

Response To Pre-Bid Queries (Pre-Bid date: 30.09.2022)				
Bid Number: GEM/2022/B/2574025 Dated: 24-09-2022				
Item Name: Heavy Duty Ultrasonic Nebulizer				
Sr. No.	Buyer Specification Document Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE FIRM	COMMITTEE RECOMMENDATION
1	Pg 1 Para 1	It should be based on ultrasonic technique.	<p>It should be based on ultrasonic technique / Vibrating Mesh Technology Justification: VMT - A very latest generation (year 2000) technology and having over 200 clinical research papers supporting it. Mesh nebulizers have become the first choice for new nebulized pharmaceutical drug developments https://www.future-science.com/doi/10.4155/tde-2017-0102</p> <p>It should be based on ultrasonic technique / Vibrating Mesh Technology Justification: VMT - A very latest generation (year 2000) technology and having over 200 clinical research papers supporting it. Mesh nebulizers have become the first choice for new nebulized pharmaceutical drug developments https://www.future-science.com/doi/10.4155/tde-2017-0102</p> <p>It should be based on ultrasonic technique / Vibrating Mesh Technology Justification: VMT - A very latest generation (year 2000) technology and having over 200 clinical research papers supporting it. Mesh nebulizers have become the first choice for new nebulized pharmaceutical drug developments https://www.future-science.com/doi/10.4155/tde-2017-0102</p>	No Change
2	Pg 1 Para 2	It should produce no noise or noise below 60 dB.	<p>It should produce no noise or noise below or upto 35 dB from 0.3 m distance Justification: The World Health Organization (WHO) advises sound pressure levels in hospitals should not exceed 35 dB https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6767712/</p> <p>It should produce no noise or noise below or up to 35 dB from 0.3 m distance Justification: The World Health Organization (WHO) advises sound pressure levels in hospitals should not exceed 35 dB https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6767712/</p>	Amended as: It should produce no noise or noise below or upto 35 dB from 0.3 m distance

Response To Pre-Bid Queries (Pre-Bid date: 30.09.2022)				
Bid Number: GEM/2022/B/2574025 Dated: 24-09-2022				
Item Name: Heavy Duty Ultrasonic Nebulizer				
Sr. No.	Buyer Specification Document Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE FIRM	COMMITTEE RECOMMENDATION
			<p>It should produce no noise or noise below or up to 35 dB from 0.3 m distance</p> <p>Justification: The World Health Organization (WHO) advises sound pressure levels in hospitals should not exceed 35 dB https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6767712/</p>	
3	Pg 1 Para 3	Particle size should be below 5-6 micron.	<p>Particle size should be below 1-5 micron.</p> <p>Justification: Particles of size <5 µm have the greatest possibility of deposition in the lung[29] and particle with size <2 µm can reach up to the alveoli[30,31]. Deposition of large particles with an aerodynamic diameter of >5 µm is held in upper airways by inertial impaction. Gravitational settling of particles with aerodynamic diameter 1 to 5 µm takes place in the central and distal tract. https://www.ijpsonline.com/articles/current-development-in-the-evaluation-methods-of-pulmonary-drug-delivery-system.html?view=mobile</p> <hr/> <p>Particle size should be below 1-5 micron.</p> <p>Justification: Particles of size <5 µm have the greatest possibility of deposition in the lung[29] and particle with size <2 µm can reach up to the alveoli[30,31]. Deposition of large particles with an aerodynamic diameter of >5 µm is held in upper airways by inertial impaction. Gravitational settling of particles with aerodynamic diameter 1 to 5 µm takes place in the central and distal tract. https://www.ijpsonline.com/articles/current-development-in-the-evaluation-methods-of-pulmonary-drug-delivery-system.html?view=mobile</p>	No Change

Response To Pre-Bid Queries (Pre-Bid date: 30.09.2022)				
Bid Number: GEM/2022/B/2574025 Dated: 24-09-2022				
Item Name: Heavy Duty Ultrasonic Nebulizer				
Sr. No.	Buyer Specification Document Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE FIRM	COMMITTEE RECOMMENDATION
			<p>Particle size should be below 1-5 micron. Justification: Particles of size <5 µm have the greatest possibility of deposition in the lung[29] and particle with size <2 µm can reach up to the alveoli[30,31]. Deposition of large particles with an aerodynamic diameter of >5 µm is held in upper airways by inertial impaction. Gravitational settling of particles with aerodynamic diameter 1 to 5 µm takes place in the central and distal tract. https://www.ijpsonline.com/articles/current-development-in-the-evaluation-methods-of-pulmonary-drug-delivery-system.html?view=mobile</p>	
4	Pg 1 Para 5	It should be able to nebulize small amount of drug: minimum 5 ml.	<p>It should be able to nebulize small amount of drug: minimum 2 ml. Justification: It should be capable enough to handle low volume of drug desired for neonatal & paediatric patient</p>	No Change
			<p>It should be able to nebulize small amount of drug: minimum 2 ml. Justification: It should be capable enough to handle low volume of drug desired for neonatal & paediatric patient</p>	
			<p>It should be able to nebulize small amount of drug: minimum 2 ml. Justification: It should be capable enough to handle low volume of drug desired for neonatal & paediatric patient</p>	
5	Pg 1 Para 6	The residual drug should be less than 2 ml.	<p>The residual drug should be less than 0.1 ml for 3 ml dose Justification: For handling lower dose like 2 ml, the residual volume should be negligible i.e <0.1 ml</p>	No Change
			<p>The residual drug should be less than 0.1 ml for 3ml dose Justification: For handling lower dose like 2 ml, the residual volume should be negligible i.e <0.1 ml</p>	
			<p>The residual drug should be less than 0.1 ml for 3ml dose Justification: For handling lower dose like 2 ml, the residual volume should be negligible i.e <0.1 ml</p>	

Response To Pre-Bid Queries (Pre-Bid date: 30.09.2022)				
Bid Number: GEM/2022/B/2574025 Dated: 24-09-2022				
Item Name: Heavy Duty Ultrasonic Nebulizer				
Sr. No.	Buyer Specification Document Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE FIRM	COMMITTEE RECOMMENDATION
6	Pg 1 Para 8	Water tank capacity should be more than 500 ml.	<p>Drug Chamber Capacity 06 ml (disposable) ; 10 ml (Reusable) ; > 30 ml with continuous nebulization Kit Justification: To avoid drug wastage specially for antibiotics where the drug dose for adult is 3-6 ml , the chamber capacity should be ideally 6 ml, and also it should have a provision to manage more drugs through dedicated continuous kit</p> <p>Drug Chamber Capacity 06 ml (disposable) ; 10 ml (Reusable) ; > 30 ml with continuous nebulization Kit Justification: To avoid drug wastage specially for antibiotics where the drug dose for adult is 3-6 ml , the chamber capacity should be ideally 6 ml, and also it should have a provision to manage more drugs through dedicated continuous kit</p> <p>Drug Chamber Capacity 06 ml (disposable) ; 10 ml (Reusable) ; > 30 ml with continuous nebulization Kit Justification: To avoid drug wastage specially for antibiotics where the drug dose for adult is 3-6 ml , the chamber capacity should be ideally 6 ml, and also it should have a provision to manage more drugs through dedicated continuous kit</p>	No Change
7	Pg 1 Para 9	It should be usable continuously for > 4 hrs.	<p>It should be usable continuously irrespective of time Justification: In Continuous mode of operation the system should be capable to operate for a longer time.</p> <p>It should be usable continuously irrespective of time Justification: In Continuous mode of operation the system should be capable to operate for a longer time.</p> <p>It should be usable continuously irrespective of time Justification: In Continuous mode of operation the system should be capable to operate for a longer time.</p>	No Change
8	Pg 1 Para 10	It should have built in timer to choose time of nebulization; time should be able to set up to 2 hrs.	<p>It should work as intermittent 15 min / Continuous mode Justification: Ideal system should have both modes</p> <p>It should work as intermittent 15 min / Continuous mode Justification: Ideal system should have both modes</p> <p>It should work as intermittent 15 min / Continuous mode Justification: Ideal system should have both modes</p>	No Change

Response To Pre-Bid Queries (Pre-Bid date: 30.09.2022)				
Bid Number: GEM/2022/B/2574025 Dated: 24-09-2022				
Item Name: Heavy Duty Ultrasonic Nebulizer				
Sr. No.	Buyer Specification Document Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE FIRM	COMMITTEE RECOMMENDATION
9	Pg 1 Para 11	It should have LCD display.	It should have LED indicator . Justification: Compact noiseless system should have a light indicator for alters from a distance	Amended as: It should have LCD / LED display.
			It should have LED indicator . Justification: Compact noiseless system should have a light indicator for alters from a distance	
			It should have LED indicator . Justification: Compact noiseless system should have a light indicator for alters from a distance	
10	Pg 1 Para 13	It should have automatic heating system to provide heated vapor.	It should not generate heat and suitable for solutions, suspension, protein, and peptide bonds Justification: Latest generation nebulizers should manage antibiotics, corticosteroids' , bronchodilators , normal saline , combination drugs and latest aerosol vaccines etc.. The temperature sensitive drugs will lose its efficacy if headed-up Ultrasonic and jet nebulizers may damage protein and other complex agents through heat or shear stress . https://pubmed.ncbi.nlm.nih.gov/12425745/	No Change
			It should not generate heat and suitable for solutions, suspension, protein, and peptide bonds Justification: Latest generation nebulizers should manage antibiotics, corticosteroids' , bronchodilators , normal saline , combination drugs and latest aerosol vaccines etc.. The temperature sensitive drugs will lose its efficacy if headed-up Ultrasonic and jet nebulizers may damage protein and other complex agents through heat or shear stress. https://pubmed.ncbi.nlm.nih.gov/12425745/	

Response To Pre-Bid Queries (Pre-Bid date: 30.09.2022)				
Bid Number: GEM/2022/B/2574025 Dated: 24-09-2022				
Item Name: Heavy Duty Ultrasonic Nebulizer				
Sr. No.	Buyer Specification Document Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE FIRM	COMMITTEE RECOMMENDATION
			<p>It should not generate heat and suitable for solutions, suspension, protein, and peptide bonds</p> <p>Justification: Latest generation nebulizers should manage antibiotics, corticosteroids, bronchodilators, normal saline, combination drugs and latest aerosol vaccines etc..</p> <p>The temperature sensitive drugs will lose its efficacy if headed-up Ultrasonic and jet nebulizers may damage protein and other complex agents through heat or shear stress.</p> <p>https://pubmed.ncbi.nlm.nih.gov/12425745/</p>	
11	Pg 1 Para 14	It should have alarm for low water level, malfunction, etc.	<p>It should have alert indicator LED</p> <p>Justification: Compact noiseless system should have a light indicator</p> <p>: A visual indicator.</p> <p>The vast number of alarms regularly overwhelms staff and may induce alarm fatigue</p> <p>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8196351/</p> <p>It should have alert indicator LED</p> <p>Justification: Compact noiseless system should have a light indicator</p> <p>: A visual indicator.</p> <p>The vast number of alarms regularly overwhelms staff and may induce alarm fatigue</p> <p>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8196351/</p> <p>It should have alert indicator LED</p> <p>Justification: Compact noiseless system should have a light indicator</p> <p>: A visual indicator.</p> <p>The vast number of alarms regularly overwhelms staff and may induce alarm fatigue</p> <p>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8196351/</p>	No Change
12	Pg 1 Para 15	It should be portable (weight less than 5 kg) and mountable on stand.	<p>It should be portable (weight less than 300 gms) and mountable on stand.</p> <p>Justification: Light weight and compact system offer a great level of portability</p>	No Change

Response To Pre-Bid Queries (Pre-Bid date: 30.09.2022)				
Bid Number: GEM/2022/B/2574025 Dated: 24-09-2022				
Item Name: Heavy Duty Ultrasonic Nebulizer				
Sr. No.	Buyer Specification Document Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE FIRM	COMMITTEE RECOMMENDATION
			<p>It should be portable (weight less than 300 gms) and mountable on stand. Justification: Light weight and compact system offer a great level of portability</p> <p>It should be portable (weight less than 300 gms) and mountable on stand. Justification: Light weight and compact system offer a great level of portability</p>	
13	Pg 1 Para 19	It should have battery backup of at least one hour.	<p>It should have battery backup of at least 45 min. Justification: For normal 6 ml dose of aerosol , the ideal delivery time is approx. 15 mins, hence back up should be at least three times i.e 45 min. It will keep the system compact & light weight.</p> <p>It should have battery backup of at least 45 min. Justification: For normal 6 ml dose of aerosol , the ideal delivery time is approx. 15 mins, hence back up should be at least three times i.e 45 min. It will keep the system compact & light weight.</p> <p>It should have battery backup of at least 45 min. Justification: For normal 6 ml dose of aerosol , the ideal delivery time is approx. 15 mins, hence back up should be at least three times i.e 45 min. It will keep the system compact & light weight.</p>	No Change
14	Pg 1 Para 21	Equipment should be European CE with four digit notified body number or US FDA or BIS approved for the quoted model and certificate to be submitted.	<p>European CE & US FDA Justification: Ensures highest quality standards</p> <p>European CE & US FDA Justification: Ensures highest quality standards</p> <p>European CE & US FDA Justification: Ensures highest quality standards</p>	No Change
15	NA	Suggested by Bidder	<p>Items to be supplied</p> <p>Detailed BOQ avoids confusion Justification: Complete unit should include</p> <ul style="list-style-type: none"> • Controller with battery backup with cable • 2 x Drug Chamber (disposable) • 1 x Drug Chamber (reusable) • 2 x Adult T-piece with Silicone Plug (Disposable) • AC/DC Adapter • Universal Mounting Bracket • Instruction Manual 	No Change

Response To Pre-Bid Queries (Pre-Bid date: 30.09.2022)				
Bid Number: GEM/2022/B/2574025 Dated: 24-09-2022				
Item Name: Heavy Duty Ultrasonic Nebulizer				
Sr. No.	Buyer Specification Document Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE FIRM	COMMITTEE RECOMMENDATION
			<p>Items to be supplied</p> <p>Detailed BOQ avoids confusion</p> <p>Justification: Complete unit should include</p> <ul style="list-style-type: none"> • Controller with battery backup with cable • 2 x Drug Chamber (disposable) • 1 x Drug Chamber (reusable) • 2 x Adult T-piece with Silicone Plug (Disposable) • AC/DC Adapter • Universal Mounting Bracket • Instruction Manual 	
			<p>Items to be supplied</p> <p>Detailed BOQ avoids confusion</p> <p>Justification: Complete unit should include</p> <ul style="list-style-type: none"> • Controller with battery backup with cable • 2 x Drug Chamber (disposable) • 1 x Drug Chamber (reusable) • 2 x Adult T-piece with Silicone Plug (Disposable) • AC/DC Adapter • Universal Mounting Bracket • Instruction Manual 	
16	NA	Suggested by Bidder	<p>Additional Item / consumables (Individual rates to be quoted)</p> <p>Justification: Drug chamber Pack of 10 (disposable) x 02 pack</p> <p>Spacer with Mask and mouthpiece for Spontaneously breathing patient pack of 10 x 02 pack</p> <p>Continuous Nebulization kit (Syring & tube) pack of 05 x 04 pack</p> <p>Additional Item / consumables (Individual rates to be quoted)</p> <p>Justification: · Drug chamber Pack of 10 (disposable) x 02 pack</p> <p>· Spacer with Mask and mouthpiece for Spontaneously breathing patient pack of 10 x 02 pack</p> <p>· Continuous Nebulization kit (Syring & tube) pack of 05 x 04 pack</p>	No Change

Response To Pre-Bid Queries (Pre-Bid date: 30.09.2022)				
Bid Number: GEM/2022/B/2574025 Dated: 24-09-2022				
Item Name: Heavy Duty Ultrasonic Nebulizer				
Sr. No.	Buyer Specification Document Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE FIRM	COMMITTEE RECOMMENDATION
			Additional Item / consumables (Individual rates to be quoted) Justification: · Drug chamber Pack of 10 (disposable) x 02 pack · Spacer with Mask and mouthpiece for Spontaneously breathing patient pack of 10 x 02 pack · Continuous Nebulization kit (Syring & tube) pack of 05 x 04 pack	