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## PART II

Statutory Notifications (S.R.O.)

GOVERNMENT OF PAKISTAN  
Ministry of National Health Services, Regulations and Coordination  
Drug Regulatory Authority of Pakistan

## NOTIFICATION

*Islamabad, the 12th September, 2019*

**S.R.O. 1047(I)/2019.**— In exercise of the powers conferred by sub-section (1) of section 20 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) read with clause (n) of section 7 and clause (d) of section 11 thereof and sub-rule (2) of rule 3 of the Bio-study Rules, 2017, the Drug Regulatory Authority of Pakistan, with the approval of the Policy Board, is pleased to direct that the fee specified in column (3) of the Table below shall be payable in respect of the services specified in column (2) thereof, namely:--

TABLE

Sr.	Description of services	Fee (Rs.)
(1)	(2)	(3)
1	Grant of new license for Bioequivalence / Bioavailability Studies Center.	300,000/-
2	Grant of new license for Contract Research Organization.	300,000/-
3	Grant of new license for Bio-analytical Laboratory for Clinical Research.	300,000/-
4	Grant of new license for Clinical Trial Site.	100,000/-
5	Grant for approval and registration of Clinical Trials.	200,000/-
6	Grant of approval and registration of Bioequivalence / Bioavailability Study.	200,000/-
7	Grant of renewal of license for Bioequivalence / Bioavailability Studies Center, Contract Research Organization, Bio-analytical Laboratory for Clinical Research. (i) If applied before expiry of validity of license. (ii) If applied within 60 days of expiry of validity of license.	300,000/- 400,000/-
8	Grant of renewal of license for Clinical Trial Site. (i) If applied before expiry of validity of license. (ii) If applied within 60 days for expiry of validity of license.	100,000/- 150,000/-
9	Approval of amendment in already approved Clinical Trial or Bioequivalence / Bioavailability Study.	25,000/-
10	Miscellaneous requests.	25,000/-

[File No. 13-1/2017-DD(PS)(Pt.)]

AAMAR LATIF,  
Deputy Director (Legal Affairs).