P.5 CONTROL OF DRUG PRODUCT

P.5.1 SPECIFICATION(S) FOR DRUG PRODUCT

Test procedure	Acceptance criteria		Method reference
	Release	End of shelf life	
Description	An orange film-coated tablet, debossed with 175 on one side	As for release	Visual inspection
Identification[a]	Consistent with the retention time and UV spectrum of the reference standard	As for release	ID by UHPLC
Assay	95% to 105% of label claim	As for release	Assay by UHPLC
Degradation products			
Impurity 1	NMT 0.2% w/w	NMT 0.8% w/w	Degradation products by UHPLC
Impurity 2	NMT 0.3% w/w	NMT 0.4% w/w	
Impurity 3	NMT 0.3% w/w	NMT 0.4% w/w	
Individual unspecified degradation products	NMT 0.2% w/w	As for release	
Total degradation products	NMT 1.4% w/w	NMT 2.3% w/w	
Dissolution	Shall comply with the requirements of the harmonised USP/JP/Ph Eur Q=80% at 30 minutes	As for release	Apparatus 2 (paddles), UV measurement
Uniformity of dosage units[a]	Shall comply with the requirements of the harmonised USP/JP/Ph Eur	As for release	Weight variation
Microbiological quality	Shall comply with the requirements of the Ph Eur	As for release	Ph Eur
Water Content	NMT 1.0%	NMT 2.0%	USP <921>

[a] This test is not applied to the analysis of stability samples but would meet the specification criterion if tested.

NMT Not more than.