

1509000276

sicor de mexico s.a de c.v.

Page 1 of 3

**PRODUCT
SPECIFICATIONS
AND
CERTIFICATE OF ANALYSIS****Product Name:** Mometasone Furoate**Control No.:** 4039700315M**Order No.:** QU50061201**Client Packing Order:****Customer Name:** LABORATORIO CHILE S.A.**Quantity:** 1.000 KG**Quality Market:** USA**Manufacturing Site:** Sicor de Mexico**Original Analysis Date:** 17-August-2015**Manufacturing Date:** July 2015**Last Analysis Date:** 27-August-2015**Re Test date:** July 2020**Packaging and storage:** Maintain in well-closed carton drums at room temperature protected from light.

TESTS AND METHODS	SPECIFICATIONS	RESULTS*
SM-CPT-033 TESTS		
Description	White to almost white fine powder.	Complies
Solubility	Practically insoluble in water, soluble in acetone and in methylene chloride, slightly soluble in alcohol	Complies
Identification IR Spectrum (KBr) HPLC	Corresponds to standard Corresponds	Complies Complies
Melting point	About 220 °C with decomposition	216°C
Loss on drying	Not more than 0.5 %	0.1%
Specific rotation (0.5 % in dioxane at 20 ° C)	Between +56 ° to +62 ° on the dried basis	+58°
Residue on ignition	Not more than 0.1 %	Less than 0.1%
Heavy metals	Not more than 30 ppm	Less than 30 ppm
HPLC Assay	97.0 % - 102.0 % on the dried basis	99.4%
Purity and related substances TLC Total impurities Each impurity	Not more than 2.0 % Not more than 1.0 %	Less than 2.0 % Less than 1.0 %

Sicor de Mexico S.A. de C.V.

Av. San Rafael No. 35, Col. Parque Industrial Lerma, Lerma de Villada, Estado de Mexico, C.P. 5200

Manufacturing site: Av San Rafael 35, Parque Industrial Lerma 52000, Lerma Estado de Mexico, Mexico TEL. 52 (728) 28 29 800 FAX. 52 (728) 28 53 429

sicor de mexico s.a de c.v.

Page 2 of 3

PRODUCT SPECIFICATIONS AND CERTIFICATE OF ANALYSIS

Product Name:	Mometasone Furoate	Order No.:	QU50061201
Control No.:	4039700315M	Client Packing Order:	
Customer Name:	LABORATORIO CHILE S.A.		
Quantity:	1.000 KG	Quality Market:	USA
Manufacturing Site:	Sicor de Mexico	Original Analysis Date:	17-August-2015
Manufacturing Date:	July 2015	Last Analysis Date:	27-August-2015
		Re Test date:	July 2020
Packaging and storage: Maintain in well-closed carton drums at room temperature protected from light.			

TESTS AND METHODS	SPECIFICATIONS	RESULTS*
SM-CPT-033 TESTS		
HPLC Purity and related substances		
HPLC Purity	Not less than 99.4 %	99.9%
Total impurities	Not more than 0.6 %	0.1%
Unknown impurities (each)	Not more than 0.10 %	Less than 0.07%
Cp 7524 Mometasone	Not more than 0.15 %	Less than 0.01%
Cp 7491 Mometasone furoate epoxide	Not more than 0.15 %	0.01%
Cp 7774 Mometasone furoate, d 9(11) analog and Cp 7521 mometasone 17,20-difuroate (sum)	Not more than 0.15 %	0.09%
Residual solvents		
Methanol	Not more than 800 ppm	Less than 50ppm
Dichloromethane	Not more than 600 ppm	Less than 50ppm
Ethyl acetate	Not more than 500 ppm	Less than 30ppm
Diisopropyl ether	Not more than 500 ppm	Less than 30ppm
Pyridine	Not more than 100 ppm	Less than 30ppm
Acetone	Not more than 900 ppm	115ppm
Bulk density	Informative	0.172g/ml
SM-CPT-033-A6 TESTS		
Particle size		
< 20 µm	100.0 % Minimum	100.0%
< 10 µm	95.0 % Minimum	99.8%

Sicor de Mexico S.A. de C.V.
Av. San Rafael No. 35, Col. Parque Industrial Lerma. Lerma de Villada, Estado de Mexico, C.P. 5200

Manufacturing site: Av. San Rafael 35, Parque Industrial Lerma 52000, Lerma Estado de Mexico, Mexico TEL. 52 (728) 28 29 800 FAX. 52 (728) 28 53 429

sicor de mexico s.a de c.v.

Page 3 of 3

**PRODUCT
SPECIFICATIONS
AND
CERTIFICATE OF ANALYSIS**

Product Name: Mometasone Furoate

Control No.: 4039700315M

Order No.: QU50061201

Client Packing Order:

Customer Name: LABORATORIO CHILE S.A.

Quantity: 1.000 KG

Quality Market: USA

Manufacturing Site: Sicor de Mexico

Original Analysis Date: 17-August-2015

Manufacturing Date: July 2015

Last Analysis Date: 27-August-2015

Re Test date: July 2020

Packaging and storage: Maintain in well-closed carton drums at room temperature protected from light.

Remarks:

1. Conforms to the requirements of the SM-CPT-033 and SM-CPT-033-A6 Specifications.
2. Micronized Product
3. The impurities Mometasone furoate 6 keto and Mometasone 11, 17-difuroate are controlled as unknown impurities (each) with limit of NMT 0.10%

Released by Quality Control Manager:

Kenia Cervantes Castro

Signature:** Kenia Cervantes Castro 1 September 2015 08:34:49PM

Print Date: 1 September 2015

QA Approval: Patricia Ramirez Aguilera

(*) Upon completion of the 'Results' column this document becomes a certificate of analysis **End of C.O.A.**

(**) This document was signed electronically and this is the manifestation of the electronic signature.

Sicor de Mexico S.A. de C.V.

Av. San Rafael No. 35, Col. Parque Industrial Lerma, Lerma de Villada, Estado de Mexico, C.P. 5200

Manufacturing site: Av. San Rafael 35, Parque Industrial Lerma 52000, Lerma Estado de Mexico, Mexico TEL. 52 (728) 28 29 800 FAX. 52 (728) 28 53 429