

April 02, 2019

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 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 Phenoxybenzamine Hydrochloride Capsules USP, 10 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 “DIBENZYLINE® (phenoxybenzamine hydrochloride Capsules, USP) 10 mg (NDA # 008708), of Concordia Pharmaceuticals Inc.”, 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 (008708) in the National Drug Code directory, two NDC package code (59212-001-01 & 66993-066-02) are available. The non-availability statement of samples for both NDC package code from the distributor indicate that the current designated reference standard samples is unavailable.
2. Approved generic product, “Phenoxybenzamine Hydrochloride Capsules USP, 10 mg (ANDA # 204522), of PAR Pharmaceutical Inc.”, listed in the Orange Book is currently the highest 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 “DIBENZYLINE® (phenoxybenzamine hydrochloride Capsules, USP) 10 mg (NDA # 008708), of Concordia Pharmaceuticals Inc.”

**AUROBINDO PHARMA USA, Inc.**

279 Princeton-Hightstown Road, East Windsor, NJ 08520, U.S.A, Phone: 732-839-9406, 732-839-9400, Fax: 732-355-9940  
Regd.Off.: Plot No. 2, Maitriviham, Ameerpet, Hyderabad – 500 038 T.S., INDIA Tel: +91 40 2373 6370 Fax: +91 40 2374 7340, Email: info@aurobindo.com

[www.aurobindo.com](http://www.aurobindo.com)

## A. Action Requested

Aurobindo Pharma Limited requests the Food and Drug Administration (FDA) to designate the approved “Phenoxybenzamine Hydrochloride Capsules USP, 10 mg (ANDA # 204522), of PAR Pharmaceutical Inc.”, as a reference standard or designate a suitable alternative 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 February 2019\* is provided in following table;

Market Status	RX	RX	RX
Active Ingredient	PHENOXYBENZAMINE HYDROCHLORIDE	PHENOXYBENZAMINE HYDROCHLORIDE	PHENOXYBENZAMINE HYDROCHLORIDE
Proprietary Name	DIBENZYLINE®	PHENOXYBENZAMINE HYDROCHLORIDE	PHENOXYBENZAMINE HYDROCHLORIDE
Application No.	N008708	A204522	A201050
Product Number	001	001	001
Dosage Form	CAPSULE	CAPSULE	CAPSULE
Route	ORAL	ORAL	ORAL
Strength	10MG	10MG	10MG
TE Code	AB	AB	AB
RLD	RLD	-	-
RS	RS	-	-
Applicant Holder	CONCORDIA PHARMACEUTICALS INC	PAR PHARMACEUTICAL INC	WEST-WARD PHARMACEUTICALS INTERNATIONAL LTD
Approval Date	Prior January 1, 1982	January 24, 2017	July 16, 2012

\* Data accessed on April 02, 2019.

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 Regd.Off.: Plot No. 2, Maitrivihar, Ameerpet, Hyderabad – 500 038 T.S., INDIA Tel: +91 40 2373 6370 Fax: +91 40 2374 7340, Email: info@aurobindo.com

[www.aurobindo.com](http://www.aurobindo.com)

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

As per Draft Guidance for Industry, ***Referencing Approved Drug Products in ANDA Submissions, Ill. 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 Approved Generic product, "Phenoxybenzamine Hydrochloride Capsules USP, 10 mg, ANDA # 204522), of PAR Pharmaceutical Inc.", as a reference standard (RS), as FDC Act §505U) allows the marketing of generic versions of previously approved drug products when the generic drug product is the subject of an ANDA.

In support of the designation of the reference standard to Approved Generic Product "Phenoxybenzamine Hydrochloride Capsules USP 10 mg ANDA # 204522 of PAR Pharmaceutical Inc.", we have included the following data:

1. Current Orange Book Search Results
2. NDC Directory Search Results
3. Drugs@FDA Search Results
4. Detailed IMS, Moving annual total (MAT) data indicating Approved Generic product Phenoxybenzamine Hydrochloride Capsules USP, 10 mg ANDA # 204522 of PAR Pharmaceutical Inc., as the leading player in the U.S market.
5. Non availability of samples statement from pharmacy.

AUROBINDO PHARMA USA, Inc.

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[www.aurobindo.com](http://www.aurobindo.com)

**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 submitted only when requested by the Commissioner. This information will be promptly provided, if so requested.

**E. Certification**

The undersigned 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**

**US Agent for Aurobindo Pharma Limited**

**Contact details of US agent:**

Aurobindo Pharma USA, Inc.,  
279 Princeton-Hightstown Road,  
East Windsor, NJ 08520, USA,  
Tel: 732-839-4380  
Cell: 908-240-1822  
Fax No.: 732- 355-9940  
E-mail: [bjohns@aurobindousa.com](mailto:bjohns@aurobindousa.com)

**AUROBINDO PHARMA USA, Inc.**

279 Princeton-Hightstown Road, East Windsor, NJ 08520, U.S.A, Phone: 732-839-9406, 732-839-9400, Fax: 732-355-9940  
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[www.aurobindo.com](http://www.aurobindo.com)


# Approved Drug Products with Therapeutic Equivalence Evaluations


Search Results for Proprietary Name, Active Ingredient or Application Number: *PHENOXYBENZAMINE HYDROCHLORIDE*


3 records returnedSearch for text in the table:



Mkt. Status	Active Ingredient	Proprietary Name	Appl No	Dosage Form	Route	Strength	<a href="#">TE Code</a>	<a href="#">RLD</a>	<a href="#">RS</a>	Applicant Holder
RX	PHENOXYBENZAMINE HYDROCHLORIDE	DIBENZYLINE	<a href="#">N008708</a>	CAPSULE	ORAL	10MG	AB	RLD	RS	CONCORDIA PHARMACEUTICALS INC
RX	PHENOXYBENZAMINE HYDROCHLORIDE	PHENOXYBENZAMINE HYDROCHLORIDE	<a href="#">A204522</a>	CAPSULE	ORAL	10MG	AB			PAR PHARMACEUTICAL INC
RX	PHENOXYBENZAMINE HYDROCHLORIDE	PHENOXYBENZAMINE HYDROCHLORIDE	<a href="#">A201050</a>	CAPSULE	ORAL	10MG	AB			WEST-WARD PHARMACEUTICALS INTERNATIONAL LTD
Mkt. Status	Active Ingredient	Proprietary Name	Appl No	Dosage Form	Route	Strength	<a href="#">TE Code</a>	<a href="#">RLD</a>	<a href="#">RS</a>	Applicant Holder



# National Drug Code Directory

 [SHARE \(HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP\\_SEARCHRESULT.CFM\)](https://www.facebook.com/sharer/sharer.php?u=https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm)

 [TWEET \(HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=NATIONAL DRUG CODE DIRECTORY&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP\\_SEARCHRESULT.CFM\)](https://twitter.com/intent/tweet/?text=NATIONAL%20DRUG%20CODE%20DIRECTORY&url=https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm)

 [LINKEDIN \(HTTPS://WWW.LINKEDIN.COM/SHAREARTICLE?MINI=TRUE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP\\_SEARCHRESULT.CFM&TITLE=NATIONAL DRUG CODE DIRECTORY&SOURCE=FDA\)](https://www.linkedin.com/sharearticle?mini=true&url=https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm&title=NATIONAL%20DRUG%20CODE%20DIRECTORY&source=fda)

 [PIN IT \(HTTPS://WWW.PINTEREST.COM/PIN/CREATE/BUTTON/?URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP\\_SEARCHRESULT.CFM&DESCRIPTION=NATIONAL DRUG CODE DIRECTORY\)](https://www.pinterest.com/pin/create/button/?url=https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm&description=NATIONAL%20DRUG%20CODE%20DIRECTORY) 

 [EMAIL \(MAILTO:?SUBJECT=NATIONAL DRUG CODE DIRECTORY&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP\\_SEARCHRESULT.CFM\)](mailto:?subject=NATIONAL%20DRUG%20CODE%20DIRECTORY&body=https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm)  [PRINT](#)

Current through April 02, 2019

You have searched Finished drug products

Search Results: '008708'

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All

 records per page 

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
 Dibenzyline	59212-001-01	10 mg/1	CAPSULE	ORAL	NDA008708	Concordia Pharmaceuticals Inc.	59212-001	Phenoxybenzamine Hydrochloride	PHENOXYBENZAMINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	01/26/1953	N/A	NDA	100 CAPSULE in 1 BOTTLE (59212-001-01)
 Phenoxybenzamine Hydrochloride	66993-066-02	10 mg/1	CAPSULE	ORAL	NDA008708	Prasco Laboratories	66993-066	Phenoxybenzamine Hydrochloride	PHENOXYBENZAMINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/11/2015	N/A	NDA AUTHORIZED GENERIC	100 CAPSULE in 1 BOTTLE (66993-066-02)

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

Drug questions email: [DRUGINFO@FDA.HHS.GOV \(mailto:DRUGINFO@FDA.HHS.Gov\)](mailto:DRUGINFO@FDA.HHS.GOV)

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

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 Drug Products

 [SHARE \(HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](https://www.facebook.com/sharer/sharer.php?u=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.Process)

 [TWEET \(HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](https://twitter.com/intent/tweet/?text=Drugs@FDA: FDA Approved Drug Products&url=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.Process)



 [EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](mailto:?subject=Drugs@FDA: FDA Approved Drug Products&body=https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.Process)

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Abbreviated New Drug Application (ANDA): 204522

Company: PAR PHARM INC

 [EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=204522\)](mailto:?subject=Drugs@FDA: FDA Approved Drug Products&body=http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=Overview.Process%26VARAPPLNO=204522)

## Products on ANDA 204522



CSV Excel Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
PHENOXYBENZAMINE HYDROCHLORIDE	PHENOXYBENZAMINE HYDROCHLORIDE	10MG	CAPSULE;ORAL	Prescription	AB	No	No

Showing 1 to 1 of 1 entries

[Approval Date\(s\) and History, Letters, Labels, Reviews for ANDA 204522](#)



[Therapeutic Equivalents for ANDA 204522](#)



Phenoxybenzamine Hydrochloride Capsules USP, 10 mg – US Market Data
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Row Labels	KG MAT Dec 2017	KG MAT Dec 2018	NSP Ext. Units MAT Dec 2017	NSP Ext. Units MAT Dec 2018
PHENOXYBENZAMINE	5	4	455,000	375,600
10MG	5	4	455,000	375,600
<b>00054034925 CAP 10MG 100</b>	<b>1</b>	<b>1</b>	<b>114,300</b>	<b>94,300</b>
PHENOXYBENZAMINE	1	1	114,300	94,300
HIKMA PHARMACEUT	1	1	114,300	94,300
<b>49884003801 CAP 10MG 100</b>	<b>1</b>	<b>3</b>	<b>51,700</b>	<b>251,000</b>
PHENOXYBENZAMINE	1	3	51,700	251,000
PAR PHARM	1	3	51,700	251,000
<b>59212000101 CAP 10MG 100</b>	<b>0</b>	<b>0</b>	<b>17,700</b>	<b>6,000</b>
DIBENZYLINE	0	0	17,700	6,000
CONCORDIA PHARMA	0	0	17,700	6,000
<b>66993006602 CAP 10MG 100</b>	<b>3</b>	<b>0</b>	<b>271,300</b>	<b>24,300</b>
PHENOXYBENZAMINE	3	0	271,300	24,300
PRASCO LABS	3	0	271,300	24,300



**From:** Janardhan Dumpeti [mailto:janar1021@gmail.com]  
**Sent:** Saturday, January 19, 2019 3:15 AM  
**To:** Jalajeshwar Reddy Ravulapelli <JalajeshwarReddy.Ravulapelli@aurobindo.com>  
**Cc:** Yugandhar Dasu <Yugandhar.Dasu@aurobindo.com>  
**Subject:** Re: Dibenzylamine (Phenoxybenzamine hydrochloride) Capsules availability-Reg

\*\*\* This email has reached your inbox from external network domain (outside of Aurobindo) \*\*\*

Hi Jalajeshwar,

The NDC no you requested are not available and the NDC available is 00054-0349-25 and the price is \$ 6500/ 100 ct bottle . let me know when you nrdf them.

Thanks  
Janardhan Dumpeti  
Pharmacist-in-charge  
New City RX LLC  
DBA-Pharmaceutical Consultants  
200 E Eckerson RD  
New City - NY-10956  
Pharmacy [845-425-1131](tel:845-425-1131)  
Cell 201-850-0752

On Fri, Jan 18, 2019 at 5:02 AM Jalajeshwar Reddy Ravulapelli <[JalajeshwarReddy.Ravulapelli@aurobindo.com](mailto:JalajeshwarReddy.Ravulapelli@aurobindo.com)> wrote:

Dear Janardhan,

Please check below product market availability. If not available, pls provide the reason.

Description	Dosage form	Strengths	Market	UOM	Qty	No of packs	MA/NDC Number	Pack size
Dibenzylamine (Phenoxybenzamine hydrochloride) Capsules USP 10mg	Capsules	10 mg	US	No's	600	6	59212-001-01	100 pack
Dibenzylamine (Phenoxybenzamine hydrochloride) Capsules USP 10mg	Capsules	10mg	US	No's	200	2	59212-001-01	100's HDPE



**Thanks&Regards**  
**Jalajeshwar Reddy.R**  
**Dept -PMT**  
**Ext: 1684.**

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**From:** KRISHNA KISHORE INAPURI [mailto:kkinapuri@gmail.com]  
**Sent:** Thursday, January 24, 2019 6:14 AM  
**To:** Jalajeshwar Reddy Ravulapelli <JalajeshwarReddy.Ravulapelli@aurobindo.com>  
**Cc:** Yugandhar Dasu <Yugandhar.Dasu@aurobindo.com>  
**Subject:** Re: Dibenzylamine (Phenoxybenzamine hydrochloride) Capsules availability-Reg

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Sorry on Back order with my wholesalers

On Fri, Jan 18, 2019 at 5:03 AM Jalajeshwar Reddy Ravulapelli <[JalajeshwarReddy.Ravulapelli@aurobindo.com](mailto:JalajeshwarReddy.Ravulapelli@aurobindo.com)> wrote:

Dear Mr. Kishore,

Please check below product market availability. If not available, pls provide the reason.

Description	Dosage form	Strengths	Market	UOM	Qty	No of packs	MA/NDC Number	Pack size
Dibenzylamine (Phenoxybenzamine hydrochloride) Capsules USP 10mg	Capsules	10 mg	US	No's	600	6	59212-001-01	100 pack
Dibenzylamine (Phenoxybenzamine hydrochloride) Capsules USP 10mg	Capsules	10mg	US	No's	200	2	59212-001-01	100's HDPE



**Thanks&Regards**  
**Jalajeshwar Reddy.R**  
**Dept -PMT**  
**Ext: 1684.**

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**From:** Mahitha [mailto:rldsales@agracepharma.com]  
**Sent:** Wednesday, January 23, 2019 10:52 AM  
**To:** Jalajeshwar Reddy Ravulapelli <JalajeshwarReddy.Ravulapelli@aurobindo.com>  
**Cc:** Yugandhar Dasu <Yugandhar.Dasu@aurobindo.com>  
**Subject:** RE: Dibenzylamine (Phenoxybenzamine hydrochloride) Capsules availability-Reg

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Dear Sir,

We herewith informing that NDC : 59212-001-01 seems to be discontinued.

PHENOXYBENZAMINE HCL 10 MG CAP - 00054-0349-25 - HIKMA PHARMACEUTICALS USA is available and we are pleased to offer at **USD7245** per pack with ex works, immediate payment and delivery basis.

Thank you,  
**Mahitha**

---

**From:** Jalajeshwar Reddy Ravulapelli [mailto:JalajeshwarReddy.Ravulapelli@aurobindo.com]  
**Sent:** 18 January 2019 15:33  
**To:** Mahitha  
**Cc:** Yugandhar Dasu  
**Subject:** Dibenzylamine (Phenoxybenzamine hydrochloride) Capsules availability-Reg

Dear Mahitha,

Please check below product market availability. If not available, pls provide the reason.

Description	Dosage form	Strengths	Market	UOM	Qty	No of packs	MA/NDC Number	Pack size
Dibenzylamine(Phenoxybenzamine hydrochloride)Capsules USP 10mg	Capsules	10 mg	US	No's	600	6	59212-001-01	100 pack
Dibenzylamine(Phenoxybenzamine hydrochloride)Capsules USP 10mg	Capsules	10mg	US	No's	200	2	59212-001-01	100's HDPE



**Thanks&Regards**  
**Jalajeshwar Reddy.R**  
**Dept -PMT**  
**Ext: 1684.**

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---

**From:** Vikrant Chudasama [mailto:vikrant.chudasama@clinicalsymbio.com]  
**Sent:** Wednesday, February 6, 2019 3:27 PM  
**To:** Jalajeshwar Reddy Ravulapelli <JalajeshwarReddy.Ravulapelli@aurobindo.com>  
**Cc:** Yugandhar Dasu <Yugandhar.Dasu@aurobindo.com>; 'Salim Shaikh ' <salim.shaikh@symbiogenetics.com>; Bapu reddy Vesireddy <Bapureddy.Vesireddy@aurobindo.com>  
**Subject:** RE: Dibenzylamine (Phenoxybenzamine hydrochloride) Capsules availability-Reg

\*\*\* This email has reached your inbox from external network domain (outside of Aurobindo) \*\*\*

Dear Jalajeshwar,

Dibenzylamine is currently out of stock.

We do not know the reason for being out of stock.

We will keep Aurobindo posted once the samples are available in the market.

Regards,  
Vikrant Chudasama  
Senior Marketing Executive

**Symbio Generics (I) Pvt. Limited**

215 Atrium, Unit- 622/ C-Wing, Andheri Kurla Rd.,  
Andheri (E), Mumbai - 400 059 INDIA  
**Board Line:** 022 – 28388 880, **Ext:** 870  
**Mobile** : +91 9619 717181  
**Website** : [www.clinicalsymbio.com](http://www.clinicalsymbio.com)

---

**From:** Jalajeshwar Reddy Ravulapelli [mailto:JalajeshwarReddy.Ravulapelli@aurobindo.com]  
**Sent:** Wednesday, February 6, 2019 11:13  
**To:** Vikrant Chudasama  
**Cc:** Yugandhar Dasu; Salim Shaikh ; Bapu reddy Vesireddy  
**Subject:** Dibenzylamine (Phenoxybenzamine hydrochloride) Capsules availability-Reg

Dear Vikrant,

Please check below product market availability. If not available, pls provide the reason.

Description	Dosage form	Strengths	Market	UOM	Qty	No of packs	MA/NDC Number	Pack size
Dibenzylamine(Phenoxybenzamine hydrochloride)Capsules USP 10mg	Capsules	10 mg	US	No's	600	6	59212-001-01	100 pack
Dibenzylamine(Phenoxybenzamine hydrochloride)Capsules USP 10mg	Capsules	10mg	US	No's	200	2	59212-001-01	100's HDPE



**Thanks&Regards**  
**Jalajeshwar Reddy.R**  
**Dept -PMT**  
**Ext: 1684.**

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**From:** Siva RK Jonnalagadda [mailto:sales@amsterdampharma.com]  
**Sent:** Saturday, January 19, 2019 2:57 AM  
**To:** Jalajeshwar Reddy Ravulapelli <JalajeshwarReddy.Ravulapelli@aurobindo.com>  
**Cc:** Yugandhar Dasu <Yugandhar.Dasu@aurobindo.com>; Amsterdam Pharmacy <amsterdampharma@yahoo.com>  
**Subject:** Re: Dibenzylamine (Phenoxybenzamine hydrochloride) Capsules availability-Reg

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Dear Jalajeshwar

This item is on back order

Only the below Generics are available

PHENOXYB HYD CAP 10MG ROX100	NDC 00054034925	phenoxybenzamine HCl	HIKMA PHARMACEUTICALS USA
PHENOXYBENZ HCl CP10MGPAR100	NDC: 49884003801	phenoxybenzamine HCl	PAR PHARMACEUTICAL INC @

Thank You



1743 Amsterdam Ave  
New York NY 10031

Siva RK Jonnalagadda  
Business Development

☎: +13479524545 📞: +13477301863

@: sales@amsterdampharma.com

🌐: www.amsterdampharma.com

On Fri, Jan 18, 2019 at 5:02 AM Jalajeshwar Reddy Ravulapelli <JalajeshwarReddy.Ravulapelli@aurobindo.com> wrote:

Dear Siva,

Please check below product market availability. If not available, pls provide the reason.

Description	Dosage form	Strengths	Market	UOM	Qty	No of packs	MA/NDC Number	Pack size
Dibenzylamine (Phenoxybenzamine hydrochloride) Capsules USP 10mg	Capsules	10 mg	US	No's	600	6	59212-001-01	100 pack
Dibenzylamine (Phenoxybenzamine hydrochloride) Capsules USP 10mg	Capsules	10mg	US	No's	200	2	59212-001-01	100's HDPE



**Thanks&Regards**  
**Jalajeshwar Reddy.R**  
**Dept -PMT**  
**Ext: 1684.**

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**From:** Deepika Nair [mailto:deepika@espeeusa.com]  
**Sent:** Thursday, March 7, 2019 10:16 AM  
**To:** Jalajeshwar Reddy Ravulapelli <JalajeshwarReddy.Ravulapelli@aurobindo.com>  
**Cc:** 'Swapnil Shah' <swapnil@espeeusa.com>; 'Trupal Patel' <trupal@espeeusa.com>; Yugandhar Dasu <Yugandhar.Dasu@aurobindo.com>; Bapu reddy Vesireddy <Bapureddy.Vesireddy@aurobindo.com>  
**Subject:** RE: Phenoxybenzamine innovator capsule

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Dear Sir,

The product is not available.

*Thanks & Regards,*

*Deepika*

---

**From:** Jalajeshwar Reddy Ravulapelli <[JalajeshwarReddy.Ravulapelli@aurobindo.com](mailto:JalajeshwarReddy.Ravulapelli@aurobindo.com)>  
**Sent:** 06 March 2019 16:34  
**To:** Deepika Nair <[deepika@espeeusa.com](mailto:deepika@espeeusa.com)>  
**Cc:** 'Swapnil Shah' <[swapnil@espeeusa.com](mailto:swapnil@espeeusa.com)>; 'Trupal Patel' <[trupal@espeeusa.com](mailto:trupal@espeeusa.com)>; Yugandhar Dasu <[Yugandhar.Dasu@aurobindo.com](mailto:Yugandhar.Dasu@aurobindo.com)>; Bapu reddy Vesireddy <[Bapureddy.Vesireddy@aurobindo.com](mailto:Bapureddy.Vesireddy@aurobindo.com)>  
**Subject:** Phenoxybenzamine innovator capsule

Dear Deepika,

Please confirm the market availability of phenoxybenzamine capsules from prasco laboratories for US market..

PIL is attached for NDC reference.. (NDC: 66993-066 -02)

Pl. do the needful as it is required on priority..



*Thanks & Regards*

*Jalajeshwar Reddy.R*

*Dept -PMT*

*Ext: 1684.*

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**From:** KRISHNA KISHORE INAPURI [mailto:kkinapuri@gmail.com]  
**Sent:** Wednesday, March 6, 2019 11:36 PM  
**To:** Jalajeshwar Reddy Ravulapelli <JalajeshwarReddy.Ravulapelli@aurobindo.com>  
**Cc:** Yugandhar Dasu <Yugandhar.Dasu@aurobindo.com>; Bapu reddy Vesireddy <Bapureddy.Vesireddy@aurobindo.com>  
**Subject:** Re: Phenoxybenzamine innovator capsule

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Sorry none of my wholesalers carry it

On Wed, Mar 6, 2019 at 6:03 AM Jalajeshwar Reddy Ravulapelli  
<[JalajeshwarReddy.Ravulapelli@aurobindo.com](mailto:JalajeshwarReddy.Ravulapelli@aurobindo.com)> wrote:

Dear Kishore,

Please confirm the market availability of phenoxybenzamine capsules from prasco laboratories for US market..

PIL is attached for NDC reference.. (NDC: 66993-066 -02)

**Pl. do the needful as it is required on priority..**



*Thanks & Regards  
Jalajeshwar Reddy.R  
Dept -PMT  
Ext: 1684.*

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**From:** Janardhan Dumpeti [mailto:janar1021@gmail.com]  
**Sent:** Thursday, March 7, 2019 5:15 AM  
**To:** Jalajeshwar Reddy Ravulapelli <JalajeshwarReddy.Ravulapelli@aurobindo.com>  
**Cc:** Yugandhar Dasu <Yugandhar.Dasu@aurobindo.com>; Bapu reddy Vesireddy <Bapureddy.Vesireddy@aurobindo.com>  
**Subject:** Re: Phenoxybenzamine innovator capsule

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Hi dear Jalajeshwar,

Sorry none of the distribuotrs has the NDC you are looking they have from Par NDC-49884-0038-01 and Hikma NDC-00054-0349-25 , check with your team and let me know .

Thanks  
Janardhan Dumpeti  
Pharmacist-in-charge  
New City RX LLC  
DBA-Pharmaceutical Consultants  
200 E Eckerson RD  
New City - NY-10956  
Pharmacy [845-425-1131](tel:845-425-1131)  
Cell 201-850-0752

On Wed, Mar 6, 2019 at 6:03 AM Jalajeshwar Reddy Ravulapelli <[JalajeshwarReddy.Ravulapelli@aurobindo.com](mailto:JalajeshwarReddy.Ravulapelli@aurobindo.com)> wrote:

Dear Janardhan,

Please confirm the market availability of phenoxybenzamine capsules from prasco laboratories for US market..

PIL is attached for NDC reference.. (NDC: 66993-066 -02)

**Pl. do the needful as it is required on priority..**



*Thanks & Regards  
Jalajeshwar Reddy.R  
Dept -PMT  
Ext: 1684.*

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