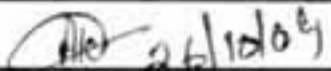
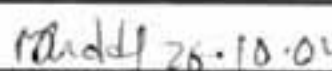





HETERO DRUGS LIMITED

(Unit - III, Formulations Division)

CERTIFICATE OF ANALYSIS

Product Name		ESTIVA 600		Mfg. Date	Jul'2004
				Exp. Date	Jun'2006
Generic Name		Efavirenz Tablets 600mg		Sampled on	19/10/2004
Batch No.	ET 40702	Batch Size	720	Reported on	26/10/2004
A R No	ETFP-274 -04	EXPORT	<input checked="" type="checkbox"/>	DOMESTIC	<input type="checkbox"/>
PRODUCT INFORMATION		Label Claim	Each film coated tablet contains EFAVIRENZ 600mg		
		Packing Mode: Blister <input type="checkbox"/>		Container <input checked="" type="checkbox"/>	
S.No	Tests	Specification			Results
01.	Description	White coloured, caplet shaped film coated tablets with break line on one side			Complies
02.	Identification	The Retention time of Major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the Standard preparation as obtained in the assay.			Complies
03.	Average Weight	959mg \pm 2%(limits:939.82mg to 978.18mg)			947.50 mg
04.	Uniformity of Weight	959mg \pm 5%(limits: 911.05mg to 1006.95mg)			Complies
05.	Moisture Content (by KF)	Not more than 6.0%			2.18%
06.	Thickness	6.9 mm to 7.4 mm			7.11 mm
07.	Tablet Size	(20.8 X 8.25) mm \pm 0.2 mm			20.84 X 8.27 mm
08.	Hardness	Not less than 4.0 kg/ cm ²			10.0 Kg/cm ²
09.	Disintegration Time	Not more than 30 minutes			00 min 38 sec
10.	Methylene chloride content (By GC as per USP)	Not more than 250 μ g/tab			Less than 1 μ g/tab
11.	Dissolution	Not less than 80% in 45 minutes			99.07%
12.	Related Substances Individual Impurity Total Impurities	Not more than 0.5% Not more than 1.5%			0.12% 0.21%
13.	Assay: Each film coated tablet contains Efavirenz 600mg	Not less than 570 mg/tab(95%) and Not more than 630mg/ tab (105%) of label claim.			598.47mg/ tab (99.75 %)
14.	Microbiological Quality a) Total Viable Aerobic Count: b) Fungi: c) Escherichia Coli:	Not more than 1000 cfu/gm Not more than 100 cfu/gm Absent/gm			20CFU Nil Absent
OPINION: The product Complies / Does Not Complies with regulatory specification and match the requirements as per IP/BP/USP/IHS standards					
		ANALYSED BY	CHECKED BY	APPROVEDBY	
NAME		A.KIRAN KUMAR	M.PRASAD REDDY	D.V.V.S.J.RAO	
DESIGNATION		Analyst-QC	Executive-QC	Manager -QC	
SIGN/DATE		 26/10/04	 26.10.04	 26.10.04	