



BIOEQUIVALENCE AND REGULATORY REQUIREMENTS FOR GENERIC PRODUCTS



CRITERIA		AGENCIES									
		US FDA	NMPA	TPD	EMA	TGA	ANVISA	WHO	ASEAN	PMDA (JAPAN)	GCC
DEMOGRAPHIC	AGE (YEARS)	18 YEARS OR OLDER	18 YEARS OR OLDER	18-55, INCLUSIVE	18 YEARS OR OLDER	18 YEARS OR OLDER	18 YEARS OR OLDER	18-55 YEARS	18-55 YEARS	NOT SPECIFIED, AS LONG AS SUBJECTS ARE ASSESSED TO BE HEALTHY	18-55 YEARS
	SEX	BOTH SEXES	BOTH SEXES. A SIMILAR PROPORTION OF EITHER SEX*	BOTH SEXES	EITHER SEX	EITHER SEX	EITHER SEX. SIMILAR PROPORTIONS OF MALES AND FEMALES BETWEEN THE SEQUENCES IN SOME DRUG PRODUCTS	BOTH SEXES	EITHER SEX		EITHER SEX
	SMOKING	NOT SPECIFIED, DEPENDING ON THE POPULATION #	PREFERABLE TO INCLUDE NON-SMOKERS	PREFERABLE TO INCLUDE NON-SMOKERS	PREFERABLE TO INCLUDE NON-SMOKERS	PREFERABLE TO INCLUDE NON-SMOKERS	PREFERABLE TO INCLUDE NON-SMOKERS	PREFERABLE TO INCLUDE NON-SMOKERS	PREFERABLE TO INCLUDE NON-SMOKERS		PREFERS NON-SMOKERS
MINIMUM SAMPLE SIZE		12	TYPICALLY 18-24	12	12	12	12 OR 24 IN THE ABSENCE OF ISCV DATA	12	12	A SUFFICIENT NUMBER SHOULD BE INCLUDED	18
PARENT DRUG /METABOLITE		PARENT COMPOUND. PRIMARY METABOLITE MAY ALSO BE USED*	PARENT COMPOUND. PRIMARY METABOLITE(S) MAY ALSO BE USED *	PARENT COMPOUND. PRODRUG PRIMARY ACTIVE METABOLITES MAY ALSO BE USED*	PARENT COMPOUND. PRIMARY ACTIVE METABOLITES MAY ALSO BE USED*	PARENT COMPOUND. PRIMARY ACTIVE METABOLITES MAY ALSO BE USED*	PARENT COMPOUND. METABOLITE CAN ALSO BE USED*	PARENT COMPOUND. PRIMARY ACTIVE METABOLITE MAY BE USED*	PARENT COMPOUND. PRIMARY ACTIVE METABOLITES MAY BE USED*	PARENT COMPOUND. PRIMARY ACTIVE METABOLITE MAY BE USED*	PARENT COMPOUND. PRIMARY ACTIVE METABOLITES MAY BE USED*
STUDY CONDITIONS (USING IR AS EXAMPLE)*		FA + FED	FA + FED	FA	FA	FA	FA	FA	FA	FA	FA

* EXCEPTIONS MAY BE APPLIED FOR SPECIFIC FORMULATIONS/CASES. PLEASE CONTACT BIOPHARMA SERVICES PK TEAM FOR MORE INFORMATION