

ref

DTC_S020098_PF_N_SPE_50520_EN_3.0 1/2

SPECIFICATIONS OF THE DRUG PRODUCT

S 20098

Film-coated tablets containing 25 mg of drug substance

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 The ratio of the retention times of the drug substance peak
The ratio of the retention times of the drug substance peak

from the test solution and from the reference solution from the test solution and from the reference solution

must be between 0.97 and 1.03. must be between 0.97 and 1.03.

- thin-layer chromatography Main spot identical in position, colour and size for test
Main spot identical in position, colour and size for test

and reference and reference

Average mass (mg) 127.8 to 150.2 (95 % to 105 % of theoretical mass of 127.8 to 141.2 (95 % to 105 % of theoretical mass of

134.5mg) 134.5mg)

Microbiological quality (skip testing) .Total aerobic microbial count (TAMC): ■1000CFU/g
.Total aerobic microbial count (TAMC): ■1000CFU/g

European Pharmacopoeia(5.1.4., non-aqueous .Total combined yeasts/moulds count (TYMC):
.Total combined yeasts/moulds count (TYMC):

preparations for oral use) ■100CFU/g ■100CFU/g

- *Escherichia Coli*: absence/1g .*Escherichia Coli*: absence/1g
(following next page) .../...

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 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 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 141.2 (95 % to 105 % of theoretical mass of 134.5mg)	127.8 to 141.2 (95 % to 105 % of theoretical mass of 134.5mg)
Microbiological quality (skip testing) European Pharmacopoeia(5.1.4., non-aqueous preparations for oral use)	.Total aerobic microbial count (TAMC): ■100CFU/g .Total combined yeasts/moulds count (TYMC): ■100CFU/g .Escherichia Coli: absence/1g	.Total aerobic microbial count (TAMC): ■100CFU/g .Total combined yeasts/moulds count (TYMC): ■100CFU/g .Escherichia Coli: absence/1g

DTC_S020098_PF_N_SPE_50520_EN_3.0 2/2

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 ■0.2% ■0.2%
- Total content of degradation products ■0.5% ■0.5%

Uniformity of content (LC)

Number Number

Stage Acceptance criteria Stage Acceptance criteria

(%/label claim) tested tested

S1 10 AV ■15.0% S1 10 AV ■15.0%

AV ■15.0% AV ■15.0%

S21 + 20 (30) S21 + 20 (30)

0.75 M ■ each unit ■ 1.25 M 0.75 M ■ each unit ■ 1.25 M

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

Number Number

Stage Acceptance criteria Stage Acceptance criteria

tested tested

S1 6 Each unit is not less than 85%. S1 6 Each unit is not less than 85%.

Average of 12units (S1+S2) is Average of 12units (S1+S2) is

S22 + 6 (12) equal to or greater than 80% and S22 + 6 (12) equal to or greater than 80% and

no unit is less than 65%. no unit is less than 65%.

AV: Acceptance value

M: Reference value

1: S2 must be carried out if the acceptance value for the ten tablets tested in S1 is higher than 15.0%.

2: S2 must be carried out as soon as one unit out of the six tablets tested in S1 is less than 85%

Tests (cont'd) Release specifications (cont'd)				Shelf-life specifications (cont'd)		
Drug substance	Content (% m/m)	Acceptance criteria	Number tested	Content (% m/m)	Acceptance criteria	Number tested
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	S21 ■ 1.25 M	+ 20 (30)	AV ■ 15.0% 0.75 M ■ each unit ■ 1.25 M
Kinetics of dissolution	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 + 6 (12) 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%.	