catalysis

Dirección de Envio
Macarena, 14
28016 Madrid / SPAIN
P.O. Box 19004
28028 Madrid / SPAIN

Dirección Fiscal
Pso. Doctor Gregorio Marañón, 6-2
45007-Toledo / España

phone +34 91 345 69 02
fax +34 91 345 97 25
e-mail catalysis@diamel.com
web page www.diamel.com

BLUE-CAP - Analytical Information (Results)

(1) GUIDELINES ANALYTICAL LABORATORIES INC., USA
Analytical Technique: **ANALYTICAL METHOD DEVELOPED BY DR. JOHN C. REEMPMEYER OF THE FDA (GRADIENT HIGH-PRESSURE LIQUID CHROMATOGRAPHY WITH DIODE ARRAY SPECTOPHOTOMETRIC DETECTION)**
(BLUE-CAP Spray)
11.03.2000

(2) MINISTRY OF HEALTH AND CONSUMPTION, Spain
Analytical Technique: **HPLC METHOD WITH UV DETECTION**
(BLUE-CAP Spray , BLUE-CAP Cream)
30.08.2000

(3) KOREA ADVANCED FOOD RESEARCH INSTITUTE, Korea
Analytical Technique: (not specified in text in English)
(BLUE-CAP Spray, BLUE-CAP Shampoo, BLUE-CAP Cream, BLUE-CAP Bath & Shower Gel)
30.03.2005

(4) MINISTRY OF HEALTH, China
Analytical Technique: (3 different analytical techniques)
(not specified in text in English)
(BLUE-CAP Spray, BLUE-CAP Cream)
13.05.2005

(5) UNIVERSITY OF INDONESIA, Indonesia
(BLUE-CAP Spray, BLUE-CAP Shampoo, BLUE-CAP Cream)
26.09.2006 and 20.09.2006

(6) BADANPOM (Indonesian FDA), Indonesia
(BLUE-CAP Spray, BLUE-CAP Shampoo, BLUE-CAP Cream)
13.10.2006

catalysis

Dirección de Envio
Macarena, 14
28016 Madrid / SPAIN
P.O. Box 19004
28028 Madrid / SPAIN

Dirección Fiscal
Pso. Doctor Gregorio Marañón, 6-2
45007-Toledo / España

phone +34 91 345 69 02
fax +34 91 345 97 25
e-mail catalysis@diamel.com
web page www.diamel.com

BLUE-CAP - Analytical Information (Results)

(7) AZOPHARMA, USA
Analytical Technique: **HPLC METHOD**
(BLUE-CAP Spray)
14.06.2007

(8) UNIVERSITY OF BELGRADE, Serbia
Analytical Technique: **HPLC METHOD WITH UV DETECTION**
(BLUE-CAP Spray, BLUE-CAP Shampoo, BLUE-CAP Cream)
21.09.2007

(9) BLOOM, CO., LTD., Japan
Analytical Technique: **HPLC METHOD**
(BLUE-CAP Cream)
24.06.2008

(10) BELAB, PT CIPTA SINTESA MUSTIKA, Indonesia
Analytical Technique: **FTIR WITH ISOLATION METHOD**
(BLUE-CAP Cream, BLUE-CAP Spray, BLUE-CAP Shampoo)
04.02.2009

Analysis Report

Client:	**Catalysis**	P.O.#:	N/A
	8185-2 NW 155st	GAL #:	00100016
	Miami Lakes, FL 33016	Date Received:	10/06/00
	USA	Turn Around Requested:	Normal
		Report #:	R00100016
Attention:	Ana Maria De Lenos	Date Report Printed:	11/03/00
Client #:	CS-171	# of Containers Recd.:	2
Product Name:	Blue Cap Spray	Sample Received:	125mg
Lot Number:	P-3	Page 1 of 1	

Samples of the above mentioned product were submitted to Guidelines Analytical Laboratories Inc. ("GAL") and screened for the presence of 49 different corticosteroids by an analytical method developed by Dr. John C. Reempmeyer, of the Food and Drug Administration, Regional Laboratory in St. Louis, MO. The method consists of gradient high-pressure liquid chromatography with diode array spectophotometric detection. No corticosteroids were found to be present in the samples submitted when tested by this analytical method.

Guidelines Analytical Laboratories Inc. is an FDA registered, inspected, independant contract laboratory serving the Pharmaceutical Industry. GAL warrants the accuracy of the test results for the samples as submitted. The foregoing express warranty is exclusive and is given in lieu of all other warranties, expressed or implied. GAL disclaims any other warranties, expressed or implied, including a warranty of fitness for particular purposes and warranty of merchantability. GAL accepts no legal responsibility for the purposes for which the client uses the test results.

Report Prepared by:_____ QC Documentation Clerk Date:_____

Testing Performed by :_____ Group Leader Chromatography Date:_____

QA Approval by:_____ Manager Quality Assurance Date:_____

GUIDELINES ANALYTICAL LABORATORIES

Sent via fax (305) 231-6327

Catalysis Corporation
8185 2 NW 155th Street
Miami Lakes, FL 33016

Attention Anna

Re: Cost estimate to repeat the FDA screening study to measure the presence of steroids in Catalysis' Blue Cap Spray product Lot# P3 MFG Date May 00

Dear Sirs:

As requested, the following is the cost estimate to repeat the screening study conducted by the FDA at their St Louis Laboratory on Blue Cap Spray Product Lot # P3 MFG Date May 00 . Please note that this quote is estimated.

Item/Description	Cost
1. Special HPLC Column (Waters Associates Symmetry C18 75 x 4.6 mm, 3.5 um	$360
2. Purchase of Triamcinolone, Flocinonide, Triamcinolone Hexacetonide and Deoxycorticosterone Pivalate Reference standards. The other reference standards Guidelines Analytical already has in house.	550
3. Assay of Blue Cap Spray lot using FDA screening method 1	350
4. Assay of Blue Cap Spray lot using FDA screening method 2	350
5. Coping charge of raw data @0.10/page estimated 100 pages	10
Sub Total	1620
3% Waste Disposal Fee	21
Total	$1641

In order to conduct this testing, GAL will have to purchase approximately $900 in specialty columns and reference standards unless these materials are provide by the client. GAL will require a deposit of $900 before the Initiation of this testing, to cover the cost of the specialty items. We estimate that it will take two days to conduct this testing. This testing can be initiated approximately 3-5 days after receipt of all the specialty materials. Since Catalysis is being charged for these specialty items, the materials (column, reference standards, etc.) will only be used to assay Catalysis products.

If you have any questions concerning this testing, please feel free to contact me.

Sincerely,

Michael Ray
President.

10320 USA Today Way, Miramar, FL 33025, USA • 954-433-7480 • Fax: 954-432-9826 • E-mail: gls@gate.net
www.guidelinesinc.com

GUIDELINES ANALYTICAL LABORATORIES

Analysis Report

Client: **Catalysis**
8185-2 NW 155 Street
Miami Lakes FL 33016-
USA
Attention: Allan Figueroa
Client # CS171
Product Name: Blue Cap Spray

Lot Number: P-3

P.O.#: N/A
GAL #: 00100016
Date Received: 10/6/00
Turn-around Req: Normal
Report #: R00100016
Date Report Printed: 11/3/00
# of Containers Recd 1 bottle
Sample Received: 125mg
Page 1 of 1

	Parameter	Method	Specifications	Results	Notebook References	Date of Assay
1	Triamcinolone	FDA Regional Lab	Report Result	Not Detected (LOQ=0.0003%)	LF-8,37-38	10/11/00
2	Hydrocortisone	FDA Regional Lab	Report Result	Not Detected (LOG=0.0002%)	LF-8,37-38	10/11/00
3	Triamcinolone Acetonide	FDA Regional Lab	Report Result	Not Detected (LOQ=0.0003%)	LF-8,37-38	10/11/00
4	Fluocinonide	FDA Regional Lab	Report Result	Not Detected (LOQ=0.0003%)	LF-8,37-38	10/11/00
5	Clobetasol Propionate	FDA Regional Lab	Report Result	Not Detected (LOQ=0.0003%)	LF-8,37-38	10/11/00
6	Betamethasone Dipropionate	FDA Regional Lab	Report Result	Not Detected (LOQ=0.0005%)	LF-8,37-38	10/11/00
7	Triamcinolone Hexacetonide	FDA Regional Lab	Report Result	Not Detected (LOQ=0.0008%)	LF-8,37-38	10/11/00
8	Desoxycorticosterone Pivalate	FDA Regional Lab	Report Result	Not Detected (LOQ=0.0005%)	LF-8,37-38	10/11/00
9	Betamethasone 17 propionate 21 butyrate	FDA Regional Lab	Report Result	Not Detected (Based on RRT on FDA Procedure)	LF-8,37-38	10/11/00

Prepared by: Date:

QC Reviewed by: Date:

QA Approval by: Date:

10320 USA Today Way, Miramar, FL 33025, USA • 954-433-7480 • Fax: 954-432-9826 • E-mail: gls@gate.net
www.guidelinesinc.com