

3.2.P.5.3 Validation of Analytical Procedures (Ketosteril, film-coated tablets)

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Test	Title of the analytical method	Validations
Dissolution (Release of calcium)	Add. to Ph. Eur. 2.9.3 Dissolution of Ketosteril Film-Coated Tablets	Validation of Dissolution Test and Determination of Calcium in Ketosteril Tablets
	in-house method (GTM-006) Quantitative Determination of Calcium by Atomic Absorption Spectrometry	
Identification Quinoline yellow E 104	in-house method Qualitative Determination of Quinoline yellow E 104	Validation Report for the Qualitative Determination (Identification) of Quinoline Yellow E 104
Assay α -Ketoisoleucine, calcium salt α -Ketoleucine, calcium salt α -Ketovaline, calcium salt α -Ketophenylalanine, calcium salt α -Hydroxymethionine, calcium salt	in-house method (GTM-304) Quantitative Determination of Keto- and Hydroxy Acids by High Performance Liquid Chromatography (HPLC)	Quantitative Determination of Keto and Hydroxy Acids in Ketosteril Film-Coated Tablets by High Performance Liquid Chromatography (HPLC)
Assay Lysine acetate Threonine Histidine Tyrosine Tryptophan	in-house method Quantitative Determination of Lysine Acetate, Threonine, Histidine, Tyrosine and Tryptophan by High Performance Liquid Chromatography (HPLC)	Validation Report for Determination of Amino Acids in Ketosteril Film-Coated Tablets by High Pressure Liquid Chromatography (HPLC)
	in-house method Quantitative Determination of Amino acids by Ultra Performance Liquid Chromatography (UPLC)	Quantitative Determination of Amino Acids in Ketosteril Film-Coated Tablets by Ultra Performance Liquid Chromatography (UPLC)
Assay Calcium	Add. to Ph. Eur. 2.2.20 Quantitative Determination of Calcium by Complexometric Retitration	Validation Report for the Content Assay of Calcium in Ketosteril Film-Coated Tablets
Residual solvent (isopropyl alcohol)	in-house method Quantitative Determination of 2-Propanol by Gas Chromatography (GC)	Determination of Residual Solvent 2-Propanol in Ketosteril Film-Coated Tablets

Method validation reports are provided on the following pages.