Wyeth

WYETH INDÚSTRIA FARMACÊUTICA LTDA		QUALITY AND COMPLIANCE OPERATION DIVISION
CERTIFICATE OF ANALYSIS		
PRODUCT: Lorazepam, USP		**CONTROLE:** MP0397/09
LOT NR.: 00027771	**MANUFACTURING DATE:** 07/2009	**EXPIRATION DATE:** 07/2014
TESTS	**SPECIFICATIONS**	**RESULTS**
- Physical Inspection	Crystalline powder, white or off-white.	Conform
- Solubility	Slightly soluble in alcohol, insoluble in water, sparingly soluble in chloroform.	Slightly soluble in alcohol, insoluble in water, sparingly soluble in chloroform.
- Cristalline Form (I.R.)	Positive	Positive
-Absortion UV	Positive	Positive
Particle size	50% less than 50 µm 95% less than 125 µm 98% less than 200 µm	100% less than 50 µm
- Residual Solvents - Cyclohexane	NMT 0.3%	Less than 0.3%
- Identification: A) FTIR B) TLC	 Positive Positive	 Positive Positive
- Related Compounds (HPLC) Related compound A	NMT 0,10%	0.00%
Related compound B	NMT 0.01% of 2-Amino-2.5-Dichlorobenzofenone	No detected
Related compound C	NMT 0.30%	0.29%
Related compound D	NMT 0.15%	No detected
Related compound E	NMT 0.15%	0.00%
Unspecified Individual Impurity	NMT 0.10%	No detected
Total Impurities	NMT 0.75%	0.29%
-Loss on Drying (105ºC/3h)	NMT 0.5%	0.1%
- Residue on Ignition	NMT 0.3%	0.1%
- Heavy Metals	NMT 0.002% (20ppm)	Less than 0.002% (20ppm)
- Assay	98.0 - 102.0% (anhydrous basis)	100.5% (anhydrous basis)
- Assay	99.0 - 101.0% (as is)	100.4% (as is)

Analysis accomplished in: 07/12/2009

Prepared by: Samantha R Costa 12/23/2009.

Confered by: Liana Gomes Oliveira 12/23/2009.