



Shionogi Pharma Co., Ltd.

1-3, Kuise Terajima 2-chome,
Amagasaki, Hyogo 660-0813, Japan

Certificate of Analysis

Date of Issue : March 23, 2022

Issue No. : PA-22023S

Article : S-033188 Tablets 20mg

Manufacturer : Shionogi Pharma Co., Ltd. Settsu Plant

Address : 5-1, Mishima 2-chome, Settsu, Osaka 566-0022, Japan

TEL : +81-6-6381-7341

Lot No. : S22009

Date of Manufacture : February 21, 2022

Specification No. : 10(1AN)0500D

Test Item	Acceptance Criteria (Release Spec.)	Result
Description	White to light yellow, oblong shaped film-coated tablets.	White oblong shaped film-coated tablets
Identification (HPLC/PDA)	Retention time of the main peak from the sample solution is consistent with the retention time of the main peak from the standard solution. UV spectra of the main peak from the sample solution and the standard solution exhibit similar intensities of absorption at the same wavelength.	Conforms
Purity Test Related Substances	S199YM : Not more than 0.3% S-033447 : Not more than 2.0% S199BE : Not more than 0.4% Individual others : Not more than 0.2% Total except S-033447 : Not more than 2.0%	S199YM : 0.0% S-033447 : 0.2% S199BE : 0.1% Individual others (largest) : 0.0% Total except S-033447 : 0.1%
Water	Not more than 6.5%	4.4%
Uniformity of Dosage Units (JP General Test/USP/Ph.Eur.)	JP/USP/Ph.Eur. Uniformity of Dosage Units	Conforms (Acceptance value: 2.5%)
Microbial Limit (JP General Test/USP/Ph.Eur.)	Microbial Enumeration: TAMC: acceptance criterion 10^3 CFU/g TYMC: acceptance criterion 10^2 CFU/g Specified Microorganisms: <i>Escherichia coli</i> : Negative	Microbial Enumeration TAMC: < 10 CFU/g TYMC: < 10 CFU/g Specified Microorganisms <i>Escherichia coli</i> : Negative
Dissolution Test (JP General Test/USP/Ph.Eur.)	Q values: 80% (30 minutes)	Conforms (Average amount dissolved: 95%, Range: 94 to 96%)
Content	95.0 to 105.0%	101.0%
Judgment	Accepted	
Date of Judgment	March 23, 2022	

Quality Control Manager for IMP (Settsu)

Signature :

Akari Omori

Akari Omori

Quality Assurance Manager for IMP (Settsu)

Signature :

Shiroe Shichin

Date :

March 24, 2022

Order No. CMC20210053 (SHIONOGI & CO., LTD, December 7, 2021)

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QC STAFF

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