

Annexure-I
Annexure to Non-Biological Drug Manufacturing License No. 247
Radiant Pharmaceuticals Limited,
B-34 & B-46, BSCIC I/E, Tongi, Gazipur-1710

Drug Admin
Registration No. **052-231-075**

Name of the Product
Vonocab 20

EC Tablets

Pack Size:	<u>Composition</u>	<u>Specification</u>	<u>Quantity</u> mg/tab	<u>Overage</u> %
20's, 30's, 50's, 60's & 100's Tablet in Alu-Alu blister pack in an inner carton with insert	<u>a) Active Ingredients:</u> Vonoprazan Fumarate	INN	26.720* (Eqv. to Vonoprazan 20mg)	-

b) Excipients:

Mannitol Spray Dried	BP	121.180*	-
Microcrystalline Cellulose PH-101	USP-NF	28.000	-
Croscarmellose Sodium	USP-NF	10.000	-
Povidone K-30	BP	7.500	-
Hydroxypropyl Cellulose (L-HPC, NBD022)	BP	15.000	-
Fumaric Acid	USP-NF	6.600	-
Colloidal Silicon Di-oxide	USP-NF	2.000	-
Magnesium Stearate	BP	3.000	-

Inclusion date:

07.08.2022

Valid up to:

06.08.2027

c) Coating Material:

Opadry White (YS17002)	Ph. Grade	10.000	-
Acryl EZE II Blue	Ph. Grade	20.000	-
Iso Propyl Alcohol**	BP	10.000	-
Purified water**	USP-NF	q.s.	-

(Export only)

Note:

* Variable quantity, to be adjusted per APIs declared/claimed potency.

** Used as solvent, will not appear in the finished product.



Major General Mohammad Yousuf
Director General
Directorate General of Drug Administration

Licensing Authority (Drugs)

Government of the People's Republic of Bangladesh