



No. F. 3-3/2008 Reg-II-South (M-214)  
Government of Pakistan  
Ministry of Health  
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Islamabad, the 28<sup>th</sup> April, 2010

M/s Getz Pharma (Pvt.) Ltd;  
29-30, Sector 27, Korangi Industrial Area,  
**Karachi**

**SUBJECT: - REGISTRATION OF DRUGS UNDER SECTION 7 OF THE DRUGS ACT, 1976 AND RULES 28, 29 AND 30 OF THE DRUGS (LICENSING, REGISTERING AND ADVERTISING) RULES, 1976.**

The drug(s) as per details given below has/have been registered subject to the conditions appearing hereinafter.

S. No	Reg. No.	Name of drug(s) & Composition	Packing	MRP	Approved Shelf Life
1	061347	Claritek 250mg/5ml Dry Suspension Each 5ml contains:- Clarithromycin .....250 mg (USP Specifications)	■■■■■	■■■■■	Two Years

**CONDITIONS:-**

- (i) The drug(s) shall be manufactured in compliance to the provision of Drugs Act, 1976 and framed thereunder.
- (ii) Every drug shall be produced in sufficient quantity so as to ensure its regular and adequate supply in the market.
- (iii) The manufacture of any drug shall not without the prior approval of the Registration Board be discontinued for a period which may result in its shortage.
- (iv) Colour Scheme of the labels / cartons & packaging material should not resemble with any other drug(s) which has or have already been registered.
- (v) One of the complete method of testing of the finished drug(s) (containing full details of minor and major steps and protocols along with specifications, lower and upper limits) shall be submitted to the following institutions within a period of one month:-
  - Chief, Drugs Control & Research Division, National Institute of Health, Islamabad.
  - Director, Central Drug Laboratory, 7<sup>th</sup> Street, Defense Housing Society, Karachi.
  - Director, Drugs Testing Laboratory, 1-Birdwood Road, Lahore.
  - Director, Drugs Testing Laboratory, Sindh, Karachi.
  - Director, Drugs Testing Laboratory, N.W.F.P, Peshawar.
- (vi) One copy of the master formula (of all registered drug) containing the names of active and inactive materials (s) along with the quantities shall be furnished to the Assistant Drugs Controller concerned within a period of one month for which a receipt shall also be obtained.

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*[Signature]*  
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- (vii) The import of raw materials will be made at competitive rates in accordance with the Import Trade Control Order.
- (viii) The name shall be changed in case it has resemblance with already registered drugs.
- (ix) The registered drugs shall conform to the specifications of official pharmacopoeia. However, if the drug is not included in any of the pharmacopoeia, it shall conform to the manufacturer's specifications.
- (x) Other conditions as contained under the Drugs Act, 1976 and rules framed there under should be strictly adhere to.

  
For Secretary,  
Registration Board

Copy to:-

1. Provincial Health Secretaries of N.W.F.P., Punjab, Sindh & Balochistan
2. DDG (E&M) DCA, Karachi
3. DDC.(Pricing)
4. DDC (RRR)
5. PS to Secretary Health
6. Master file.
7. Company's file