d30

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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

from the test solution and from the reference solution

must be between 0.97 and 1.03.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.

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

and referenceMain 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)

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):

≤100CFU/g

.Escherichia Coli : absence/1 g.Total aerobic microbial count (TAMC): ≤1000 CFU/g

.Total combined yeasts/moulds count (TYMC):

≤100CFU/g

.Escherichia Coli : absence/1 g

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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)

(%/label claim)StageNumber

testedAcceptance criteria StageNumber

testedAcceptance criteria

S1 10 AV ≤15.0 % S1 10 AV ≤15.0 %

S21+ 20 (30)AV ≤15.0 %

0.75 M ≤each unit ≤1.25 MS21+ 20 (30)AV ≤15.0 %

0.75 M ≤each unit ≤1.25 M

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

StageNumber

testedAcceptance criteria StageNumber

testedAcceptance 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 %.

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 %.