Revised: May 2022 (8th version, Section of Adverse Reactions)
Revised: February 2021 (7th version)

Antiplatelet Agent

ASPIRIN ENTERIC-COATED TABLETS 100mg "TOWA"

Storage:
Store at room temperature.
Expiration date:
Indicated on the package and label.

Standard Commodity Classification No. of Japan 873399	
Approval No.	22000AMX01416
Date of listing in the NHI reimbursement price	July 2008
Date of initial marketing in Japan	July 2008

CONTRAINDICATIONS (Aspirin Enteric-coated Tablets is contraindicated in the following patients.)

1) Patients with a history of hypersensitivity to any of the ingredients of this product, or salicylic acid preparations
2) Patients with peptic ulcer(s) [The inhibitory action of this product on prostaglandin biosynthesis reduces gastric blood flow, which may aggravate peptic ulcer(s). (Regarding patients with a history of peptic ulcer(s), see "Careful Administration".)]
3) Patients with a bleeding tendency [Since this product may cause abnormal platelet function, the bleeding tendency may be heightened.]
4) Patients with current or a history of aspirin asthma (asthmatic attacks induced by nonsteroidal anti-inflammatory drugs or such) [Serious aspirin-induced asthmatic attacks may occur.]
5) Pregnant women within 12 weeks before the expected delivery date (See "Use during Pregnancy, Delivery or Lactation".)
6) Low birth weight infants, neonates, nursing infants (See "Pediatric Use".)

CONPOSITION AND PRODUCT DESCRIPTION

Active ingredient per tablet	Aspirin (Japanese Pharmacopoeia) ····· 100mg		
Inactive ingredient	Microcrystalline Cellulose, Corn Starch, Carmellose, Magnesium Aluminometasilicate, Methacrylic Acid Copolymer LD, Sodium Lauryl Sulfate, Polysorbate 80, Triethyl Citrate, Talc		
Product description	White film-coated tablets		
Identification code	Tablet	Tw206	
	Package		
Appearance	Top surface	Bottom surface	Side surface
			
Diameter (mm)	7.3		
Thickness (mm)	3.2		
Weight (mg)	139		

INDICATION

- Suppression of thrombus/embolus formation in the following diseases:
  Angina pectoris (chronic stable angina pectoris, unstable angina pectoris)
  Myocardial infarction
  Ischemic cerebrovascular disorder (transient ischemic attack (TIA), cerebral infarction)
- Suppression of thrombus/embolus formation after coronary artery bypass grafting (CABG) or percutaneous transluminal coronary angioplasty (PTCA)
- Kawasaki's disease (including cardiovascular scquclac due to Kawasaki's disease)

DOSAGE AND ADMINISTRATION

- For suppression of thrombus/cmbolus formation in angina pectoris (chronic stable angina pectoris, unstable angina pectoris), myocardial infarction, and ischemic cerebrovascular disorders (transient ischemic attack [TIA], cerebral infarction) or for suppression of thrombus/embolus formation after coronary artery bypass grafting (CABG) or percutaneous transluminal coronary angioplasty (PTCA)
  The usual adult dosage for oral use is 100 mg of aspirin once daily.
  The dose may be increased up to 300 mg according to symptoms.
- For Kawasaki's disease (including cardiovascular sequelae due to Kawasaki's disease)
  For patients with pyrexia during the acute phase of the disease, 30 to 50 mg/kg (body weight)/day of aspirin is administered orally in 3 divided doses. For patients not presenting with pyrexia during the convalescent phase to chronic phase, 3 to 5 mg/kg (body weight)/day of aspirin is administered orally once daily.
  The dosage may be adjusted according to the patient's symptom.

[PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION]

1) If immediate onset of the antiplatelet effect of this product is required in the initial treatment of acute myocardial infarction and acute-phase cerebral infarction, this product for the initial dose must be crushed before it is placed in the mouth or it must be chewed if possible.
2) Administration of this product at a dose several times higher than the specified dose is recommended as the initial treatment for patients with myocardial infarction and patients who underwent percutaneous transluminal coronary angioplasty (PTCA).
3) It is recommended that administration of this product be started as soon as a diagnosis of Kawasaki's disease has been established.
4) Since increased platelet aggregation activity is observed for several months after the onset of Kawasaki's disease, this product should be administered for 2 to 3 months after the disease onset including the convalescent phase. If no coronary artery disorder is found in coronary artery

tests such as two-dimensional echocardiography, administration of this product should be discontinued. For patients with coronary artery aneurysm(s), continuation of this product is recommended until the regression of such aneurysm(s) is confirmed.

5) In the treatment of Kawasaki's disease, platelet function may not sufficiently be suppressed by low-dose administration of this product. Therefore, the measurement of platelet aggregation activity should be considered as appropriate.

PRECAUTIONS

1. Careful Administration

(Aspirin Enteric-coated Tablets should be administered with care in the following patients.)

1) Patients with a history of peptic ulcer [Recurrence of peptic ulcer may occur.]
2) Patients with current or a history of blood abnormalities [Exacerbation or recurrence of blood abnormalities may occur.]
3) Patients with a predisposition to bleeding tendency [Bleeding may be worsened.]
4) Patients with current or a history of liver disorders [Liver disorders may worsen or recur.]
5) Patients with current or a history of renal disorders [Renal disorders may worsen or recur.]
6) Patients with bronchial asthma [Some patients with bronchial asthma may also have aspirin asthma, and thus this product may induce serious asthma attacks in such patients.]
7) Patients with the habit of daily alcohol intake [Coadministration of this product with alcohol may induce or increase hemorrhage of the digestive tract (See "Drug Interactions").]
8) Elderly patients [See "Use in the Elderly".]
9) Pregnant women (However, this drug is contraindicated in pregnant women within 12 weeks of the expected delivery date.) or women who may be pregnant (See "Use during Pregnancy, Delivery or Lactation.")
10) Pediatric patients [See "Pediatric Use".]
11) Patients who are scheduled to receive surgery, cardiac catheterization or tooth extraction within one week [This product may increase the amount of blood loss during surgery, cardiac catheterization or tooth extraction.]
12) Patients with peptic ulcer due to a long-term administration of nonsteroidal anti-inflammatory drugs requiring a long-term administration of this product and being treated with misoprostol [While misoprostol is indicated to peptic ulcer caused by nonsteroidal anti-inflammatory drugs, some peptic ulcers may show resistance to misoprostol. Therefore, administration of this product should be continued carefully with close monitoring the course.]

2. Important Precautions

1) Although actual use condition of salicylic acid preparations differs from Japan, there are epidemiological study reports showing relationship between salicylic acid preparations and **Reye's syndrome** in the U.S. Therefore, **in principle, this product should not be administered to a patient younger than 15 years old with chickenpox and influenza**. When this product is necessarily administered to such patient, it should be carefully administered and the patient's conditions should be closely monitored after administration. [Reye's syndrome: a pathology with a high mortality rate, which is preceded with viral disease such as chickenpox and influenza and symptoms such as violent vomiting, disturbance of consciousness, convulsion (acute cerebral edema), fat deposition in the liver and other organs, mitochondrial deformation, sharp increases in AST (GOT), ALT (GPT), LDH and CK (CPK), hyperammonemia, hypoprothrombinemia and hypoglycemia very rarely develop in a short period of time in children.]
2) When this product is administered to patients with cerebral infarction, attention should be paid to interactions with other drugs that inhibit platelet aggregation. In addition, this drug should be administered carefully to patients with persistent hypertension, during which time adequate blood pressure control should be performed (see "Drug Interactions").
3) During treatment with this product for acute-phase Kawasaki's disease, liver function tests should be performed as appropriate. If any abnormalities are observed, appropriate measures should be taken, **including dose reduction and treatment interruption**.
4) During long-term treatment with this product for patients with Kawasaki's disease (including cardiovascular sequelae due to Kawasaki's disease), laboratory tests (including urine analysis, and blood and liver function tests) should be performed periodically. If any abnormalities are observed, appropriate measures should be taken, **including dose reduction and treatment interruption**.

3. Interactions

Precautions for coadministration (Aspirin Enteric-coated Tablets should be administered with care when coadministered with the following drugs.)

Drugs	Signs, Symptoms and Treatment	Mechanism and Risk Factors
Anticoagulants Coumarin anticoagulants Warfarin potassium	Coadministration of this product with coumarin anticoagulants may increase the effects of such anticoagulants, leading to prolonged bleeding time, hemorrhage of the digestive tract and such; therefore, these drugs should be carefully coadministered, during which time caution should be exercised, including dose reduction of coumarin anticoagulants.	This product replaces and liberates coumarin anticoagulants bound to plasma proteins. This product also has the effects to inhibit platelet aggregation and bleed by stimulating the digestive tract.

Drugs	Signs, Symptoms and Treatment	Mechanism and Risk Factors
Anticoagulants Blood coagulation inhibitors Heparin preparations Danaparoid sodium Factor Xa inhibitors Rivaroxaban etc. Antithrombin agents Dabigatran etexilate methanesulfonate etc. Thrombomodulin alfa etc.	Coadministration of this product with these drugs may increase the risk of bleeding; thus, caution should be exercised with close monitoring.	Since this product has the effect to inhibit platelet aggregation, coadministration with these drugs may lead to increased bleeding tendency.
Drugs with the effect to inhibit platelet aggregation Ticlopidine hydrochloride Cilostazol Clopidogrel sulfate Thromboxane synthase inhibitors Ozagrel sodium Prostaglandin E_1 preparations, E_1 and I_2 derivatives Beraprost sodium etc. Sarpogrelate hydrochloride Ethyl Icosapentate etc.	Coadministration of this product with these drugs may increase the risk of bleeding; thus, caution should be exercised with close monitoring.	Since this product has the effect to inhibit platelet aggregation, coadministration with these drugs may lead to increased bleeding tendency.
Thrombolytics Urokinase t-PA preparations etc.		
Antidiabetic agents Human insulin Tolbutamide etc.	Coadministration of this product with antidiabetic agents may enhance the effects of these agents, causing hypoglycemia; therefore, these drugs should be carefully coadministered, during which time caution should be exercised, including dose reduction of antidiabetic agents.	This product (administered at a high dose) replaces and liberates antidiabetic agents bound to plasma proteins. High-dose administration of this product exerts a hypoglycemic effect.
Methotrexate	Adverse reactions to methotrexate (e.g., bone marrow depression, hepatic/renal/ gastrointestinal disorders) may increase in frequency and severity.	This product (administered at a high dose) replaces and liberates methotrexate bound to plasma proteins. This product is also considered to inhibit the renal excretion of methotrexate.
Sodium valproate	Coadministration of this product with sodium valproate may enhance the effect of sodium valproate, resulting in tremors or such.	This product (administered at a high dose) replaces and liberates sodium valproate bound to plasma proteins.

Drugs	Signs, Symptoms and Treatment	Mechanism and Risk Factors
Phenytoin	It has been reported that coadministration of this product with phenytoin lowers total phenytoin concentration but does not lower unbound phenytoin levels. If dose increase is performed based on total phenytoin concentration, clinical symptoms and such should be carefully monitored.	This product (administered at a high dose) replaces and liberates phenytoin bound to plasma proteins.
Corticosteroids Betamethasone Prednisolone Methylprednisolone etc.	It has been reported that dose reduction of corticosteroids during coadministration with this product (at a high dose) leads to salicylism. Coadministration of this product with corticosteroids may also increase hemorrhage of the digestive tract.	Mechanism unknown
Lithium preparations	Coadministration of this product with lithium has been reported to cause lithium poisoning.	This product (administered at a high dose) inhibits renal prostaglandin biosynthesis and reduces renal blood flow, which may result in decreased renal excretion of lithium.
Thiazide diuretics Hydrochlorothiazide etc. Loop diuretics Furosemide	Coadministration of this product with these drugs has been reported to decrease the effects of these drugs.	This product inhibits renal prostaglandin biosynthesis, leading to retention of water and salts in the body. This is considered to antagonize the effect of diuretics to excrete water and salts.
Beta-blockers Propranolol hydrochloride Pindolol etc. Angiotensin-converting-enzyme (ACE) inhibitors Enalapril maleate etc.	Coadministration of this product with these drugs has been reported to decrease the effects of these drugs.	This product is considered to inhibit the biosynthesis and release of renal prostaglandins with vasodilating action, thereby increasing blood pressure.
Nitroglycerin preparations	Coadministration of this product with nitroglycerin may decrease the effect of nitroglycerin.	This product is considered to constrict coronary arteries by inhibiting prostaglandin biosynthesis, thereby decreasing the action of nitroglycerin.
Uricosuric agents Probenecid Benzbromarone	Coadministration of this product with these drugs may decrease the effects of these drugs.	This product (administered at a high dose) antagonizes the uricosuric effects of these drugs.
Nonsteroidal anti-inflammatory antipyretic analgesics Indometacin Diclofenac sodium etc.	Coadministration of this product with these drugs may cause hemorrhage and decreased renal function.	Mechanism unknown

Drugs	Signs, Symptoms and Treatment	Mechanism and Risk Factors
Ibuprofen Naproxen Piroxicam Sulpyrine	Coadministration of this product with these drugs has been reported to decrease the inhibitory effect of this product on platelet aggregation.	Decreased platelet aggregation may occur due to the inhibition of these drugs against the binding of this product to cyclooxygenase-1 (COX-1) in platelets.
Carbonic anhydrase inhibitors Acetazolamide etc.	Coadministration of this product with acetazolamide has been reported to increase the frequency and severity of adverse reactions to acetazolamide, leading to central nervous system symptoms such as lethargy and confusion, metabolic acidosis and such.	This product replaces and liberates acetazolamide bound to plasma proteins.
Donepezil hydrochloride	Coadministration of this product with this drug may cause peptic ulcers.	The cholinergic system is activated, and gastric acid secretion is promoted.
Tacrolimus hydrate Cyclosporine	Coadministration of this product with these drugs may cause renal disorders.	Renal disorders as adverse reactions may be mutually intensified.
Zafirlukast	Coadministration of this product with zafirlukast may lead to increased plasma concentrations of zafirlukast.	Mechanism unknown
Prostaglandin D_2, thromboxane A_2 receptor antagonists Ramatroban Seratrodast	Drug interaction studies (*in vitro*) to investigate human plasma protein binding have demonstrated that unbound fractions of these drugs may increase after coadministration with this product.	It is considered that this product replaces these drugs at the plasma protein binding site, which leads to increased blood concentrations of unbound drugs.
Selective serotonin reuptake inhibitors (SSRIs) Fluvoxamine maleate Sertraline hydrochloride etc.	Abnormal skin hemorrhages (e.g., ecchymosis, purpura) and hemorrhage symptoms (e.g., gastrointestinal hemorrhage) have been reported.	SSRIs inhibit platelet aggregation, and thus coadministration of SSRIs with this product is considered to increase bleeding tendencies.
Alcohol	Hemorrhage of the digestive tract may increase.	Gastric mucosal disorder due to alcohol intake and the inhibitory effect of this product on prostaglandin biosynthesis are considered to additively increase hemorrhage of the digestive tract.

4. Adverse Reactions

No investigation such as a post-marketing surveillance clearly showing the incidence of adverse reactions has been conducted.

1) Clinically significant adverse reactions (incidence unknown)

(1) **Shock, anaphylaxis**: Shock or anaphylaxis (dyspnea, generalized flushing, angioedema, urticaria, etc.) may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this product should be discontinued and appropriate measures should be taken.

(2) **Hemorrhages**:
Intracranial hemorrhage such as cerebral hemorrhage: Intracranial hemorrhage such as cerebral hemorrhage may occur (initial symptoms: headache, nausea/vomiting, consciousness disturbed, hemiplegia, etc.). Patients should be closely monitored, and if any such symptoms are observed, administration of this product should be discontinued, and appropriate treatment should be given.
Pulmonary hemorrhage, hemorrhage of the digestive tract, epistaxis, bleeding of the ocular fundus, etc.: Pulmonary hemorrhage, hemorrhage of the digestive tract, epistaxis, bleeding of the ocular fundus and such may occur. Patients should be closely monitored, and if any such symptoms are observed, administration of this product should be discontinued, and appropriate treatment should be given.

(3) **Toxic Epidermal Necrolysis: TEN, Mucocutaneo-ocular syndrome (Stevens-Johnson syndrome) , Exfoliative dermatitis**: Toxic epidermal necrolysis, mucocutaneo-ocular syndrome (Stevens-Johnson syndrome) or exfoliative dermatitis may occur. Patients should be carefully monitored, and if such symptoms occur, administration of this product should be discontinued and appropriate measures should be taken.

(4) **Aplastic anemia, Thrombocytopenia, leukocytopenia**: Aplastic anemia, thrombocytopenia or leukocytopenia may occur. Patients should be carefully monitored, and if any abnormalities are observed, administration of this product should be discontinued and appropriate measures should be taken.

(5) **Asthma attack:** Asthma attack may be induced.

(6) **Hepatic dysfunction, jaundice**: Hepatic dysfunction or jaundice associated with remarkably increased AST (GOT), ALT (GPT), or γGTP may occur. Patients should be carefully closely monitored, and if any abnormalities are observed, appropriate measures such as discontinuation of treatment should be taken.

(7) **Peptic ulcers, small/large intestine ulcers:** Peptic ulcers such as gastric/duodenal ulcers associated with melena may occur. Small/large intestine ulcers may occur in association with hemorrhage of the digestive tract, intestinal perforation or stenosis/obstruction. Patients should be closely monitored, and if any such abnormalities are observed, administration of this product should be discontinued, and appropriate treatment should be given.

2) Other adverse reactions

	Incidence unknown
Gastrointestinal	Gastrointestinal disorder, vomiting, abdominal pain, heartburn, constipation, diarrhea, esophagitis, lip swelling, hematemesis, a feeling of nausea, nausea, anorexia, stomach discomfort
Hypersensitivity*1)	Urticaria, rash, edema
Hematologic*2)	Anemia, decreased platelet function (prolonged bleeding time)
Dermatologic	Pruritus, rash on the skin, urticarial lesion, diaphoresis
Psychoneurologic*3)	Dizziness, excitation, headache
Hepatic	Increased AST (GOT), increased ALT (GPT)
Renal	Renal dysfunction
Cardiovascular	Decreased blood pressure, angiitis, epigastric pain
Respiratory	Bronchitis, rhinitis
Sensory organs	Keratitis, conjunctivitis, tinnitus, deafness
Others*4)	Hyperpnea, metabolic acidosis, malaise, hypoglycemia

*1:If such symptoms are observed, administration of this product should be discontinued.

*2):If any abnormalities are observed, administration of this product should be discontinued and appropriate measures should be taken.
*3):If any symptoms are observed, the dosage should be reduced or administration of this product should be discontinued.
*4):The dosage should be reduced or administration of this product should be discontinued. (Blood concentration is considered to be remarkably increased.)

5. Use in the Elderly

Since elderly patients generally have reduced physiological functions such as renal and hepatic functions, adverse reactions are likely to occur. Therefore, this product should be carefully administered to elderly patients under close monitoring of their conditions.

6. Use during Pregnancy, Delivery or Lactation

1) This product should not be administered to pregnant women who are expected to give birth within 12 weeks. [Prolonged pregnancy, premature closure of ductus arteriosus, suppression of uterine contractions, and increased intrapartum hemorrhage may occur. According to a large-scale epidemiological study conducted outside Japan, any causal relationship is considered unlikely between oral aspirin use during pregnancy and delivery of a baby with congenital anomaly; however, it has been reported that the risks of maternal anemia, antepartum/postpartum hemorrhage, prolonged delivery time, dystocia, stillbirth, neonatal weight loss/death and such may increase due to long-term use of this product. It has also been reported that abnormal hemorrhage occurred in patients who received this product in the third trimester and in their newborns. In addition, a study in rats administered during late pregnancy has demonstrated that weak fetal ductus arteriosus constriction was observed.]
2) This product should be used in pregnant women (excluding pregnant women who are expected to give birth within 12 weeks) or in women who may possibly be pregnant or women in lactation only if the expected therapeutic benefits outweigh the possible risks associated with treatment. Cyclooxygenase inhibitors (oral and suppository) have been reported to cause fetus renal impairment and decreased urine output, and associated oligohydramnios when used in pregnant women. [Teratogenic effects have been reported in animal studies (in rats). This may lead to prolonged pregnancy or postmature delivery.]
3) If this product is administered to lactating mothers, breast feeding should be discontinued during treatment. [It has been reported that this product is excreted in human breast milk.]

7. Pediatric Use

1) This product must not be given to low birth weight babies, neonates, or nursing infants because they cannot swallow this tablet.
2) This product should be administered carefully to infants only after confirmation that they can swallow this tablet.
3) Since adverse reactions are likely to occur in pediatric patients, this product should be carefully administered under close monitoring of the patient's condition. Hepatic impairment has been reported to have occurred in the treatment of Kawasaki's disease. Caution should be exercised with implementation of liver function tests as appropriate (See "Important Precautions").
4) This product should not be administered to patients with Chickenpox or influenza who are under 15 years of age. However, if, due to unavoidable circumstances, administration of this product is essential, this drug should be administered with caution, and the patient's condition should be closely monitored after administration (See "Important Precautions").
5) If Chickenpox or influenza develops in a patient aged < 15 years who is receiving this product for Kawasaki's disease, treatment should be suspended. However, if, due to unavoidable circumstances, treatment is continued, this drug should be carefully administered, and the patient's condition should be closely monitored after administration (See "Important Precautions").

8. Overdose

Signs and symptoms: Initial symptoms such as tinnitus, dizziness, headache, vomiting, deafness, and mild tachypnea may occur, which may progress to severe hyperpnea, respiratory alkalosis, metabolic acidosis, convulsions, coma, respiratory failure or such with increase in blood concentrations of this product.
Treatment: Therapeutic emesis, gastric lavage, administration of activated charcoal (after emesis and gastric lavage), correction of acidosis by infusion, urine alkalinization therapy (if renal function is normal), hemodialysis, or peritoneal dialysis should be performed as necessary.

9. Precautions Concerning Use

1) Precautions concerning oral administration:
(1) Since this product is an enteric-coated tablet formulation, the tablet should not be broken, crushed, or ground before being placed in the mouth and should be ingested without being chewed, unless it is used for the initial treatment of acute myocardial infarction or acute-phase cerebral infarction.
(2) It is recommended to avoid taking this drug on an empty stomach.

2) Precautions regarding dispensing:
For drugs that are dispensed in a PTP (press-through package) sheet, instruct the patient to remove the drug from the package prior to use [It has been reported that, if the PTP sheet is swallowed, the sharp corners of the sheet may puncture the esophageal mucosa, causing perforation and resulting in severe complications such as mediastinitis.]

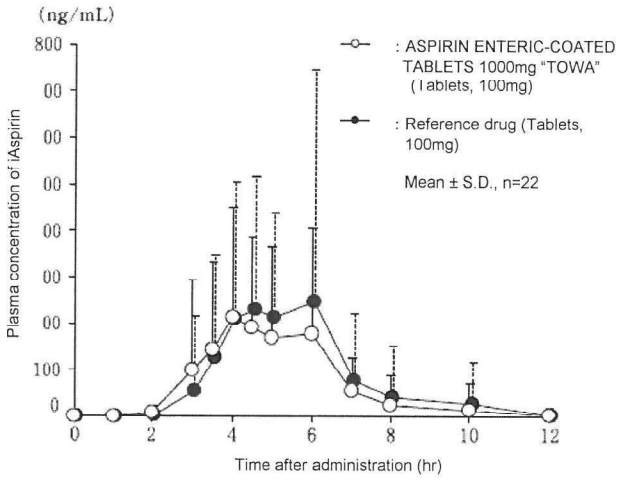
10. Other Precautions

1) In *in vitro* studies, drugs metabolized by glucuronidation such as aspirin have been reported to have inhibited glucuronidation of an antiviral drug (zidovudine).
2) Temporary infertility has been reported in women receiving long-term treatment with nonsteroidal anti-inflammatory analgesic drugs.

PHARMACOKINETICS

1. Bioequivalence test
<Reference data>

A crossover study was conducted in which single doses of one tablet (equivalent to 100 mg of aspirin) each of ASPIRIN ENTERIC-COATED TABLETS 100mg "TOWA" and the standard formulation were administered orally to healthy adult males (n = 22) under fasting conditions and plasma concentrations of unchanged aspirin were measured. The pharmacokinetic parameters (AUC, Cmax) of aspirin obtained from the study were statistically analyzed; the analysis results showed that differences in the mean logarithmic values of the assessed parameters were within the range of log (0.90) to log (1.11) and that dissolution rates were equivalent under all the conditions specified for dissolution tests, confirming the bioequivalence of these 2 drugs. (based on Guidelines for Bioequivalence Testing of Generic Drugs, Iyakushin Notification No. 786, May 31, 2001)[1]



	Determined parameter		Reference parameter	
	AUC_{12} (ng·hr/mL)	Cmax (ng/mL)	Tmax (hr)	$MRT_{1/2}$ (hr)
ASPIRIN ENTERIC-COATED TABLETS 100mg "TOWA (Tablets, 100mg)	787±234	508.57±172.24	5.02±1.68	0.527±0.368
Reference drug (Tablets, 100mg)	932±523	643.06±451.11	5.50±1.88	0.466±0.212*

(Mean ± S.D., n=22)
*:n=21

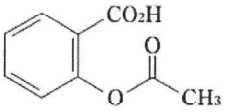
Plasma concentration and parameters such as AUC and Cmax may differ according to study conditions such as selection of subjects and frequency/time of body fluid sample collection.

PHARMACOLOGY

Low-dose aspirin inhibits platelet aggregation by selectively inhibiting the biosynthesis of prostaglandins in platelets.[2]

PHYSICOCHEMISTRYPHYSICOCHEMICAL PROPERTIES

Structural formula:



Nonproprietary name:
Aspirin
Chemical name:
2-Acetoxybenzoic acid
Molecular formula:
$C_9H_8O_4$
Molecular weight:
180.16
Description:
Aspirin occurs as white crystals, granules or powder. It is odorless, and has a slight acid taste.
It is freely soluble in ethanol (95) and in acetone, soluble in diethyl ether, and slightly soluble in water.
It dissolves in sodium hydroxide TS and in sodium carbonate TS. In moist air, it gradually hydrolyzes to salicylic acid and acetic acid.
Melting point:
About 136°C (bath fluid is heated at 130°C)

PRECAUTIONS FOR HANDLING

Stability test

In an accelerated test using final packaged products (at 40°C and 75% relative humidity for 6 months), ASPIRIN ENTERIC-COATED TABLETS 100mg "TOWA" was estimated to be stable for 3 years under normal distribution conditions[3].

PACKAGING

ASPIRIN ENTERIC-COATED TABLETS 100mg "TOWA":
Boxes of 100 tablets, 1,000 tablets (PTP)
Boxes of 700 tablets (14 tablets x 50, PTP)

REFERENCES

1) Internal data of Towa Pharmaceutical Co., Ltd.: Bioequivalence test
2) The 15th revision Japanese Pharmacopoeia explanatory, C-99, 2006
3) Internal data of Towa Pharmaceutical Co., Ltd.: Stability test

Manufacturer and Distributor
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