEAMMQ) Single unknown: not more than 0.10% w/w Total known and unknown:not more than 0.5% w/w	 N.D. N.D. N.D. N.D. N.D. N.D. 0.05% 0.05% 0.04% 0.08% 0.09% 0.07%
Uniformity of Content 10 patches 30 patches	 Acceptance value AV_{10} not more than 15.0 Acceptance value AV_{30} not more than 15.0 and no individual content outside (0.75×M)to(1.25×M) of AV_{30}	 2.31 -
Drug Release (Dissolution Test)	≧ 250mg at 30 minutes	286.0 mg 284.5 mg 284.4 mg 282.9 mg 281.7 mg 283.7 mg $\overline{X}$ 283.8 mg
Microbial Limits (for shelf-life:tested at beginning and end of stability studies)	Total viable aerobic count(tamc): n.m.t. 10^2cfu/patch Yeast and moulds(tymc): n.m.t. 10^1cfu/patch Pseudomonas aeruginosa(in 1 patch):negative Staphylococcus aureus(in 1 patch):negative	n.m.t.10cfu/patch n.m.t.10cfu/patch Absence Absence

Test results for TEIKOKU Release to GRUNENTHAL.

Total Judgment	Conforming
Date of Judgment	March 27, 2020
Quality control manager	Date 2020 / 3 / 27 Tatsuo Ando
Responsible Person for Testing	Date 2020 / 3 / 27 Yuka Kouno
Quality assurance manager	Date 2020 / 3 / 27 Yasunori Matsushita

TEIKOKU
SEIYAKU CO.,LTD.
567 SANBONMATSU, HIGASHIKAGAWA
KAGAWA 769-2695 JAPAN
PHONE (0879)25-2221
FAX (0879)24-1555

Certificate of Compliance for Products

Product: lidocaine 5% medicated plaster
Strength: 700mg lidocaine per plaster (10×14 cm)
Dosage form: Medicated plaster
Lot-No.: 30132
Delivered Quantity: 137,600 envelopes (with 5 sheets each)
Date of Manufacture: 13 March 2020
Expiry Date: February 2023
Storage Condition: Room Temperature

Active Pharmaceutical Ingredient: lidocaine
Lot-No.: 1011
Manufacturer: Moehs Catalana SA

Manufacturing Site of Product: Teikoku Seiyaku Co., Ltd.
Manufacturing License No.: 37AZ000005

I hereby certify that the above information is authentic and accurate.

This batch of product has been manufactured, including packaging and quality control at the above mentioned site in full compliance with GMP requirements of the Directive 2003/94, with GMP requirements of the local Regulatory Authority and with the specifications and the current manufacturing instructions.
The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Name/Position:	Signature:	Date:
Yasunori Matsushita Quality Assurance Manager		2020 Apr. 8

Grünenthal GmbH
Zieglerstraße 6
52078 Aachen
Germany

GRÜNENTHAL

Manufacturer's Batch Certificate

Data importing country

Material name:	Versatis 5 % patches a 5
Importing country:	Chile
Marketing authorization number:	Registro ISP N°:F-16134

Data manufacturer

Product:	Versatis 5 % patches a 5 CHL
Package size and type:	5 patches in 1 sachet
Dosage form:	patches
Batch no.:	666R03
Manufacturing date:	03/2020
Expiry date:	02/2023

Material name	Manuf. stage	Batch no.	Name and address manufacturer (Authorization number)
Versatis 5 % patches a 5	Packing	666R03	Grünenthal GmbH Zieglerstraße 6 52078 Aachen Germany (DE_NW_04_MIA_2015_0049)
Versatis 5 % patches	Bulk	30132	Teikoku Seiyaku Co., LTD 567 Sanbonmatsu Higashikagawa Kagawa 769-2695 Japan (37AZ000005)

Comments/remarks

Deviation(s): no

I hereby certify that the above information is authentic and accurate. This batch of product has been fabricated/manufactured, including packaging and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

28.08.2020

Dr. Ralf Maucher

(Qualified Person)