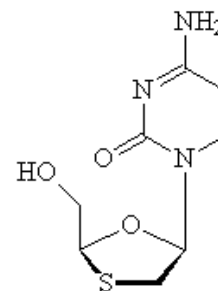


EFAVIRENZ

Globe Specification



Globe Reference:
CIPA 5010148

Formula	C ₁₄ H ₈ ClF ₂ NO ₂ Mr= 315,7
Action and use	Anti – retroviral
Characteristics	White to slightly pink crystalline powder.
Solubility	Conform
IDENTIFICATION	
. Infrared spectrum	Conform
. Specific rotation to 25°C	-89°C a -100°C
. Liquid chromatograph	Conform
. DCS	Conform
ESSAYS	
. Residue on ignition	Not more than 0.2 per cent
. Heavy metals	Not more than 0.002% (20 ppm)
. Loss on drying	Not more than 1,0 per cent
. Size of particles	90 per cent less than 20 µm and 50 per cent less than 6 µm
. Apparent density	Less than 0.20 g/ml
. Compressed density	Less than 0.25 g/ml
Related Substances:	
- Main	Not more than 0.20 per cent
- Individual impurity	Not more than 0.10 per cent
- Impurity total	Not more than 0.80 per cent
. Enantiomeric excess	Minimum 99.0 per cent
-	
ASSAY	
. Efavirenz in g by 100 g calculated in relation anhydrous substance	97,0 to 103,0 per cent
Storage Condition	Protect from heat and humidity keep drum in fresh air keep under ambient temp (15° to 30°)
Packaging	25 Kg fiber drum with double polyethylene bags



GLOBE QUÍMICA
TECHNOLOGICAL EXPERTISE

CERTIFICATE COMPANY IN GOOD MANUFACTURING
PRACTICES – GMP

GLOBE QUÍMICA S.A.

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FINE CHEMICALS