

SCORING TABLE

Score	SECTION B: Strength of data for MoA for COVID-19	SECTION B: Importance of MoA and target in the disease	SECTION C: Strength of results at pre-clinical stage	SECTION D: Availability of Human Safety Data (demonstrated through clinical studies)	SECTION F: Clarity and certainty on formulations, method of administration, drug delivery for COVID19	SECTION G: Status & Outcome Clinical Trials for COVID-19	Section H: Clarity and degree of certainty about supply chain and manufacturability in India	Score	SECTION K: Outcome of clinical trial
0	NA	NA	NA	NA	NA	NA	NA	0	No Outcome/Negative Outcome - Data from atleast 2 randomized trials with appropriate controls, from different groups
1	No evidence for MoA in other Coronaviruses and COVID-19	Target and MoA is not relevant to COVID-19	No pre-clinical data available	No data available	Drug not approved for any indication/ No RoA formulation data available	No ongoing trials	Not manufactured or sold in India	1	No Outcome/Negative Outcome - Data from any observational studies or trials lacking proper controls from different or same groups
2	MoA in other Viruses/Coronaviruses is known. For COVID-19 not proven	Target/MoA maybe relevant for COVID-19 but issues exist with achieving on target action	Pre-clinical data shows that drug is not effective for other Viruses/Coronaviruses or COVID-19	Investigational Drug. No data available	Drug not approved for any indication but RoA, formulation data available for specific conditions	Trials in progress. Results awaited.	Synthesis undertaken by R&D Labs	2	Mixed evidence – Equal number of positive and negative reports from designed trials
3	MoA for COVID-19 is known but scientific data is not convincing/not adequate	Target/MoA is relevant for the disease but may not have an effect on disease outcome if targeted	Pre-clinical data, demonstrating +ve outcome of the drug exists for other types of Coronavirus Diseases, but no data available for COVID-19	Investigational Drug. Data is available but not adequate	RoA known for approved indication but data not available for formulation/RoA for COVID-19 OR data indicates that RoA could be different for COVID-19	Trials in progress. Early results/Interim data available. More data needed/Data is not convincing	Manufactured in India by 1-2 companies; issues with raw materials and other supplies	3	Indication of Positive Outcome - Early data/ limited number of studies. (Any kind of study- observational studies/trials lacking proper controls/designated trials) NO Negative Studies
4	MoA for COVID-19 is known, data is convincing/adequate	Target/MoA is relevant for COVID-19 and outcome can be moderate if modulated	Pre-clinical data shows +ve effect of drug on COVID-19 through limited type of assays (in-vitro/in-vivo)	Approved Drug. Data is available for < 2 years of use	Data available. Proposed RoA /Formulation for COVID-19 is likely the same as that for Approved Indication	50% of Clinical Trials showing Positive outcome (Drug improved primary and/or secondary outcomes) shown in trials	Manufactured in India by < 3 companies; No issues exist with manufacturing and sales	4	Positive Outcome - Data from atleast any observational studies or trials lacking proper controls from different or same groups. NO negative studies
5	MoA for COVID-19 is established, multiple sources of data confirm the same	Target/MoA is relevant for COVID-19 and outcome can be significant if modulated	Pre-clinical data shows +ve effect of drug on COVID-19 through in-vitro and in-vivo studies, confirmed by multiple sources	Approved Drug. Data is available for > 2 years of use	Data available. RoA formulation confirmed by demonstration in clinical studies for COVID-19	>75% of trials showing positive outcome of the drug (Drug improved primary and/or secondary outcomes) shown in trials	Manufactured in India by > 3 companies; No issues exist with manufacturing and sales	5	Data from atleast 2 randomized trials with appropriate controls, from different groups NO negative studies

Source: TFORD-COVID19-India (c) Venture Center, 2020