

F-3-5/2013-DDC (Alt. Med.)
Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services, Regulations & Coordination
~*~*~*~*~

Islamabad, the 10th June, 2016

NOTIFICATION

S.R.O. (I)/2016. – In exercise of the powers conferred by section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), the Drug Regulatory Authority of Pakistan, with prior approval of the Federal Government, is pleased to direct that the following amendments shall be made in the Alternative Medicines and Health Products (Enlistment) Rules, 2014, namely: -

In the aforesaid Rules, in SCHEDULE A, for Form NO. 9, 10, 11 and 12, the following new Forms shall be substituted, namely: -

“FORM No. 9
[see Rule 9 (1)]

Application for issuance of Certificate for GMP or Free Sale or Certificate of Pharmaceutical products

I/We.....

.....owner of M/s. with valid Enlistment /
Manufacturing Licence No..... do hereby apply for the issuance
of Certificate for GMP or Free Sale on prescribed Format.

- 2) The fee deposit receipt is enclosed with the application.
- 3) My firm is in compliance to WHO Traditional Medicines, Good Manufacturing Practices 2005 or any other applicable GMP guide lines, as specified by DRAP.
- 4) Enlistment Certificate as manufacturer, Enlistment Certificate for the Products, purchase order and relevant documents as per required list are attached.
 - (a) Reference of firm name and Enlistment number.
 - (b) Product name to be mentioned on the subject form.
 - (c) Copy of the form to be attached for GMP / Free Sale Certificate.

Name of Owner
Signature

Seal of the Firm / Company
Dated

FORM No. 10
[see rule 9(2)]

GOOD MANUFACTURING PRACTICES OR FREE SALE CERTIFICATE(S)

Certificate of Good Manufacturing Practices (GMP) / Free Sale Certificate to manufacturer of the Alternative Medicine/ Health Products/Baby Milks and Foods/Medicated Cosmetic products etc.

It is certified that manufacturing unit (enlistment holder or licensee), namely.....situated at.....Enlistment No. / Licence No.....complies with the requirements of Good Manufacturing Practices of medicines and health products as prescribed by the Authority under the Drug Regulatory Authority of Pakistan Act, 2012; or

2. The product namelyenlisted with the Authority *vide* enlistment No.....is on free sale in the local market.

3. This certificate shall not be construed as either an expressed or implied warranty of any of the named products or facility, nor shall it be used for advertising or other similar purposes.

This certificate is valid for a period of one year.

Date..... *Signature*.....
Place..... *Designation*.....

Designated Officer
Division of Health and OTC Products
Drug Regulatory Authority of Pakistan

FORM No. 11
[see rule 10(3)]

INVOICE OR WARRANTY

Invoice no.....dated.....20.....
to M/s.....situated at.....
It is certified that I Mr.....s/o
Mr.....having NIC No.....being
manufacturer or importer or (authorized agent *vide* authority letter
No.....dated.....on behalf of
M/s.....)

1. It is hereby certified that following finished products have been supplied by me, namely:-

S. No.	Total No. of items sold.				
	Name of product and pack size	Batch number (or lot No.)	No. of units sold	Distribution price	Retail price

Grant total.....

2. It is hereby certified and I undertake that above mentioned finished products of specified batch number (or lot number) supplied by me do not contravene any provision of the DRAP Act, 2012 and rules framed there under. The authorized agent (with valid distribution authority letter) shall pass on this warranty to the retailers in his area of jurisdiction during the supply of medicine and health products.

a.....

b.....

Date..... *Signature*.....

Place..... *Designation*.....

Seal of manufacture or /importer

FORM No. 12
[see rule 10(5)]

AUTHORITY LETTER TO THE AUTHORIZED AGENT

No.....dated.....

It is certified that Mr.....s/o
Mr.....having NIC No.....
Proprietor of M/s.....situated at
..... is hereby authorized as agent to
distribute and supply our products (list enclosed) and issue invoice warranty on our behalf within his area
of jurisdiction as stated below.

- a
- b

Date..... *Signature*.....
Place: *Designation*.....

Seal of manufacture or importer”.

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(ABDUL SAMAD KHAN)
Director (Health & OTC Products)
Division