

PRODUCTO: IRBESARTAN

ITEMS	SPECIFICATIONS
APPEARANCE	White to off-white, crystalline powder
SOLUBILITY	Slightly soluble in alcohol and in methylene chloride, practically insoluble in water
IDENTIFICATION	<ul style="list-style-type: none"> a) Infrared absorption: the IR spectrum is consistent with that obtained with the reference b) The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation, as obtained in the assay
WATER	NMT 0.5%
LIMIT OF AZIDE	NMT 10 ppm
HEAVY METALS	NMT 0.002%
RELATED COMPOUNDS <ul style="list-style-type: none"> ➤ Compound A ➤ Any other impurity ➤ Total impurities 	<ul style="list-style-type: none"> NMT 0.2% NMT 0.1% NMT 0.5%
RESIDUAL SOLVENTS (GC) <ul style="list-style-type: none"> a) Ethanol b) Toluene c) t-Butyl methyl ether 	<ul style="list-style-type: none"> NMT 5000 ppm NMT 890 ppm NMT 5000 ppm
ASSAY (on the anhydrous basis)	98.0%~102.0%