

DOCUMENT REFERENCE NUMBER
003/AMINO

Proposed Management Techniques

Amino Chemicals forms part of a large bulk active ingredients producer named DiPharma SpA. This company is ISO registered (see Appendix 003/Amino/1). All our activities are under the careful watch of the mother company, who effects transfer of technology to ensure that Amino maintains a high quality profile in line with Good Manufacturing Procedures.

Amino Chemicals has been inspected by the US Food and Drug Administration and has been passed by the same agency (see Appendix 003/Amino/2).

During 2002 the site manufactured only trial batches on a pilot scale (approx. 200 / 300 kg of each final product) to allow customers to carry out preliminary tests on their new drug applications. During this period the site was only partially occupied since these pilot productions were carried out on a non-continuous basis.

During the first quarter of 2003, the site has begun to manufacture a product called Fosinopril Sodium on an industrial basis and the present production rate is approximately 200kg/week.

It is envisaged that another two products will be manufactured on a pilot scale over the next few months, namely Fexofenadine Hydrochloride and Losartan. It is anticipated that industrial production of these will commence next year.

Dipharma**Department of Research and Development**

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TELEFAX MESSAGE
n. 060-2003

Attention to	Mr. Zaffagnini
Company	Amino Chemicals
Fax no.	+356.21.24.92.26
Phone no.	
Date	22 Maggio, 2003
No. of pages	1+1
Subject	Certificato Certiquality

Come da accordi.

Cordiali saluti



Sara Consonni

Appendix 003/Amino/1

Federazione - Federation



member of IQNet

CISQ è una Federazione sovrasettoriale
comprendente enti di certificazione
e di Gestione
operanti nel settore di propria
competenza.

CISQ is a multi-sector, independent,
non-profit Federation of Italian bodies
for certification of Management
Systems operating in its own
specialty.

La validità del presente certificato
è subordinata a sorveglianza
periodica annuale e al riesame
complessivo del Sistema di Gestione
con periodicità triennale.

The validity of this certificate
is subject to surveillance
periodic review of Management
Systems every three years.

CERTIFICAZIONE ITALIANA DEI SISTEMI QUALITÀ AZIENDALI ITALIAN CERTIFICATION OF COMPANY QUALITY SYSTEMS



CERTIFICATO n. **529/2**
CERTIFICATE No

SI CERTIFICA CHE IL SISTEMA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY

DIPHARMA SPA

UNITÀ OPERATIVE
OPERATIVE UNITS

33031 BASILIANO (UD) - S.S. DI PONTEBBANA 103
33036 MERETO DI TOMBA (UD) - VIA XXIV MAGGIO 40

UNI EN ISO 9002

È CONFORME ALLA NORMA
IS IN COMPLIANCE WITH THE STANDARD

PER LE SEGUENTI ATTIVITÀ
CONCERNING THE FOLLOWING ACTIVITIES

SETTORE EA 13

Produzione e vendita di: esplosivi; principi attivi per uso
farmaceutico ed intermedi chimici

Production and sale of explosives, active ingredients for
pharmaceuticals and chemical intermediates.

IL PRESENTE CERTIFICATO È SOGGETTO AL RISPETTO DEL REGOLAMENTO
PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THIS CERTIFICATE SHALL SATISFY THE REQUIREMENTS
OF THE RULES FOR THE CERTIFICATION OF MANAGEMENT SYSTEMS

Prima emissione*
First issue*

15/12/1995

Emissione corrente
Current issue

25/01/2002

CERTIQUALITY VIA S. GIUSEPPE, 4 - 20123 MILANO - ITALIA

SINCERT
2345012 Registro nr. 006A

OCT-18-2002 14:04

FDA OC DMPG

301 594 1033 P.02

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

1 October 2002

Dr Philip Micallef
Managing Director
Amino Chemicals Ltd.
A 61 Industrial Estate
Marsa, LQA 06, Malta

Dear Dr Micallef

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your manufacturing facility in Marsa, Malta, on 16, 17 and 20 May 2002, by FDA investigator Melissa J Garcia and chemist Michele L. Obert.

We have received your written responses to the FDA 483 Inspectional Observations dated 19 July and 12 August 2002 through Jose D. Games, PhD. Based on this response we are classifying your facility as acceptable. The corrective actions will be further evaluated during the next routine inspection of your facility. It remains your responsibility to assure continued compliance with current good manufacturing practices.

Additionally we enclose a copy of the EIR for the inspection. This report is being provided to you for information purposes. The Agency is working to make sure its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the FOIA and C.F.R. Part 20. This, however, does not preclude you from requesting and, possibly obtaining any additional information under FOIA.

If you have any questions, you may contact me at 7520 Standish Place, HFD-322, Rockville, MD, 20855, by telephone at (301)594-0095 or by fax at (301)594-1033.

Sincerely

Karen K. Moksnes
Compliance Officer
Foreign Inspection Team, HFD-322

Enclosure

Appendix 003/Amino/2.

TOTAL P.02

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List of Raw Materials

LIST OF MATERIALS USED

ACETONE

ACETONITRILE

HYDROCHLORIC ACID 35/36%

ISOBUTIRONITRILE

1-(2-(AMINO)1(4-METHOXYPHENYL)

ACETIC ACID

MONOCHLOROACETIC ACID

N-BUTYL ALCOHOL

ISOPROPYL ALCOHOL

ACTIVE CARBON

ACTIVATED COKE

METHANOL

AMMONIA

BENZYL ALCOHOL

2-BUTYL-4-(5)CHLORO-5(4)-IMIDAZOLECARBOXALDEHYDE 99% MIN.

CARBONYL DIIMIDAZOLE

CYCLOHEXANE

CARBON DIOXIDE

DIMETHYLFORMAMIDE

ETHYL ACETATE

FEXO 7/P

FOSINOPRIL ZPA6

FOSINOPRIL ZPA7

ETHYLENE GLYCOL

1,1,1,3,3,3, HEXAMETHYLDISILAZANE

ISOPROPYL ACETATE

METHYL ETHYL CHETONE

METHYLISOBUTYL CHETONE

N-TRIPHENYL-5-(4'-(BROMOMETHYL)-BIPHENYL)-BIPHENYL-2-YL)TETRAZOLE

N-HEXANE

N-METIL-1-(METILICO)-2-NITROETENEAM

BENZIMIDAZOLE

4-PHENYL-1-BUTENE

POTASSIUM HYDROXIDE

SULPHURIC ACID 96%

METILATED SODIUM IN METHANOL

SODIUM BORO HYDRIDE

SODIUM 2 ETHYL HEXANOATE

CAUSTIC SODA

TRIETHYLAMINE

TETRAHYDROFURAN

TETRABUTYL AMMONIUM BROMIDE

TRIMETHYLCHLOROSILANE

TOLUENE

2-(2-METHOXYPHENOXY)ETHYLAMINE

4-(2,3-EPOXYPROPOXY)9H-CARBAZOLE

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List of Other Substances used on the Premises.

Please see 004/Amino for full list of materials used on the premises. We consider all materials to be raw materials.