m2

DTC_S020098_PF_N_SPE_50520_EN_3.0 1/2 SPECIFICATIONS OF THE DRUG PRODUCT

Tests	Release specifications	Shelf-life specifications
Appearance	Orange-yellow, oblong, film-coated tablets	Orange-yellow, oblong, film-coated tablets
Identification of drug substance . Liquid chromatography . Thin-layer chromatography	The ratio of the retention times of the drug substance peak from the test solution and from the reference solution must be between 0.97 and 1.03. Main spot identical in position, colour and size for test and reference	The ratio of the retention times of the drug substance peak from the test solution and from the reference solution must be between 0.97 and 1.03. Main spot identical in position, colour and size for test and reference
Average mass (mg)	127.8 to 150.2 (95 % to 105 % of theoretical mass of 134.5 mg)	127.8 to 141.2 (95 % to 105 % of theoretical mass of 134.5 mg)

Microbiological quality (skip testing) . Total aerobic microbial count (TAMC): ■ 1000 CFU/g . Total aerobic microbial count (TAMC): ■ 1000 CFU/g European Pharmacopoeia (5.1.4., non-aqueous . Total combined yeasts/moulds count . Total combined yeasts/moulds count (TYMC):

Microbiological quality (skip testing) European Pharmacopoeia (5.1.4., non-aqueous preparations for oral use)	. Total aerobic microbial count (TAMC): ■ 1000 CFU/g Total combined yeasts/moulds count (TYMC): ■ 100 CFU/g . Escherichia Coli: absence/1 g	. Total aerobic microbial count (TAMC): ■ 1000 CFU/g . Total combined yeasts/moulds count (TYMC): ■ 100 CFU/g . Escherichia Coli: absence/1 g

Tests (cont'd)	Release specifications (cont'd)			Shelf-life specifications (cont'd)		
Drug substance content (LC) (mg/tablet)	23.75 to 26.25 (95 % to 105 % of the theoretical content)			23.75 to 26.25 (95 % to 105 % of the theoretical content)		
Degradation products (LC) (% m/m): . individual content of any degradation product . total content of degradation products	■ 0.2 % ■ 0.5 %			■ 0.2 % ■ 0.5 %		
Uniformity of content (LC) (%/label claim)	Stage	Number tested	Acceptance criteria	Stage	Number tested	Acceptance criteria
	S1	10	AV ■ 15.0 %	S1	10	AV ■ 15.0 %
	S21	+ 20 (30)	AV ■ 15.0 % 0.75 M ■ each unit ■ 1.25 M	S21	+ 20 (30)	AV ■ 15.0 % 0.75 M ■ each unit ■ 1

Kinetics of dissolution (UV) (%) Q = 80 % at 45 min Q = 80 % at 45 min Number Number

Kinetics of dissolution (UV) (%)	Q = 80 % at 45 min			Q = 80 % at 45 min		
	Stage	Number tested	Acceptance criteria	Stage	Number tested	Acceptance criteria
	S1	6	Each unit is not less than 85 %.	S1	6	Each unit is not less than 85 %.
	S22	+ 6 (12)	Average of 12 units (S1+S2) is equal to or greater than 80 % and no unit is less than 65 %.	S22	+ 6 (12)	Average of 12 units (S1+S2) is equal to or greater than 80 % and no unit is less than 65 %.