July 10, 2020

To,
Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir/Madam,

The undersigned ('petitioner') submits this Citizen Petition electronically under Section 505(j) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 10.25(a), 10.30 and 314.93, to request the Food and Drug Administration to **designate a suitable alternative reference standard (RS)** for purpose of conducting *in vivo* bioequivalence studies to support our ANDA application for Carbidopa and Levodopa Tablets 10 mg/100 mg, 25 mg/100 mg and 25 mg/250 mg with reference to the current Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations).

The request is being made on the following grounds;

1. Current Orange Book lists "**SINEMET®** (carbidopa-levodopa) tablets (NDA # 017555) 25 mg /250 mg of Merck Sharp and Dohme Corp", as Reference Standard (RS) as well as Reference Listed Drug (RLD). However, though not listed as discontinued in electronic Orange Book, as per IMS (MAT) data quantity of the current reference standard is so limited that a potential ANDA applicant is not able to obtain a sufficient quantity for *in vivo* bioequivalence testing. Please also note that as per the record for application number (017555) in the National Drug Code directory, two NDC package codes (0006-6723-68 & 0006-3917-68) are available for strength 25 mg/250 mg. The non-availability statement of samples for both NDC package code from the distributor indicate that the current designated reference standard samples are unavailable.

2. Approved generic product, "Carbidopa and Levodopa Tablets (ANDA # 078536) of Sun Pharmaceutical Industries, Inc.", listed in the Orange Book is currently one of the leading marketed drug product and hence, eligible to be designated as Reference Standard due to limited or non-availability of the current Orange Book listed reference

standard "SINEMET® (carbidopa-levodopa) tablets (NDA # 017555) 25 mg /250 mg of Merck Sharp and Dohme Corp",

A. Action Requested

Aurobindo Pharma Limited requests the Food and Drug Administration (FDA) to designate the approved "Carbidopa and Levodopa Tablets 25 mg / 250 mg (ANDA 078536) of Sun Pharmaceutical Industries, Inc." as a new Reference Standard, upon which ANDA applicant can rely for purpose of *in vivo* bioequivalence testing required for ANDA filing.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products, which are eligible for submission as Abbreviated New Drug Applications (ANDA's) in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (The Orange Book).

FDC Act §505(j) allows the marketing of generic versions of previously approved drug products when the generic drug product is the subject of an ANDA. To obtain ANDA approval, the application sponsor must show, among other things, that with respect to a listed drug (i.e., a previously approved drug product), the generic drug product has the same active ingredient(s) in the same strength, has essentially identical labeling.

Approved Drug Products with Therapeutic Equivalence Evaluations (The Orange Book) database current through July 2020* is provided in following table;

Market Status	**RX**	**RX**	**RX**	**RX**	**RX**	**RX**
Active Ingredient	CARBIDOPA; LEVODOPA	CARBIDOPA; LEVODOPA	CARBIDOPA; LEVODOPA	CARBIDOPA; LEVODOPA	CARBIDOPA; LEVODOPA	CARBIDOPA; LEVODOPA
Proprietary Name	SINEMET	CARBIDOPA; LEVODOPA	CARBIDOPA; LEVODOPA	CARBIDOPA; LEVODOPA	CARBIDOPA; LEVODOPA	CARBIDOPA; LEVODOPA
Application No.	**N017555**	**A074260**	**A078536**	**A077120**	**A073607**	**A090324**
Product Number	002	003	003	003	001	003
Dosage Form / Route	Tablet, Oral	Tablet, Oral	Tablet, Oral	Tablet, Oral	Tablet, Oral	Tablet, Oral
Strength	25 mg/ 250 mg	25 mg/ 250 mg	25 mg/ 250 mg	25 mg/ 250 mg	25 mg/ 250 mg	25 mg/ 250 mg
TE Code	AB	AB	AB	AB	AB	AB
RLD	**RLD**	No	No	No	No	No
RS	**RS**	No	No	No	No	No
Applicant Holder	Merck Sharp And Dohme Corp	Actavis Elizabeth LLC	Sun Pharmaceutical Industries Ltd.	Apotex Inc.	Mayne Pharma LLC	Mylan Pharmaceuticals Inc.
Approval Date	Prior to Jan 1, 1982	Sep. 3, 1993	Oct. 28, 2008	June 2, 2008	Aug. 28, 1992	Sep. 28, 2009

* Data accessed on July 10, 2020.

Other approved ANDAs (# A073587, A074080 and A073383) of Carbidopa and Levodopa Tablets are listed in the discontinued section of the orange Book.

Due to market unavailability of designated reference standard in sufficient quantity, evaluation/comparison of Aurobindo's generic drug against reference standard could not be executed.

As per Draft Guidance for Industry, ***Referencing Approved Drug Products in ANDA Submissions, III. C.2 and 3***,

"FDA also will consider selecting a new reference standard when the Agency determines that the quantity of the current reference standard in distribution is so limited that a potential ANDA applicant is not able to obtain a sufficient quantity for in vivo bioequivalence testing (even if the current reference standard is not in the Discontinued Section of the Orange Book). When selecting a new reference standard, FDA generally selects a drug product that is therapeutically equivalent to the discontinued RLD and is the market leader based on units sold."

"If there is a reference standard in the Active Section of the Orange Book but there are limited or no quantities of the reference standard in distribution, or a potential ANDA applicant believes a reference standard other than the one selected by FDA is appropriate, then the potential applicant may submit a citizen petition under 21 CFR 10.25(a) and 10.30 to request that FDA select that different listed drug also as a reference standard."

The Petitioner (Aurobindo Pharma Limited) therefore requests FDA to designate one of the approved generic products and preferably "Carbidopa and Levodopa Tablets 25 mg/250 mg (ANDA # 078536) of Sun Pharmaceutical Industries, Inc.", as a new Reference Standard (RS) considering it appears as one of the leading marketed Drug product in the U.S. market in terms of number of tablets sold (as per IMS data) and should therefore be more readily accessible and more appropriate for RS designation.

In support of the designation of the reference standard to Approved Generic Product "Carbidopa and Levodopa Tablets 25 mg/250 mg (ANDA 078536) of Sun Pharmaceutical Industries, Inc.", we have included the following data:

1. Current Orange Book Search Results
2. NDC Directory Search Results
3. Drugs@FDA Search Results
4. Non availability of samples statement from pharmacy/distributor.

5. Detailed IMS, Moving Annual Total (MAT) data indicating Approved Generic product "Carbidopa and Levodopa Tablets (ANDA 078536) of Sun Pharmaceutical Industries, Inc.", as one of the leading player in the U.S market.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 C.F.R. 25.31(a) and 25.15(d).

D. Economic Impact Statement

Pursuant to 21 C.F.R. 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition. This information will be promptly provided, if so requested.

E. Certification

The undersigned (petitioner) certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which is unfavorable to this petition.

Sincerely yours,

Blessy Johns

Digitally signed by Blessy Johns
DN: c=US, st=New Jersey, l=Dayton, o=Aurobindo Pharma USA, Inc., cn=Blessy Johns, email=bjohns@aurobindousa.com
Date: 2020.07.10 10:39:14 -04'00'

Blessy Johns
US Agent for Aurobindo Pharma Limited

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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Mkt.Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	CARBIDOPA; LEVODOPA	CARBIDOPA AND LEVODOPA	A074260	TABLET	ORAL	25MG; 250MG	AB			ACTAVIS ELIZABETH LLC
RX	CARBIDOPA; LEVODOPA	CARBIDOPA AND LEVODOPA	A077120	TABLET	ORAL	25MG; 250MG	AB			APOTEX INC
RX	CARBIDOPA; LEVODOPA	CARBIDOPA AND LEVODOPA	A073607	TABLET	ORAL	25MG; 250MG	AB			MAYNE PHARMA LLC
RX	CARBIDOPA; LEVODOPA	CARBIDOPA AND LEVODOPA	A090324	TABLET	ORAL	25MG; 250MG	AB			MYLAN PHARMACEUTICALS INC
RX	CARBIDOPA; LEVODOPA	CARBIDOPA AND LEVODOPA	A078536	TABLET	ORAL	25MG; 250MG	AB			SUN PHARMACEUTICAL INDUSTRIES LTD
RX	CARBIDOPA; LEVODOPA	SINEMET	N017555	TABLET	ORAL	25MG; 250MG	AB	RLD	RS	MERCK SHARP AND DOHME CORP
RX	CARBIDOPA; LEVODOPA	CARBIDOPA AND LEVODOPA	A078893	TABLET, ORALLY DISINTEGRATING	ORAL	25MG; 250MG	AB		RS	MYLAN PHARMACEUTICALS INC
RX	CARBIDOPA; LEVODOPA	CARBIDOPA AND LEVODOPA	A078690	TABLET, ORALLY DISINTEGRATING	ORAL	25MG; 250MG	AB			SUN PHARMACEUTICAL INDUSTRIES LTD
DISCN	CARBIDOPA; LEVODOPA	CARBIDOPA AND LEVODOPA	A073587	TABLET	ORAL	25MG; 250MG				ANI PHARMACEUTICALS INC
DISCN	CARBIDOPA; LEVODOPA	CARBIDOPA AND LEVODOPA	A074080	TABLET	ORAL	25MG; 250MG				SCS PHARMACEUTICALS
DISCN	CARBIDOPA; LEVODOPA	CARBIDOPA AND LEVODOPA	A073383	TABLET	ORAL	25MG; 250MG				WATSON LABORATORIES INC
DISCN	CARBIDOPA; LEVODOPA	CARBILEV	A076643	TABLET, FOR SUSPENSION	ORAL	25MG; 250MG				RANBAXY LABORATORIES LTD
DISCN	CARBIDOPA; LEVODOPA	CARBIDOPA AND LEVODOPA	A090631	TABLET, ORALLY DISINTEGRATING	ORAL	25MG; 250MG				IMPAX LABORATORIES INC
DISCN	CARBIDOPA; LEVODOPA	PARCOPA	A076699	TABLET, ORALLY DISINTEGRATING	ORAL	25MG; 250MG **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**				UCB INC

National Drug Code Directory

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Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class	DEA
SINEMET	0006-3915-68	10 mg/1, 100 mg/1	TABLET	ORAL	NDA017555	Merck Sharp & Dohme Corp.	0006-3915	carbidopa and levodopa	CARBIDOPA; LEVODOPA	HUMAN PRESCRIPTION DRUG	05/02/1975	N/A	NDA	100 TABLET in 1 BOTTLE (0006-3915-68)	Aromatic Amino Acid [EPC], Amino Acids, Aromatic [CS]	N/A
SINEMET	0006-3916-68	25 mg/1, 100 mg/1	TABLET	ORAL	NDA017555	Merck Sharp & Dohme Corp.	0006-3916	carbidopa and levodopa	CARBIDOPA; LEVODOPA	HUMAN PRESCRIPTION DRUG	05/02/1975	N/A	NDA	100 TABLET in 1 BOTTLE (0006-3916-68)	Aromatic Amino Acid [EPC], Amino Acids, Aromatic [CS]	N/A
SINEMET	0006-3917-68	25 mg/1, 250 mg/1	TABLET	ORAL	NDA017555	Merck Sharp & Dohme Corp.	0006-3917	carbidopa and levodopa	CARBIDOPA; LEVODOPA	HUMAN PRESCRIPTION DRUG	05/02/1975	N/A	NDA	100 TABLET in 1 BOTTLE (0006-3917-68)	Aromatic Amino Acid [EPC], Amino Acids, Aromatic [CS]	N/A
SINEMET	0006-6722-68	10 mg/1, 100 mg/1	TABLET	ORAL	NDA017555	Merck Sharp & Dohme Corp.	0006-6722	carbidopa and levodopa	CARBIDOPA; LEVODOPA	HUMAN PRESCRIPTION DRUG	03/03/2020	N/A	NDA	100 TABLET in 1 BOTTLE (0006-6722-68)	Aromatic Amino Acid [EPC], Amino Acids, Aromatic [CS]	N/A
SINEMET	0006-6723-68	25 mg/1, 250 mg/1	TABLET	ORAL	NDA017555	Merck Sharp & Dohme Corp.	0006-6723	carbidopa and levodopa	CARBIDOPA; LEVODOPA	HUMAN PRESCRIPTION DRUG	03/03/2020	N/A	NDA	100 TABLET in 1 BOTTLE (0006-6723-68)	Aromatic Amino Acid [EPC], Amino Acids, Aromatic [CS]	N/A
SINEMET	0006-6724-68	25 mg/1, 100 mg/1	TABLET	ORAL	NDA017555	Merck Sharp & Dohme Corp.	0006-6724	carbidopa and levodopa	CARBIDOPA; LEVODOPA	HUMAN PRESCRIPTION DRUG	03/03/2020	N/A	NDA	100 TABLET in 1 BOTTLE (0006-6724-68)	Aromatic Amino Acid [EPC], Amino Acids, Aromatic [CS]	N/A

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Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also: **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
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National Drug Code Directory

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Search Results: *'078536'*

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Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class
CARBIDOPA AND LEVODOPA	62756-517-83	10 mg/1, 100 mg/1	TABLET	ORAL	ANDA078536	Sun Pharmaceutical Industries, Inc.	62756-517	CARBIDOPA AND LEVODOPA	CARBIDOPA; LEVODOPA	HUMAN PRESCRIPTION DRUG	10/28/2008	N/A	ANDA	30 TABLET in 1 BOTTLE (62756-517-83)	Aromatic Amino Acid [EPC], Amino Acids, Aromatic [CS]
CARBIDOPA AND LEVODOPA	62756-518-13	25 mg/1, 100 mg/1	TABLET	ORAL	ANDA078536	Sun Pharmaceutical Industries, Inc.	62756-518	CARBIDOPA AND LEVODOPA	CARBIDOPA; LEVODOPA	HUMAN PRESCRIPTION DRUG	10/28/2008	N/A	ANDA	500 TABLET in 1 BOTTLE (62756-518-13)	Aromatic Amino Acid [EPC], Amino Acids, Aromatic [CS]
CARBIDOPA AND LEVODOPA	62756-519-83	25 mg/1, 250 mg/1	TABLET	ORAL	ANDA078536	Sun Pharmaceutical Industries, Inc.	62756-519	CARBIDOPA AND LEVODOPA	CARBIDOPA; LEVODOPA	HUMAN PRESCRIPTION DRUG	10/28/2008	N/A	ANDA	30 TABLET in 1 BOTTLE (62756-519-83)	Aromatic Amino Acid [EPC], Amino Acids, Aromatic [CS]
CARBIDOPA AND LEVODOPA	66267-649-90	25 mg/1, 100 mg/1	TABLET	ORAL	ANDA078536	NuCare Pharmaceuticals, Inc.	66267-649	CARBIDOPA AND LEVODOPA	CARBIDOPA; LEVODOPA	HUMAN PRESCRIPTION DRUG	10/28/2008	N/A	ANDA	90 TABLET in 1 BOTTLE (66267-649-90)	Aromatic Amino Acid [EPC], Amino Acids, Aromatic [CS]
CARBIDOPA AND LEVODOPA	62756-519-08	25 mg/1, 250 mg/1	TABLET	ORAL	ANDA078536	Sun Pharmaceutical Industries, Inc.	62756-519	CARBIDOPA AND LEVODOPA	CARBIDOPA; LEVODOPA	HUMAN PRESCRIPTION DRUG	10/28/2008	N/A	ANDA	100 TABLET in 1 BOTTLE (62756-519-08)	Aromatic Amino Acid [EPC], Amino Acids, Aromatic [CS]
CARBIDOPA AND LEVODOPA	62756-518-08	25 mg/1, 100 mg/1	TABLET	ORAL	ANDA078536	Sun Pharmaceutical Industries, Inc.	62756-518	CARBIDOPA AND LEVODOPA	CARBIDOPA; LEVODOPA	HUMAN PRESCRIPTION DRUG	10/28/2008	N/A	ANDA	100 TABLET in 1 BOTTLE (62756-518-08)	Aromatic Amino Acid [EPC], Amino Acids, Aromatic [CS]
CARBIDOPA AND LEVODOPA	62756-518-83	25 mg/1, 100 mg/1	TABLET	ORAL	ANDA078536	Sun Pharmaceutical Industries, Inc.	62756-518	CARBIDOPA AND LEVODOPA	CARBIDOPA; LEVODOPA	HUMAN PRESCRIPTION DRUG	10/28/2008	N/A	ANDA	30 TABLET in 1 BOTTLE (62756-518-83)	Aromatic Amino Acid [EPC], Amino Acids, Aromatic [CS]
CARBIDOPA AND LEVODOPA	62756-519-18	25 mg/1, 250 mg/1	TABLET	ORAL	ANDA078536	Sun Pharmaceutical Industries, Inc.	62756-519	CARBIDOPA AND LEVODOPA	CARBIDOPA; LEVODOPA	HUMAN PRESCRIPTION DRUG	10/28/2008	N/A	ANDA	1000 TABLET in 1 BOTTLE (62756-519-18)	Aromatic Amino Acid [EPC], Amino Acids, Aromatic [CS]
CARBIDOPA AND LEVODOPA	62756-519-88	25 mg/1, 250 mg/1	TABLET	ORAL	ANDA078536	Sun Pharmaceutical Industries, Inc.	62756-519	CARBIDOPA AND LEVODOPA	CARBIDOPA; LEVODOPA	HUMAN PRESCRIPTION DRUG	10/28/2008	N/A	ANDA	100 TABLET in 1 BOTTLE (62756-519-88)	Aromatic Amino Acid [EPC], Amino Acids, Aromatic [CS]
CARBIDOPA AND LEVODOPA	62756-517-13	10 mg/1, 100 mg/1	TABLET	ORAL	ANDA078536	Sun Pharmaceutical Industries, Inc.	62756-517	CARBIDOPA AND LEVODOPA	CARBIDOPA; LEVODOPA	HUMAN PRESCRIPTION DRUG	10/28/2008	N/A	ANDA	500 TABLET in 1 BOTTLE (62756-517-13)	Aromatic Amino Acid [EPC], Amino Acids, Aromatic [CS]
CARBIDOPA AND LEVODOPA	62756-517-88	10 mg/1, 100 mg/1	TABLET	ORAL	ANDA078536	Sun Pharmaceutical Industries, Inc.	62756-517	CARBIDOPA AND LEVODOPA	CARBIDOPA; LEVODOPA	HUMAN PRESCRIPTION DRUG	10/28/2008	N/A	ANDA	100 TABLET in 1 BOTTLE (62756-517-88)	Aromatic Amino Acid [EPC], Amino Acids, Aromatic [CS]
CARBIDOPA AND LEVODOPA	62756-518-88	25 mg/1, 100 mg/1	TABLET	ORAL	ANDA078536	Sun Pharmaceutical Industries, Inc.	62756-518	CARBIDOPA AND LEVODOPA	CARBIDOPA; LEVODOPA	HUMAN PRESCRIPTION DRUG	10/28/2008	N/A	ANDA	100 TABLET in 1 BOTTLE (62756-518-88)	Aromatic Amino Acid [EPC], Amino Acids, Aromatic [CS]

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class
CARBIDOPA AND LEVODOPA	62756-518-18	25 mg/1, 100 mg/1	TABLET	ORAL	ANDA078536	Sun Pharmaceutical Industries, Inc.	62756-518	CARBIDOPA AND LEVODOPA	CARBIDOPA; LEVODOPA	HUMAN PRESCRIPTION DRUG	10/28/2008	N/A	ANDA	1000 TABLET in 1 BOTTLE (62756-518-18)	Aromatic Amino Acid [EPC], Amino Acids, Aromatic [CS]
CARBIDOPA AND LEVODOPA	62756-519-13	25 mg/1, 250 mg/1	TABLET	ORAL	ANDA078536	Sun Pharmaceutical Industries, Inc.	62756-519	CARBIDOPA AND LEVODOPA	CARBIDOPA; LEVODOPA	HUMAN PRESCRIPTION DRUG	10/28/2008	N/A	ANDA	500 TABLET in 1 BOTTLE (62756-519-13)	Aromatic Amino Acid [EPC], Amino Acids, Aromatic [CS]
CARBIDOPA AND LEVODOPA	62756-517-08	10 mg/1, 100 mg/1	TABLET	ORAL	ANDA078536	Sun Pharmaceutical Industries, Inc.	62756-517	CARBIDOPA AND LEVODOPA	CARBIDOPA; LEVODOPA	HUMAN PRESCRIPTION DRUG	10/28/2008	N/A	ANDA	100 TABLET in 1 BOTTLE (62756-517-08)	Aromatic Amino Acid [EPC], Amino Acids, Aromatic [CS]
CARBIDOPA AND LEVODOPA	62756-517-18	10 mg/1, 100 mg/1	TABLET	ORAL	ANDA078536	Sun Pharmaceutical Industries, Inc.	62756-517	CARBIDOPA AND LEVODOPA	CARBIDOPA; LEVODOPA	HUMAN PRESCRIPTION DRUG	10/28/2008	N/A	ANDA	1000 TABLET in 1 BOTTLE (62756-517-18)	Aromatic Amino Acid [EPC], Amino Acids, Aromatic [CS]

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U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Drugs@FDA: FDA-Approved Drugs

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application No.	Company
SINEMET	CARBIDOPA; LEVODOPA	25MG;250MG	TABLET;ORAL	Prescription	Yes	AB	017555	MERCK SHARP DOHME
CARBIDOPA AND LEVODOPA	CARBIDOPA; LEVODOPA	25MG;250MG	TABLET;ORAL	Prescription	No	AB	074260	ACTAVIS ELIZABETH
CARBIDOPA AND LEVODOPA	CARBIDOPA; LEVODOPA	25MG;250MG	TABLET;ORAL	Prescription	No	AB	077120	APOTEX INC
CARBIDOPA AND LEVODOPA	CARBIDOPA; LEVODOPA	25MG;250MG	TABLET;ORAL	Prescription	No	AB	073607	MAYNE PHARMA
CARBIDOPA AND LEVODOPA	CARBIDOPA; LEVODOPA	25MG;250MG	TABLET;ORAL	Prescription	No	AB	090324	MYLAN
CARBIDOPA AND LEVODOPA	CARBIDOPA; LEVODOPA	25MG;250MG	TABLET;ORAL	Prescription	No	AB	078536	SUN PHARM INDS