Office of The Commissioner
Food & Drug Administration (MS),
Survey No. 341, 2nd floor,
Bandra – Kurla Complex,
Bandra (East), Mumbai – 400 051

Date:- 25/1/2012

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This certificate confirms to the format recommended by the World Health Organization (general instructions and explanatory notes attached.)

Certificate No. WHO-GMP/CERT/KD-New-9-2012/142/11.

On the basis of the inspection carried out on **27.12.2011** we certify that the site indicated on this certificate complies with **Good Manufacturing Practices** for the dosage forms, categories and activities listed in Table 1.

Name and Address of Manufacturing Site:
M/s.RPG Life Sciences Limited.
25, MIDC Land, Thane-Belapur Road,
Navi Mumbai-400 705

1. Manufacturer's Licence Number: **In Form 25-No. 194**

2. Table1.

Pharmaceutical Product (s)	Category (ies)	Activity (ies)
Starting Material (s)		
Active Pharmaceutical Ingredient (as per enclosed Annexure)	General (Other than Cytotoxic, Penicillin, Cephalosporin and Hormones)	Synthesis, Production, Purification, Packaging, Labeling and Quality Control

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until 24 JAN 2014. It becomes invalid if the activities and / or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Name of Authorized Person: O. S. SADHWANI

Signature:

Stamp and date:
Joint Commissioner (Law)
Food And Drug Administration
Maharashtra State, Bandra
Mumbai, INDIA

25 JAN 2012

Explanatory notes

1. This certificate, which is in format recommended by WHO, certifies the status of the site listed in point 1 of the certificate.
2. The certification number should be traceable within the regulatory authority issuing the certificate.
3. Where the regulatory authority issues a license for the site, this number should be specified. Record "not applicable" in cases where there is no legal framework for the issuing of a license.
4. Table 1

List the dosage forms, starting material, categories and activities. Examples are given below.

Example 1

Pharmaceutical Product (s)	Category (ies)	Activity (ies)
Dosage form (s):		
Tablets	Cytotoxic	Packaging
	Hormone	Production, Packaging, Quality Control
	Penicillin	Repackaging and Labeling
Injectables	Cephalosporin	Aspetic Preparation, Packaging, Labeling

Example 2

Pharmaceutical Product (s)	Category (ies)	Activity (ies)
Starting Material (s)		
Paracetamol	Analgesic	Synthesis, Production, Purification, Packaging, Labeling and Quality Control

Use, whenever available, International Nonproprietary Names (INNS) or otherwise national nonproprietary names.

5. The certificate remains valid until the specified date. The certificate becomes invalid if the activities and / or categories certified are changed or if the site is no longer considered to be in compliance with GMP.
6. The requirements for good practices the manufacturer and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials. Good manufacturing practices and inspection. Volume 2, 1999. World Health Organization, Geneva and subsequent updates.

Annexure

Name and Address of Manufacturing Site:
M/s.RPG Life Sciences Limited.
25, MIDC Land, Thane-Belapur Road,
Navi Mumbai-400 705

Valid up to: 2 4 JAN 2014

Manufacturer's licence number: **In Form 25 No.194**

List of Products Approved for WHO GMP

S.N.	Pharmaceutical Product (s)
	Starting Material (s)
1.	Mercaptopurine USP
2.	Propantheline Bromide B.P./USP
3.	Risperidone B.P./E.P./USP
4.	Haloperidol B.P./E.P./USP
5.	Diphenoxylate Hydrochloride B.P./E.P./USP
6.	Azathioprine B.P./E.P./USP
7.	Lamotrigine B.P./E.P.
8.	Nicorandil
9.	Haloperidol Deaconate B.P./E.P.
10.	Quinfamide
11.	Clopidogrel Bisulfate USP
12.	Clopidogrel Hydrogen Sulfate E.P.
13.	Ticlopidine Hydrochloride B.P
14.	Mycophenolate Sodium
15.	Pantoprazole Sodium Sesquihydrate B.P./E.P./USP

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

Address of Certifying Authority
Foods & Drugs Administration (H.Q)
Maharashtra State, 2nd Floor,
Survey No. 314,
Bandra Kurla Complex,
Bandra (E), Mumbai 400 0051
Tel : (022) 26592361 / 26592365
Fax : (022) 26590992

Name of Authorized Person: **O. S. SADHWANI**

Signature:

Stamp and Date:
Joint Commissioner (Law)
Food And Drug Administration
Maharashtra State, Bandra
Mumbai, INDIA

2 5 JAN 2012