1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

AMEP® 10mg, tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Drug substance:

Amlodipine besylate ..... 13,90 mg
(Equivalent to Amlodipine.....10 mg)

Excipients:

Microcrystalline cellulose..... 140,00 mg
Calcium hydrogen phosphate dihydrate ..... 71,70 mg
Carboxymethyl Starch (Type A)..... 8,00 mg
Magnesium stearate..... 4,40 mg
Silica colloidal anhydrous .....2,00 mg

For one tablet

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.

AMEP 10 mg is white circular tablets with 'AP/10' embossed on one side and a median line on the other.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

- Hypertension
- Chronic stable angina pectoris.
- Vasospastic angina (Prinzmetal's)

4.2. Posology and method of administration

Posology

Adults

For both hypertension and angina the usual initial dose is 5 mg of AMEP once daily which may be increased to a maximum dose of 10 mg depending on the individual patient's response.

In hypertensive patients, AMEP Tablets have been used in combination with a thiazide diuretic, alpha blocker, beta blocker, or an angiotensin converting enzyme inhibitor. For angina, amlodipine tablets may be used as monotherapy or in combination with other antianginal medicinal products in patients with angina that is refractory to nitrates and/or to adequate doses of beta blockers.

No dose adjustment of AMEP is required upon concomitant administration of thiazide diuretics, beta blockers, and angiotensin-converting enzyme inhibitors.

Special populations

Elderly patients

AMEP used at similar doses in elderly or younger patients is equally well tolerated. Normal dosage regimens are recommended in the elderly, but increase of the dosage should take place with care (see section 4.5 and 5.2).

Hepatic impairment

Dosage recommendations have not been established in patients with mild to moderate hepatic impairment; therefore the dose should be chosen with caution and should be started at the lowest effective dose (see sections 4.5 and 5.2). The pharmacokinetics of amlodipine have not been studied in severe hepatic impairment. Amlodipine should be started at the lowest dose and increased slowly in patients with severe hepatic impairment.

Renal impairment

Changes in amlodipine plasma concentrations are not correlated with degree of renal impairment, therefore the normal dosage is recommended. Amlodipine is not dialysable.

Paediatric population

Children and adolescents:

Children and adolescents with hypertension from 6 years to 17 years of age.

The recommended antihypertensive oral dose for children aged 6 to 17 years is 2,5 mg once daily as a starting dose, which may be increased up to 5 mg once daily if the desired blood pressure is not reached after four weeks. Doses greater than 5 mg once daily have not been studied in pediatric patients (see sections 4.1 and 4.2).

A 2,5 mg dose of amlodipine is not possible with this medicine.

Children under 6 years of age: No data is available.

4.3. Method of administration

Tablet for oral administration.

4.4. Contraindications

Amlodipine is contra-indicated in patients with:

- Hypersensitivity to dihydropyridine derivatives, to amlodipine or any of the excipients
- Severe hypotension
- Shock (including cardiogenic shock)
- Obstruction of the outflow-tract of the left ventricle (e.g. high grade aortic stenosis).
- Haemodynamically unstable heart failure after acute myocardial infarction

4.5. Special warnings and precautions for use

The safety and efficacy of amlodipine in hypertensive crisis have not been established.

Patients with cardiac impairment

Patients with heart failure should be treated with caution. In a long-term, placebo-controlled study in patients with severe heart failure (NYHA classes III and IV), the reported incidence of pulmonary oedema was higher in the amlodipine treated group than to the placebo group. (see section Pharmacodynamic properties). Calcium channel blockers including amlodipine should be used with caution in patients with congestive heart failure because they may increase the risk of cardiovascular events and mortality.

Use in patients with impaired hepatic function

The half-life of amlodipine is increased and its AUC (Area Under the Curve) is greater in patients with hepatic impairment; dosage recommendations have not been established. Therefore, amlodipine should be initiated at the lowest effective dose and with caution, both during initiation of treatment and during dose escalation. Slow dose escalation and careful monitoring may be necessary in patients with severe hepatic impairment.

Use in elderly patients

In the elderly, an increase in the dosage should be carried out with caution (see sections posology and method of administration and pharmacokinetic properties).

Use in renal impairment

Amlodipine can be used in these patients at normal doses. Changes in plasma concentrations of Amlodipine do not correlate with the degree of renal impairment. Amlodipine is not dialyzable.

4.6. Interaction with other medicinal products and other forms of interaction

Effects of other medicinal products on amlodipine

CYP3A4 inhibitors:

Concomitant use of Amlodipine with strong or moderate inhibitors CYP3A4 (protease inhibitors, azole antifungals, macrolides like erythromycin or clarithromycin, verapamil or diltiazem) may give rise to significant increase in amlodipine plasma concentrations resulting an increased risk of hypotension. The clinical translation of these Pharmacokinetics variations may be more pronounced in the elderly. Clinical monitoring and dose adjustment may thus be required.

CYP3A4 inducers:

No data are available on the effect of inducers of CYP3A4, the plasma concentration of amlodipine may vary. Therefore, blood pressure should be monitored and dosage adjustment should be considered during and after concomitant medication, especially with strong inducers of CYP3A4 (eg, rifampicin, millepertuis, [hypericum perforatum]).

Administration of amlodipine with grapefruit or grapefruit juice is not recommended as bioavailability may be increased in some patients resulting in increased blood pressure lowering effects.

Dantrolene (infusion):

In animals, lethal ventricular fibrillation and cardiovascular collapse have been observed in association with hyperkalaemia after administration of verapamil and IV dantrolene. In view of the risk of hyperkalaemia, it is recommended to avoid concomitant administration of calcium channel blockers such as amlodipine in patients at risk of malignant hyperthermia and in the management of malignant hyperthermia.

Effects of amlodipine on other medicinal products

The hypotensive effects of amlodipine are in addition to those of other drugs with antihypertensive properties.

Tacrolimus:

There is a risk of increased plasma concentrations of tacrolimus when co-administered with amlodipine, but the pharmacokinetic mechanism of this interaction is not fully understood. In order to avoid tacrolimus toxicity, administration of amlodipine to a patient treated with tacrolimus requires monitoring of tacrolimus plasma concentrations and dose adjustment of tacrolimus if necessary.

The Inhibitors of Mechanistic Target Of Rapamycin (mTOR):

mTOR inhibitors such as sirolimus, temsirolimus and everolimus are substrates of CYP3A. Amlodipine is a weak inhibitor of CYP3A. When used concomitantly with amlodipine, mTOR inhibitors may increase in their activity.

Ciclosporin:

No drug interaction studies have been conducted with ciclosporin and amlodipine in healthy volunteers or other populations with the exception of renal transplant patients, where variable trough concentration increases (average 0% - 40%) of ciclosporin were observed. Consideration should be given for monitoring ciclosporin levels in renal transplant patients on amlodipine, and ciclosporin dose reductions should be made as necessary.

No interaction studies have been performed with ciclosporin and amlodipine in healthy volunteers or other populations, except in patients who have undergone kidney transplantation; a variable increase in the minimum concentration of ciclosporin was then observed (average from 0% to 40%). Cyclosporin levels should be monitored in renal transplant recipients treated with amlodipine and a reduction in the dose of cyclosporin should be considered if necessary.

Simvastatin:

Co-administration of repeated doses of 10 mg amlodipine with 80 mg simvastatin results in a 77% increase in exposure to simvastatin compared to simvastatin alone. The daily dose of simvastatin should be limited to 20 mg in patients treated with amlodipine.

In clinical interaction studies, amlodipine did not affect the pharmacokinetics of atorvastatin, digoxin, or warfarin.

4.7. Fertility, pregnancy and lactation

Pregnancy

In women, the safety of amlodipine during pregnancy has not been established.

In animal studies, reproductive toxicity has been observed at high doses (see preclinical safety section).

Use during pregnancy is only recommended when a safer alternative is not available and when the disease itself carries greater risks to the mother and fetus.

Lactation

Amlodipine is excreted in breast milk. The proportion of maternal dose received by the infant has been estimated at an interquartile range of 3 to 7%, with a maximum of 15%. The effect of amlodipine on infants is unknown. The decision to continue or discontinue breast-feeding or to continue or discontinue treatment with amlodipine should be made taking into account the benefit of breast-feeding for the child and the benefit of treatment with amlopidine for the mother.

Fertility

Reversible biochemical changes in the sperm head have been reported in some patients treated with calcium channel blockers. Clinical data are insufficient regarding the potential effect of Amlodipine on fertility. In a study in rats, adverse effects were detected on male fertility (see preclinical safety section).

4.8. Effects on ability to drive and use machines

Amlodipine may have minor or moderate influence on the ability to drive and use machines. If patients treated with Amlodipine experience dizziness, headache, fatigue or nausea, their ability to react may be impaired. Precautions are recommended especially at the start of treatment.

4.9. Undesirable effects

Summary of the safety profile

The most frequently reported side effects during treatment are drowsiness, dizziness, headache, palpitations, flushing, abdominal pain, nausea, ankle swelling, oedema and fatigue.

Tabulated list of adverse reactions

The following adverse reactions have been observed and reported during treatment with amlodipine with the following frequencies:

The following adverse reactions have been observed and reported during treatment with Amlodipine with the following frequencies: very common (≥ 1/10); common (≥ 1/100 to <1/10); uncommon (≥ 1/1000 to ≤ 1/100); rare (≥ 1 / 10,000 to ≤ 1 / 1,000); very rare (≤1 / 10,000).

Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

System organ class	Frequency	Adverse reactions
Blood and lymphatic system disorders	Very rare	Leukocytopenia, thrombocytopenia
Immune system disorders	Very rare	Allergic reactions
Metabolism and nutrition disorders	Very rare	Hyperglycaemia
Psychiatric disorders	Uncommon	Insomnia, mood changes (including anxiety), depression
	Rare	Confusion
Nervous system disorders	Common	Somnolence, dizziness, headache (especially at the beginning of the treatment)
	Uncommon	Tremor, dysgeusia, syncope, hypoesthesia, paresthesis

	Very rare	Hypertonia, peripheral neuropathy
Eye disorders	Common	Visual disturbance (including diplopia)
Ear and labyrinth disorders	Uncommon	Tinnitus
Cardiac disorders	Common	Palpitations
	Uncommon	Arrhythmia (including bradycardia, ventricular tachycardia and atrial fibrillation)
	Very rare	Myocardial infarction,
Vascular disorders	Common	Flushing
	Uncommon	Hypotension
	Very rare	Vasculitis
Respiratory, thoracic and mediastinal disorders	Common	Dyspnoea,
	Uncommon	Cough, rhinitis
Gastrointestinal disorders	Common	Abdominal pain, nausea, dyspepsia, altered bowel habits (including diarrhoea and constipation)
	Uncommon	Vomiting, , dry mouth
	Very rare	Pancreatitis, gastritis, gingival hyperplasia
Hepatobiliary disorders	Very rare	Hepatitis, jaundice, hepatic enzymes increased*
Skin and subcutaneous tissue disorders	Uncommon	Alopecia, purpura, skin discolouration, hyperhidrosis, pruritus, rash, exanthema, urticaria
	Very rare	Angioedema, erythema multiforme, exfoliative dermatitis, Stevens-Johnson syndrome, Quincke oedema, photosensitivity
	Not known frequency	Toxic epidermal necrolysis
Musculoskeletal, connective tissue and bone disorders	Common	Ankle swelling, muscle cramps
	Uncommon	Arthralgia, myalgia, back pain
Renal and urinary disorders	Uncommon	Micturition disorder, nocturia, increased urinary frequency
Reproductive system and breast disorders	Uncommon	Impotence, gynecomastia
General disorders and administration site conditions	Very common	Oedema
	Common	Fatigue, asthenia
	Uncommon	Chest pain, pain, discomfort
Investigations	Uncommon	Weight increase, weight decrease

* Generally evoking cholestasis
Exceptional cases of extrapyramidal syndrome have been reported.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.10. Overdose

In humans, the experience of intentional overdose is limited.

Symptoms

Available data suggest that large overdosage could result in excessive peripheral vasodilatation and possibly reflex tachycardia. Marked and probably prolonged systemic hypotension up to and including shock with fatal outcome have been reported.

Treatment

Clinically significant hypotension due to amlodipine overdose calls for active cardiovascular support including frequent monitoring of respiratory and cardiac function, elevation of extremities, and attention to circulating fluid volume and urine output.

A vasoconstrictor may be helpful in restoring vascular tone and blood pressure, provided that there is no contraindication to its use. Intravenous administration of calcium gluconate may be beneficial in reversing the effects of calcium channel inhibition.

Gastric lavage may be worthwhile in some cases. In healthy volunteers, the use of charcoal up to 2 hours after administration of amlodipine 10mg has been shown to reduce the absorption rate of amlodipine.

Since amlodipine is highly protein-bound, dialysis is not likely to be of benefit.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Selective calcium channel blockers with mainly vascular effects.

ATC code: C08CA01

Amlodipine is a calcium ion influx inhibitor of the dihydropyridine group (slow channel blocker or calcium ion antagonist) and inhibits the transmembrane influx of calcium ions into cardiac muscle and vascular smooth muscle.

The mechanism of the antihypertensive effect of amlodipine is related to a direct relaxant effect on vascular smooth muscle. The precise mechanism by which amlodipine relieves angina has not been fully determined, but amlodipine reduces the total ischemic burden by the following two actions:

1) Amlodipine dilates peripheral arterioles and therefore reduces the total peripheral resistance (afterload) against which the heart works. As long as the heart rate remains stable, this reduction in the workload of the heart decreases myocardial energy consumption and oxygen requirements.

2) The mechanism of action of amlodipine also probably involves dilation of the major coronary arteries and coronary arterioles, in normal and ischemic regions. This dilation increases the delivery of oxygen to the myocardium in patients with coronary artery spasm (Prinzmetal's angina).

In patients with hypertension, once daily dosing provides clinically significant reductions of blood pressure in both supine and standing positions throughout the 24-hour interval. Due to slow onset of action, acute hypotension is not associated with Amlodipine administration.

In patients with angina, once daily administration of amlodipine increases total exercise time, the delay of occurrence of anginal attack and ST segment depression of 1 mm. Amlodipine decreases both angina attack frequency and glyceryl trinitrate tablet consumption.

Amlodipine has not been associated with any adverse metabolic effects or changes in plasma lipids and is suitable for use in patients with asthma, diabetes, and gout.

Use in patients with coronary artery disease (CAD)

The efficacy of Amlodipine in preventing clinical events in patients with coronary artery disease was evaluated in an independent, multicenter, randomized, double-blind, placebo-controlled study in 1997 patients: the study CAMELOT (Comparison of Amlodipine vs Enalapril to Limit Occurrences of Thrombosis, comparison of Amlodipine and enalapril in the limitation of thrombosis episodes). 663 of these patients, were treated with Amlodipine 5-10 mg, 673 were treated with enalapril 10-20 mg, and 655 with placebo, in addition to standard treatment with statins, beta blockers , diuretics and aspirin for two years. The main efficacy results are shown in Table 1. The results indicate that treatment with Amlodipine was associated with fewer hospitalizations for angina and revascularization procedures in patients with coronary artery disease.

Table 1. Incidence of significant clinical outcomes for CAMELOT					
	Cardiovascular event rates No. (%)			Amlodipine vs. Placebo	
Outcomes	Amlodipine	Placebo	Enalapril	Hazard Ratio (95% CI)	*P* Value
Primary Endpoint					
Adverse cardiovascular events	110 (16.6)	151 (23.1)	136 (20.2)	0.69 (0.54-0.88)	0.003
Individual Components					
Coronary revascularization	78 (11.8)	103 (15.7)	95 (14.1)	0.73 (0.54-0.98)	0.03
Hospitalization for angina	51 (7.7)	84 (12.8)	86 (12.8)	0.58 (0.41-0.82)	0.002
Nonfatal MI	14 (2.1)	19 (2.9)	11 (1.6)	0.73 (0.37-1.46)	0.37
Stroke or TIA	6 (0.9)	12 (1.8)	8 (1.2)	0.50 (0.19-1.32)	0.15
Cardiovascular death	5 (0.8)	2 (0.3)	5 (0.7)	2.46 (0.48-12.7)	0.27
Hospitalization for CHF	3 (0.5)	5 (0.8)	4 (0.6)	0.59 (0.14-2.47)	0.46
Resuscitated cardiac arrest	0	4 (0.6)	1 (0.1)	NA	0.04
New-onset peripheral vascular disease	5 (0.8)	2 (0.3)	8 (1.2)	2.6 (0.50-13.4)	0.24

Abbreviations: CHF/ congestive heart failure; CI/ confidence interval; MI/ myocardial infarction; TIA/ transient ischemic attack.

Patients with cardiac failure

Use in patients with heart failure: Hemodynamic studies and controlled studies based on stress tests in patients with NYHA Class II-IV heart failure have shown that amlodipine does not cause clinical deterioration of exercise tolerance, left ventricular ejection fraction and clinical symptoms.

Haemodynamic studies and exercise based clinical trials in NYHA Class II-IV heart failure patients have shown that amlodipine did not lead to clinical deterioration as measured by exercise tolerance, left ventricular ejection fraction and clinical symptomatology.

A controlled study Vs placebo- (PRAISE) designed to evaluate patients with NYHA class III-IV heart failure receiving digoxin, diuretics and ACE inhibitors showed that amlodipine did not cause increased mortality risk or mortality and combined morbidity with heart failure.

In a controlled long-term follow-up study Vs placebo (PRAISE-2) on Amlodipine in patients with NYHA class III and IV heart failure without clinical symptoms or objective findings suggesting or underlying ischemic disease, treated with stable doses of ACE inhibitors, digitalis and diuretics, Amlodipine had no effect on total cardiovascular mortality. In this same population, Amlodipine has been associated with increased reports of pulmonary oedema.

Heart failure preventive treatment study (Treatment to Prevent Heart Attack Trial, ALLHAT)

The ALLHAT (Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial), randomized, double-blind, morbidity and mortality study was performed to compare recent treatments: amlodipine 2,5 to 10 mg / day (calcium channel blocker) or lisinopril 10 to 40 mg / day (ACE inhibitor) as first-line treatment compared to a thiazide diuretic, chlortalidone at a dose of 12,5 to 25 mg / day in mild to moderate hypertension.

A total of 33 357 hypertensive patients aged 55 or older were randomized and followed for a mean of 4,9 years. The patients had at least one additional coronary artery disease risk factor, including: previous myocardial infarction or stroke (> 6 months prior to enrolment) or documentation of other atherosclerotic cardiovascular diseases (overall 51,5%), type 2 diabetes (36,1%), HDL-C < 35 mg/dL (11,6%), left ventricular hypertrophy diagnosed by electrocardiogram or echocardiography (20,9%), current cigarette smoking (21,9%).

The primary endpoint was a composite of fatal coronary artery disease or non-fatal myocardial infarction. No significant difference was observed in the primary endpoint between treatment with Amlodipine and treatment with chlortalidone: RR: 0.98; CI 95% (0.90 to 1.07); p = 0.65. Among the secondary endpoints, the incidence of heart failure (part of a

composite cardiovascular endpoint) was significantly higher in the amlodipine group compared to the chlortalidone group (10.2% versus 7. 7%; RR: 1.38; 95% CI [1.25 to 1.52]; p <0.001). However, there was no significant difference in mortality from any cause between treatment with Amlodipine and treatment with chlortalidone: RR: 0.96; CI 95% [0.89 to 1.02]; p = 0.20.

Use in children (at least six years old):

In a study involving 268 children aged 6 to 17 years with predominantly secondary hypertension, comparison of a dose of 2.5mg and 5.0 mg of amlodipine with placebo, showed that both doses reduced Systolic Blood Pressure significantly more than placebo. The difference between the two doses was not statistically significant.

The long-term effects of amlodipine on growth, puberty and general development have not been studied. The long-term efficacy of amlodipine on therapy in children to reduce cardiovascular morbidity and mortality in adulthood has also not been established.

5.2. Pharmacokinetic properties

Absorption, Distribution, plasma protein binding

After oral administration of therapeutic doses, amlodipine is well absorbed with peak blood levels between 6-12 hours post dose. Absolute bioavailability is estimated to be 64 and 80%. The volume of distribution is approximately 21 l/kg. In vitro studies have shown that amlodipine circulating in blood is bound to plasmatic proteins up to 97.5%.

The bioavailability of Amlodipine is not affected by food intake.

Biotransformation/Elimination

The plasma elimination half-life is about 35-50 hours and is consistent with once daily dosing. Amlodipine is extensively metabolized by the liver to inactive metabolites with 10% of the parent compound and 60% of metabolites excreted in the urine.

Use in hepatic impairment

Very limited clinical data are available regarding amlodipine administration in patients with hepatic impairment. Patients with hepatic insufficiency have decreased clearance of amlodipine resulting in a longer half-life and an increase in AUC of approximately 40-60%.

In the elderly

The time to reach peak plasma concentrations is similar in elderly and younger patients. The clearance tends to be decreased with resulting increases in AUC and terminal elimination half-life in elderly patients. Increase in AUC and elimination half-life in patients with congestive heart failure were as expected for the patient age group studied.

Use in Children

A population PK study has been conducted in 74 hypertensive children aged from 1 to 17 years (with 34 patients aged 6 to 12 years and 28 patients aged 13 to 17 years) receiving amlodipine between 1.25 and 20 mg given either once or twice daily. In children 6 to 12 years and in adolescents 13-17 years of age the typical oral clearance (CL/F) was 22.5 and 27.4 L/hr respectively in males and 16.4 and 21.3L/hr respectively in females. Large variability in exposure between individuals was observed. Data reported in children below 6 years is limited.

5.3. Preclinical safety data

Reproductive toxicology

Reproductive toxicology studies in rats and mice have shown delayed date of delivery, prolonged duration of labour and decreased pup survival at dosages approximately 50 times greater than the maximum recommended dosage for humans based on mg/kg.

Impairment of fertility

There was no effect on the fertility of rats treated with amlodipine (males for 64 days and females 14 days prior to mating) at doses up to 10 mg/kg/day (8 times* the maximum recommended human dose of 10 mg on a mg/m^2 basis). In another rat study in which male rats were treated with amlodipine besylate for 30 days at a dose comparable with the human dose based on mg/kg, decreased plasma follicle-stimulating hormone and testosterone were found as well as decreases in sperm density and in the number of mature spermatids and Sertoli cells.

Carcinogenesis, mutagenesis

Rats and mice treated with amlodipine in the diet for two years, at concentrations calculated to provide daily dosage levels of 0.5, 1.25, and 2.5 mg/kg/day showed no evidence of carcinogenicity. The highest dose (for mice, similar to, and for rats twice* the maximum recommended clinical dose of 10 mg on a mg/m^2 basis) was close to the maximum tolerated dose for mice but not for rats.

Mutagenicity studies revealed no drug related effects at either the gene or chromosome levels.

* Based on patient weight of 50 Kg.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Silica colloidal anhydrous
Magnesium stearate
Calcium hydrogen phosphate dihydrate
Carboxymethyl Starch (Type A)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

No special storage conditions.

6.5 Nature and contents of container

PVC / ALU blister.

Pack sizes: 14, 28, or 56 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES

Name and address of Headquarter:

COOPER PHARMA
41, rue Mohamed DIOURI, 20110
Casablanca - Morocco

Manufacturing site address:

COOPER PHARMA
Route 107, Km 2,5 Douar Oulad Sidi Abbou - Tit Melil
Casablanca - Morocco

8. MARKETING AUTHORISATION NUMBER

20/4360/DGC/PHS/2018

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first authorization: 06 Jun 2018

Date of last renewal: Not applicable

10. DATE OF REVISION OF THE TEXT

03/2019

PRESCRIPTION AND DELIVERY CONDITIONS

Table A (List I)