valisure
the pharmacy that checks

June 13, 2019

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Valisure Citizen Petition

Dear Sir or Madam:

The undersigned, on behalf of Valisure LLC and ValisureRX LLC (collectively, "Valisure" or "Petitioner"), submits this Citizen Petition ("Petition") pursuant to Sections 301(21 U.S.C. § 331), 501 (21 U.S.C. § 351), 502 (21 U.S.C. § 352), 505 (21 U.S.C. § 355), 702 (21 U.S.C. § 372), 704 (21 U.S.C. § 374), and 705 (21 U.S.C. § 375) of the Federal Food, Drug and Cosmetic Act (the "FDCA"), in accordance with 21 C.F.R. 10.20 and 10.30, to request the Commissioner of Food and Drugs ("Commissioner") to issue a regulation, revise industry guidance, and take such other actions set forth below.

A. Action Requested

Valisure has tested and detected high levels of N,N-Dimethylformamide ("DMF") in specific lots of the drug valsartan, an angiotensin II receptor blocker ("ARB"). DMF is a chemical that was reclassified in 2018 as a Group 2A probable human carcinogen by the World Health Organization ("WHO") and International Association for Research of Cancer ("IARC").[1] This Petition requests that the Commissioner take the following actions:

1) review and significantly lower the acceptable intake/permitted daily exposure limit of DMF, as listed in the current FDA guidance *Q3C – Tables and List, Guidance for Industry*, from its current level of 8,800,000 nanograms to less than 1,000 nanograms (and potentially as low as 96 nanograms);

2) request a recall of identified lots of valsartan on the basis that, due to contamination with a probable human carcinogen, these drugs are adulterated under Section 501 of the FDCA (21 U.S.C. § 351) and misbranded under Section 502 of the FDCA (21 U.S.C. § 352);

3) conduct examinations and investigation under Section 702 (a) of the FDCA (21 U.S.C. § 372(a)) regarding these products, their manufacturing processes, and the manufacturer submissions made for FDA approval under 704 (a)of the FDCA (21 U.S.C. § 374(a)) and effect labeling revisions as needed;

[1] International Agency for Research on Cancer and World Health Organization, *IARC Monographs on the Identification of Carcinogenic Hazards to Humans,* Volume 47, 71, 115 (2018) (https://monographs.iarc.fr/list-of-classifications-volumes/).

4) provide information to the public regarding these products under Section 705(b) of the FDCA (21 U.S.C. § 375(b)); and

5) promulgate regulations requiring robust independent chemical batch-level testing and verification of the chemical content of batches of pharmaceuticals of drugs and, while these regulations are pending, issue guidance requesting such testing and verification.

Background on Petitioner

Valisure is an online pharmacy currently licensed in 37 states and an analytical laboratory that is ISO 17025 accredited by the International Organization for Standardization ("ISO"). Valisure is registered with the Drug Enforcement Administration (Pharmacy: FV7431137, Laboratory: RV0484814) and the FDA (FEI #: 3012063246). Valisure's mission is to help ensure the safety, quality and consistency of medications and supplements in the market. In response to rising concerns about counterfeit medications, generics, and overseas manufacturing, Valisure developed proprietary analytical technologies that it uses in addition to FDA standard assays to test every batch of every medication it dispenses.

In an August 7, 2018, inspection of Valisure's facilities by the FDA, it was determined that since Valisure's unique testing facility is not a part of the pharmaceutical manufacturing system and does not perform release testing, stability testing or any related services for pharmaceutical manufacturers, Valisure did not require FDA registration. However, Valisure has elected to maintain voluntary registration status with the FDA. Valisure also received guidance that since it operates outside of the manufacturing industry using the appropriate ISO guidelines as opposed to GMPs, any product failures or concerns that Valisure identifies should be reported back to the pharmaceutical industry. Valisure has complied with this guidance and regularly provides reports to applicable parties in the pharmaceutical industry.

As discussed below, given the increased risk to public safety, the concern of medical practitioners regarding DMF in pharmaceuticals, and the fact that FDA did not amend the acceptable intake of DMF or take other appropriate action following the chemical's reclassification to Group 2A status by WHO and IARC, Valisure seeks to utilize this Citizen Petition to bring these concerns directly to the attention of the Commissioner and the FDA, and request that they take action.

B. Statement of Grounds

DMF is classified by the FDA as a Class 2 solvent[2] and is commonly used in the production of pharmaceutical active ingredients. According to the FDA, Class 2 solvents "should be limited in pharmaceutical products because of their inherent toxicity."[3]

[2] Food and Drug Administration, *Q3C – Tables and List* (June 2017), page 3 (https://www.fda.gov/media/71737/download) .
[3] *Id.* at 6.

In the recent wave of ARB recalls due to the discovery of probable human carcinogens, it has become apparent that the switch in the manufacturing industry to the use of the DMF solvent may be largely responsible for the formation of nitrosamine carcinogens such as N-nitrosodimethylamine ("NDMA") and N-nitrosodiethylamine ("NDEA").[4] The carcinogenic nature of nitrosamines in general, and specifically NDMA and NDEA, has been well characterized in the scientific community since as early as the 1960s.[5] The WHO and the IARC have classified both NDMA and NDEA as Group 2A compounds thereby defining them as "probably carcinogenic to humans."[6] The FDA currently recognizes the danger of such compounds and, as a result, has set strict daily acceptable intake limits on NDMA and NDEA in pharmaceuticals of 96 nanograms and 26.5 nanograms respectively.[7] There have been a multitude of manufacturer recalls of ARB medications, including valsartan, due to the detection of NDMA and NDEA contamination in excess of these limits.[8]

Despite the very strict FDA recommendations for daily limits of NDMA and NDEA, the chemical DMF, which since 2018 has shared the same Group 2A carcinogenicity classification,[9] currently has an FDA permitted daily exposure limit of 8,800,000 nanograms,[10] which is 9,166,667% higher than the acceptable intake limit of NDMA. This disparity lacks a rational basis and is of significant concern, particularly because of Valisure's recent findings that high levels of DMF exist in certain on-market lots of valsartan medication.

Consistent with the revised designation by WHO and IARC to Group 2A, DMF was listed in late 2017 as a cancer-causing chemical by California for the purposes of Proposition 65.[11] A review

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[4] *See* Parr, M.K. and Joseph, J.F., *NDMA Impurity in Valsartan and Other Pharmaceutical Products: Analytical Methods for the Determination of N-Nitrosamines,* J. Pharm. Biomed. Anal. 164: 536 (February 2019) (https://www.ncbi.nlm.nih.gov/pubmed/30458387).

[5] *E.g.,* Argus, M.F. and Hoch-Ligeti, C., *Comparative Study of the Carcinogenic Activity of Nitrosamines,* JNCI: Journal of the National Cancer Institute 27: 695 (September 1961) (https://academic.oup.com/jnci/article-abstract/27/3/695/958026).

[6] International Agency for Research on Cancer and World Health Organization, *IARC Monographs on the Identification of Carcinogenic Hazards to Humans,* Volume 17, Supp. 7 (1987) (https://monographs.iarc.fr/list-of-classifications-volumes/) and *Preamble to IARC Monographs on the Identification of Carcinogenic Hazards to Humans* (2019) (https://monographs.iarc.fr/wp-content/uploads/2019/01/Preamble-2019.pdf).

[7] Food and Drug Administration, *FDA updates table of interim limits for nitrosamine impurities in ARBs,* (February 28, 2019) (https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan).

[8] *See* Food and Drug Administration, *Search List of Recalled Angiotensin II Receptor Blockers (ARBs) Including Valsartan, Losartan and Irbesartan* (https://www.fda.gov/drugs/drug-safety-and-availability/search-list-recalled-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and).

[9] International Agency for Research on Cancer and World Health Organization, *IARC Monographs on the Identification of Carcinogenic Hazards to Humans,* Volume 47, 71, 115 (2018) (https://monographs.iarc.fr/list-of-classifications-volumes/).

[10] Food and Drug Administration, *Q3C – Tables and List* (June 2017), page 3 (https://www.fda.gov/media/71737/download).

[11] California Office of Environmental Health Hazard Assessment, *Dimethylformamide* (October 2017) (https://oehha.ca.gov/chemicals/dimethylformamide).

by the California Environmental Protection Agency had expressed concern regarding the potential genotoxicity and permeation-enhancing activity of DMF whereby it "may act as an escort to facilitate the easy entry of either endogenous or exogenous carcinogens."[12] Considering that valsartan has on many occasions been found to contain other probable human carcinogens like NDMA and NDEA, the presence of DMF could serve to further exacerbate even low levels of such carcinogens, which have also been found in Valisure's analysis of the same lots containing DMF. The results of Valisure's testing of valsartan lots is set forth below.

This data is of significant concern to medical practitioners who already struggle to prescribe safe medications and who rely on external government and private sector oversight to ensure contaminant-free drugs. Due to its discovery of significant levels of DMF contamination, Valisure's pharmacy will no longer sell the affected lots of valsartan it has acquired, nor can it obtain a refund for these tainted products because they technically conform with the very high permitted daily exposure limit for DMF in published FDA guidance.

DMF is categorized by the FDA as a Class 2 solvent with a permitted daily exposure limit of 8,800,000 nanograms. Given the recent implication of DMF in the ARB recalls and the increased industry scrutiny of related chemicals, Petitioner notes that the WHO and IARC reclassified DMF to Group 2A probable carcinogen status in 2018 (see Attachment A), while the most recent revision of the FDA regulation of residual solvents is dated July 2017. As this Group 2A carcinogen status is a relatively new development, Petitioner urges the Commissioner and the FDA to expeditiously reevaluate the current permitted daily exposure limits on DMF and significantly lower them so that this probable carcinogen is not present in significant amounts in the American drug supply, and to take other such actions outlined in this Petition as deemed appropriate.

Permitted Daily Exposure Limit Revision

Petitioner requests that the FDA take the rational approach of benchmarking permitted daily exposure limits against other Group 2A compounds like the nitrosamines NDMA and NDEA. NDMA is particularly relevant in this case given its connection to the use of DMF as a solvent in Active Pharmaceutical Ingredient ("API") industry manufacturing and that at least in the case of valsartan, both NDMA and DMF often co-contaminate tablets. FDA should revise the DMF permitted daily exposure limit for pharmaceutical products to allow less than 1,000 nanograms and potentially as low as 96 nanograms.

As set forth in the summary table below, Petitioner has detected high levels of DMF in specific lots of valsartan and undetectable levels of DMF in others. Petitioner's pharmacy acquired medications from the manufacturers reasonably available to it through its distributors. Valisure's ISO 17025 accredited laboratory used FDA recommended GC/MS headspace analysis method

[12] California Environmental Protection Agency, *Evidence on the Carcinogenicity of N,N-Dimethylformamide (Draft)* (August 2008), page 31 (https://oehha.ca.gov/media/downloads/proposition-65/chemicals/dmfhid080808.pdf).

FY19-005-DPA[13] for the determination of DMF levels. Certified reference material was used for DMF calibration and deuterated DMF used as an internal control.

API	Distributor	Dose (mg)	Lot	NDMA (ng)	DMF (ng)
Valsartan	Alembic	40	1805007840	< 25	107
Valsartan	Alembic	80	1805007896	not detected	62
Valsartan	Alembic	160	1805007540	not detected	not detected
Valsartan	Alembic	160	1805008342	not detected	not detected
Valsartan	Alembic	320	1805009609	not detected	not detected
Valsartan	Amneal	80	BG15818A	< 25	207
Valsartan	Amneal	160	BG16018A	< 25	179
Valsartan	Aurobindo	40	VUSA18001-A	< 25	210
Valsartan	Aurobindo	40	VUSA18009-A	< 25	206
Valsartan	Aurobindo	80	VUSB18001-A	< 25	209
Valsartan	Aurobindo	80	VUSB18013-A	< 25	268
Valsartan	Aurobindo	160	VUSC18005-A	not detected	470
Valsartan	Aurobindo	160	VUSC18007-B	< 25	197
Valsartan	Aurobindo	320	VUSD18007-A	< 25	376
Valsartan	Aurobindo	320	VUSD18021-A	< 25	212
Valsartan	Cadista	40	VR119002A	not detected	51
Valsartan	Cadista	40	VR119003A	not detected	not detected
Valsartan	Cadista	80	VR218026A	not detected	not detected
Valsartan	Cadista	160	VR318P007	not detected	not detected
Valsartan	Cadista	160	VR318P006	not detected	not detected
Valsartan	Cadista	320	VR418051A	not detected	not detected
Valsartan	Cadista	320	VR419008A	not detected	not detected
Valsartan	Macleods	40	EVF804A	< 25	4,091
Valsartan	Macleods	40	EVF903A	< 25	5,222
Valsartan	Macleods	80	EVG803A	< 25	10,708
Valsartan	Macleods	160	EVH805A	29	17,268
Valsartan	Macleods	320	EVI807A	37	31,195
Valsartan	Macleods	320	EVI818A	28	76,460
Valsartan	Novartis	40	AH1207H	< 25	353
Valsartan-HCTZ	Alembic	320-12.5	1805010695	132	982
Valsartan-HCTZ	Aurobindo	320-12.5	HRSA18037-A	< 25	746
Valsartan-HCTZ	Lupin	320-12.5	G802870	< 25	997

[13] Food and Drug Administration, *Combined N-Nitrosodimethlyamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay,* FY19-005-DPA-S (January 2019) (https://www.fda.gov/media/117843/download).

Valsartan-HCTZ	Macleods	320-12.5	BVO829A	52	82,285
Valsartan-HCTZ	Novartis	320-12.5	AG9492E	< 25	204

Table 1. NDMA and DMF amounts reported are average values for multiple single-tablets measurements. Appendix A contains a table of all individual tablet results. "< 25" indicates detectable amounts were observed below the lowest calibration point.

Recall Request and Other Actions

This Petition seeks to have the Commissioner and FDA request recalls for the identified lots of valsartan, consistent with FDA's mandate to ensure the safety of the drug supply in America. The following lots of valsartan contained elevated levels of DMF detected during testing by Valisure's laboratory.

API	Distributor	Dose (mg)	Lot	Expiration Dates
Valsartan	Alembic	40	1805007840	Jun-20
Valsartan	Amneal	80	BG15818A	Jul-20
Valsartan	Amneal	160	BG16018A	Jul-20
Valsartan	Aurobindo	40	VUSA18001-A	Jul-21
Valsartan	Aurobindo	40	VUSA18009-A	Sep-21
Valsartan	Aurobindo	80	VUSB18001-A	Jun-21
Valsartan	Aurobindo	80	VUSB18013-A	Sep-21
Valsartan	Aurobindo	160	VUSC18005-A	Jun-21
Valsartan	Aurobindo	160	VUSC18007-B	Jul-21
Valsartan	Aurobindo	320	VUSD18007-A	Jul-21
Valsartan	Aurobindo	320	VUSD18021-A	Sep-21
Valsartan	Macleods	40	EVF804A	Jul-20
Valsartan	Macleods	40	EVF903A	Feb-21
Valsartan	Macleods	80	EVG803A	Jul-20
Valsartan	Macleods	160	EVH805A	Aug-20
Valsartan	Macleods	320	EVI807A	Aug-20
Valsartan	Macleods	320	EVI818A	Nov-20
Valsartan	Novartis	40	AH1207H	Jun-20
Valsartan-HCTZ	Alembic	320-12.5	1805010695	Aug-21
Valsartan-HCTZ	Aurobindo	320-12.5	HRSA18037-A	Oct-21
Valsartan-HCTZ	Lupin	320-12.5	G802870	Feb-20
Valsartan-HCTZ	Macleods	320-12.5	BVO829A	Sep-21
Valsartan-HCTZ	Novartis	320-12.5	AG9492E	Mar-20

Table 2. Medication lots highlighted in yellow represent particularly high levels of DMF contamination in the thousands and tens of thousands of nanograms and red highlighting indicates NDMA levels in excess of the FDA 96 nanogram daily acceptable intake limit.

The impact of such recalls is important for public safety and is not expected to create significant drug shortages or otherwise overly burden the U.S. healthcare system. As indicated above, in Valisure's analysis of multiple manufacturers, it was shown that multiple manufacturers of on-market valsartan have produced lots that do not contain detectable levels of the DMF contaminant.

In addition, for the reasons stated above, FDA should conduct examinations and investigation under Section 702 (a) of the FDCA (21 U.S.C. § 372(a)) regarding these products, their manufacturing processes, and the manufacturer submissions made for FDA approval under 704 (a)of the FDCA (21 U.S.C. § 374(a)) and effect labeling revisions as needed. Further, FDA should provide information to the public regarding these medications under Section 705(b) of the FDCA (21 U.S.C. § 375(b)).

Batch-level Testing and Verification of Drug Products in the United States

Petitioner is also requesting that the FDA promulgate regulations requiring robust independent chemical batch-level testing and verification of medications. In the interim, while these regulations are pending, FDA should issue formal guidance recommending such testing and verification.

This is necessary in order to serve public health and help protect Americans from adulterated drug products, an issue of growing concern. Grounds for this request are also rooted in strong support from the medical community, as evidenced by a recent resolution from the American College of Cardiology ("ACC"), calling for the American Medical Association to advocate for legislation requiring independent testing and verification of the chemical content of batches of pharmaceuticals. The resolution is at Attachment B.

C. Environmental Impact

Petitioner claims a categorical exclusion under 21 C.F.R. § 25.31, and believes that this Petition qualifies for a categorical exclusion from the requirement to submit an environmental assessment or environmental impact statement. To Petitioner's knowledge, no extraordinary circumstances exist.

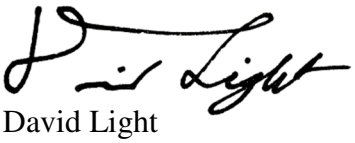
D. Economic Impact

Pursuant to 21 C.F.R. § 10.30(b), economic impact information will be submitted by the Petitioner only upon request of the Commissioner following review of this Petition.

E. Certification

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

Respectfully submitted,



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Appendix A

The table below represents results from individual tablets analyzed by Valisure and summarized in the above petition in Table 1.

API	Distributor	MG	LOT	NDMA (ng)	DMF (ng)
Valsartan	Alembic	160	1805007540	not detected	not detected
Valsartan	Alembic	160	1805007540	not detected	not detected
Valsartan	Alembic	160	1805007540	not detected	not detected
Valsartan	Alembic	160	1805007540	not detected	not detected
Valsartan	Alembic	40	1805007840	not detected	8
Valsartan	Alembic	40	1805007840	not detected	not detected
Valsartan	Alembic	40	1805007840	not detected	32
Valsartan	Alembic	40	1805007840	not detected	not detected
Valsartan	Alembic	40	1805007840	not detected	169
Valsartan	Alembic	40	1805007840	not detected	68
Valsartan	Alembic	40	1805007840	8	472
Valsartan	Alembic	80	1805007896	not detected	45
Valsartan	Alembic	80	1805007896	not detected	not detected
Valsartan	Alembic	80	1805007896	not detected	not detected
Valsartan	Alembic	80	1805007896	not detected	not detected
Valsartan	Alembic	80	1805007896	not detected	251
Valsartan	Alembic	80	1805007896	not detected	152
Valsartan	Alembic	80	1805007896	not detected	46
Valsartan	Alembic	80	1805007896	not detected	not detected
Valsartan	Alembic	160	1805008342	not detected	not detected
Valsartan	Alembic	160	1805008342	not detected	not detected
Valsartan	Alembic	160	1805008342	not detected	not detected
Valsartan	Alembic	160	1805008342	not detected	not detected
Valsartan	Alembic	320	1805009609	not detected	not detected
Valsartan	Alembic	320	1805009609	not detected	not detected
Valsartan	Alembic	320	1805009609	not detected	not detected
Valsartan	Alembic	320	1805009609	not detected	not detected
Valsartan	Novartis	40	AH1207H	11	341
Valsartan	Novartis	40	AH1207H	not detected	278
Valsartan	Novartis	40	AH1207H	not detected	341
Valsartan	Novartis	40	AH1207H	17	452
Valsartan	Amneal	80	BG15818A	12	212
Valsartan	Amneal	80	BG15818A	not detected	193
Valsartan	Amneal	80	BG15818A	not detected	165
Valsartan	Amneal	80	BG15818A	8	257
Valsartan	Amneal	160	BG16018A	11	474

Valsartan	Amneal	160	BG16018A	not detected	227
Valsartan	Amneal	160	BG16018A	not detected	17
Valsartan	Amneal	160	BG16018A	not detected	not detected
Valsartan	Macleods	40	EVF804A	13	3,646
Valsartan	Macleods	40	EVF804A	18	3,884
Valsartan	Macleods	40	EVF804A	not detected	5,683
Valsartan	Macleods	40	EVF804A	11	3,605
Valsartan	Macleods	40	EVF804A	not detected	3,636
Valsartan	Macleods	40	EVF903A	22	4,418
Valsartan	Macleods	40	EVF903A	16	4,717
Valsartan	Macleods	40	EVF903A	22	6,774
Valsartan	Macleods	40	EVF903A	11	4,906
Valsartan	Macleods	40	EVF903A	12	5,296
Valsartan	Macleods	80	EVG803A	25	8,746
Valsartan	Macleods	80	EVG803A	30	13,463
Valsartan	Macleods	80	EVG803A	11	12,503
Valsartan	Macleods	80	EVG803A	17	10,026
Valsartan	Macleods	80	EVG803A	15	8,800
Valsartan	Macleods	160	EVH805A	33	14,627
Valsartan	Macleods	160	EVH805A	43	21,762
Valsartan	Macleods	160	EVH805A	13	19,419
Valsartan	Macleods	160	EVH805A	30	15,184
Valsartan	Macleods	160	EVH805A	28	15,347
Valsartan	Macleods	320	EVI807A	21	35,803
Valsartan	Macleods	320	EVI807A	38	26,334
Valsartan	Macleods	320	EVI807A	46	27,466
Valsartan	Macleods	320	EVI807A	51	33,566
Valsartan	Macleods	320	EVI807A	29	27,479
Valsartan	Macleods	320	EVI807A	39	36,520
Valsartan	Macleods	320	EVI818A	25	64,711
Valsartan	Macleods	320	EVI818A	30	69,805
Valsartan	Macleods	320	EVI818A	29	70,976
Valsartan	Macleods	320	EVI818A	35	100,953
Valsartan	Macleods	320	EVI818A	23	74,796
Valsartan	Macleods	320	EVI818A	24	77,518
Valsartan	Cadista	40	VR119002A	not detected	113
Valsartan	Cadista	40	VR119002A	not detected	47
Valsartan	Cadista	40	VR119002A	not detected	34
Valsartan	Cadista	40	VR119002A	not detected	12
Valsartan	Cadista	40	VR119003A	not detected	not detected
Valsartan	Cadista	40	VR119003A	not detected	not detected

Valsartan	Cadista	80	VR218026A	not detected	not detected
Valsartan	Cadista	80	VR218026A	not detected	not detected
Valsartan	Cadista	80	VR218026A	not detected	not detected
Valsartan	Cadista	80	VR218026A	not detected	not detected
Valsartan	Cadista	160	VR318P007	not detected	not detected
Valsartan	Cadista	160	VR318P007	not detected	not detected
Valsartan	Cadista	160	VR318P007	not detected	not detected
Valsartan	Cadista	160	VR318P007	not detected	not detected
Valsartan	Cadista	160	VR318P006	not detected	not detected
Valsartan	Cadista	160	VR318P006	not detected	not detected
Valsartan	Cadista	320	VR418051A	not detected	not detected
Valsartan	Cadista	320	VR418051A	not detected	not detected
Valsartan	Cadista	320	VR418051A	not detected	not detected
Valsartan	Cadista	320	VR418051A	not detected	not detected
Valsartan	Cadista	320	VR419008A	not detected	not detected
Valsartan	Cadista	320	VR419008A	not detected	not detected
Valsartan	Cadista	320	VR419008A	not detected	not detected
Valsartan	Cadista	320	VR419008A	not detected	not detected
Valsartan	Aurobindo	40	VUSA18001-A	15	481
Valsartan	Aurobindo	40	VUSA18001-A	3	109
Valsartan	Aurobindo	40	VUSA18001-A	not detected	173
Valsartan	Aurobindo	40	VUSA18001-A	not detected	76
Valsartan	Aurobindo	40	VUSA18009-A	9	252
Valsartan	Aurobindo	40	VUSA18009-A	28	388
Valsartan	Aurobindo	40	VUSA18009-A	10	35
Valsartan	Aurobindo	40	VUSA18009-A	16	151
Valsartan	Aurobindo	80	VUSB18001-A	9	329
Valsartan	Aurobindo	80	VUSB18001-A	not detected	175
Valsartan	Aurobindo	80	VUSB18001-A	not detected	146
Valsartan	Aurobindo	80	VUSB18001-A	11	186
Valsartan	Aurobindo	80	VUSB18013-A	21	549
Valsartan	Aurobindo	80	VUSB18013-A	27	246
Valsartan	Aurobindo	80	VUSB18013-A	15	73
Valsartan	Aurobindo	80	VUSB18013-A	17	204
Valsartan	Aurobindo	160	VUSC18005-A	not detected	577
Valsartan	Aurobindo	160	VUSC18005-A	not detected	545
Valsartan	Aurobindo	160	VUSC18005-A	not detected	344
Valsartan	Aurobindo	160	VUSC18005-A	not detected	416
Valsartan	Aurobindo	160	VUSC18007-B	not detected	268
Valsartan	Aurobindo	160	VUSC18007-B	not detected	210
Valsartan	Aurobindo	160	VUSC18007-B	8	168

Valsartan	Aurobindo	160	VUSC18007-B	not detected	144
Valsartan	Aurobindo	320	VUSD18007-A	6	330
Valsartan	Aurobindo	320	VUSD18007-A	not detected	392
Valsartan	Aurobindo	320	VUSD18007-A	not detected	304
Valsartan	Aurobindo	320	VUSD18007-A	not detected	476
Valsartan	Aurobindo	320	VUSD18021-A	6	256
Valsartan	Aurobindo	320	VUSD18021-A	not detected	219
Valsartan	Aurobindo	320	VUSD18021-A	9	167
Valsartan	Aurobindo	320	VUSD18021-A	8	206
Valsartan-HCTZ	Alembic	320-12.5	1805010695	140	675
Valsartan-HCTZ	Alembic	320-12.5	1805010695	115	887
Valsartan-HCTZ	Alembic	320-12.5	1805010695	93	1,169
Valsartan-HCTZ	Alembic	320-12.5	1805010695	180	1,195
Valsartan-HCTZ	Novartis	320-12.5	AG9492E	14	147
Valsartan-HCTZ	Novartis	320-12.5	AG9492E	12	272
Valsartan-HCTZ	Novartis	320-12.5	AG9492E	13	185
Valsartan-HCTZ	Novartis	320-12.5	AG9492E	13	144
Valsartan-HCTZ	Novartis	320-12.5	AG9492E	14	317
Valsartan-HCTZ	Novartis	320-12.5	AG9492E	13	258
Valsartan-HCTZ	Novartis	320-12.5	AG9492E	14	105
Valsartan-HCTZ	Macleods	320-12.50	BVO829A	59	93,825
Valsartan-HCTZ	Macleods	320-12.50	BVO829A	47	69,970
Valsartan-HCTZ	Macleods	320-12.50	BVO829A	50	83,060
Valsartan-HCTZ	Lupin	320-12.5	G802870	7	942
Valsartan-HCTZ	Lupin	320-12.5	G802870	13	1,097
Valsartan-HCTZ	Lupin	320-12.5	G802870	9	880
Valsartan-HCTZ	Lupin	320-12.5	G802870	13	1,069
Valsartan-HCTZ	Aurobindo	320-12.5	HRSA18037-A	8	635
Valsartan-HCTZ	Aurobindo	320-12.5	HRSA18037-A	15	780
Valsartan-HCTZ	Aurobindo	320-12.5	HRSA18037-A	11	707
Valsartan-HCTZ	Aurobindo	320-12.5	HRSA18037-A	16	861