

**GUIDELINES FOR REGISTRATION OF IMPORTED ENOXAPARINS APPROVED IN  
281<sup>ST</sup> MEETING**

For registration of Enoxaparins the applicants will provide following documents along with Form-5A:

- i. The physical and chemical characteristics of enoxaparin.
- ii. The nature of the heparin material and the chemical process used to break up heparin chains into smaller pieces.
- iii. The nature and arrangement of components that constitute enoxaparin.
- iv. Certain laboratory measurements of the product's anticoagulant activity
- v. Certain aspects of the drug's effect in humans.