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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):

≤ 100 CFU/g

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

.Total combined yeasts/moulds count (TYMC):

$\leq 100 \text{ CFU/g}$

.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 $\leq 0.2\%$ $\leq 0.2\%$

.total content of degradation products $\leq 0.5\%$ $\leq 0.5\%$

Uniformity of content (LC)

(%/label claim) Stage Number

tested Acceptance criteria Stage Number

tested Acceptance criteria

S1 10 AV $\leq 15.0\%$ S1 10 AV $\leq 15.0\%$

S2 1+ 20 (30) AV $\leq 15.0\%$

$0.75 \text{ M} \leq \text{each unit} \leq 1.25 \text{ M}$ S2 1+ 20 (30) AV $\leq 15.0\%$

$0.75 \text{ M} \leq \text{each unit} \leq 1.25 \text{ M}$

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 %.

S2 2+ 6 (12) Average of 12 units (S1+S2) is

equal to or greater than 80% and

no unit is less than 65 %.S2 2+ 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 doit être effectué si la valeur d'acceptation pour les dix tablettes testées dans S1 est supérieure à 15,0 %.

2: S2 doit être effectué dès que l'une des six tablettes testées dans S1 est inférieure à 85 %.