



SQUARE PHARMACEUTICALS LIMITED  
DHAKA UNIT

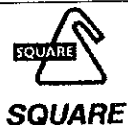
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**Certificate of Analysis (COA) for Working Standard**

Material : ENOXAPARIN SODIUM BP	Batch No. : 1000020603
Manuf. : Dongying Tiandong Biochemical	Date of Mfg : 21 Jul' 14
Supplier: Dongying Tiandong Biochemical	Expiry date of materials : 30 Jun' 17
Date of Analysis : 19 Jan' 15	Date of Expiry (as std.): 18 Jan' 17
Method of Analysis : UV (Thrombolyzer)	Ref. Spec. No : RMSP/QC/314/03
Reference standard : N/A	No. of Container : 24
Batch no of WS : N/A	Date of storage : 30 Mar' 15
Ref. Log Book : LB/QC/0055/15, Page No : 9	Storage Condition : 2 - 8 ° C

Tests	Specification	Results
1. Appearance	A White or almost white powder, Hygroscopic.	White powder, Hygroscopic
2. Identification	A. 13C NMR spectrum: Spectra of Test solution & Standard solution are similar. B. Assay test: Ratio of Anti-factor Xa activity and Anti-factor IIa activity is between 3.3 to 5.3; C. The weight-average molecular weight of Enoxaparin Sodium is between 3800 to 5000 Da; A molecular weight of less than 2000 Da, M(<2000): Is between 12.0% to 20.0%; A molecular weight between 2000 and 8000 Da, M(2000-8000): Is between 68.0% to 82.0%; D. Sodium test	A.[Complies]; B. Complies (ratio: 3.79); C. The weight-average molecular weight of Enoxaparin Sodium: 4272 Da Molecular weight of less than 2000 Da, M(<2000): 19.6%; Molecular weight between 2000 & 8000 Da, M(2000-8000): 74.37% D. Complies
3. Loss on drying	Not more than 10% w/w	3.86%
4. Benzyl alcohol content	Not more than 0.1%	0.008%

Prepared by:	Prepared by:	Approved by:
<i>As</i> 30 Mar '15	<i>Pina</i> 30 Mar '15	<i>H</i> 30 Mar '15
Abul Basar Md. Yeahea	Dr. Parimal Talukder	Dr. Md. Zahurul Hossain
Executive, QC	Manager, R&D	AGM, QA



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<b>5. Assay</b>	Anti-Factor Xa International Units (IU) per mg: Not less than 90 and not more than 125. Anti-Factor IIa IU Per mg: Not less than 20.0 and not more than 35.0 calculated on the dried basis.	Anti-Factor Xa IU per mg: 101.57 IU/mg (ODB); Anti-Factor Xa IU per mg: 97.65 IU/mg (As it is); Anti-Factor IIa IU per mg: 26.77 IU/mg (ODB); Anti-Factor IIa IU per mg: 25.74 IU/mg (As it is);
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Prepared by:	Checked by:	Approved by:
<i>As</i> 30 Mar'15	<i>Parimal</i> 30 Mar'15	<i>H</i> 30 Mar'15
Abul Basar Md. Yeahea	Dr. Parimal Talukder	Dr. Md. Zahurul Hossain
Executive, QC	Manager, R&D	AGM, QA