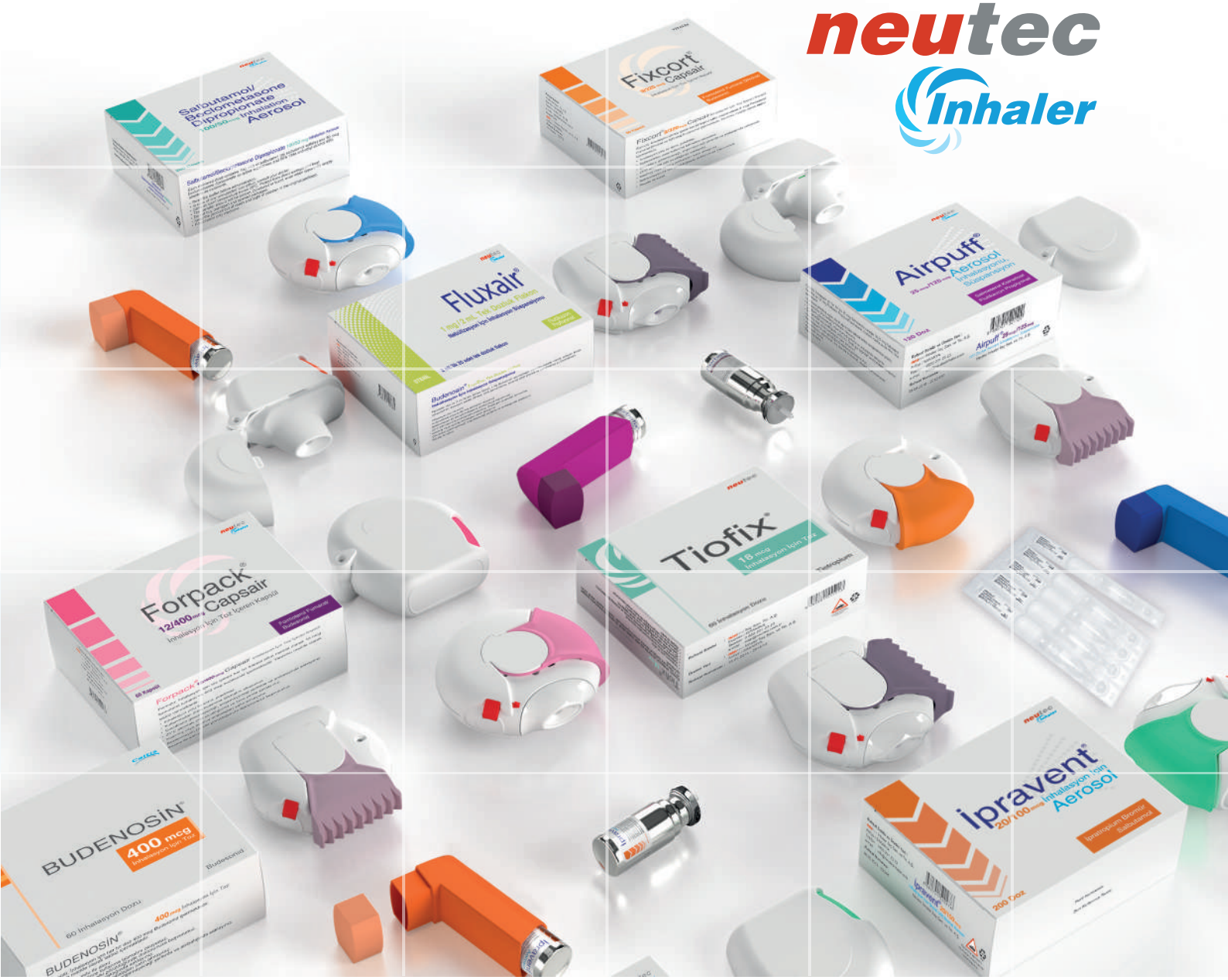
neutec Inhaler



NEUTEC INHALER

AFFORDABLE ASTHMA & COPD TREATMENT

Design The Future

www.neutec.com.tr

DRY POWDER INHALER AIRMASTER®

NEUAIR

* SALMETEROL XINAFOATE
* FLUTICASONE PROPIONATE
  - 50 / 100 mcg
  - 50 / 250 mcg
  - 50 / 500 mcg

TIOFIX

* TIOTROPIUM BROMIDE
  - 18 mcg

TIOFORM

* TIOTROPIUM BROMIDE
* FORMOTEROL FUMARATE
  - 18 / 12 mcg

RESPIDAY

* FORMOTEROL FUMARATE
* BUDESONIDE
  - 4.5 / 160 mcg
  - 9 / 320 mcg

BUDENOSIN

* BUDESONIDE
  - 200 mcg
  - 400 mcg

FORPACK

* FORMOTEROL FUMARATE
* BUDESONIDE
  - 12 / 200 mcg
  - 12 / 400 mcg

AEROHIT

* FLUTICASONE PROPIONATE
  - 100 mcg
  - 250 mcg
  - 500 mcg

AEROSOL

FORBEFIX

* FORMOTEROL FUMARATE
* BECLOMETASONE DIPROPIONATE
  - 6 / 100 mcg
  - 6 / 200 mcg

CLENID

* CICLESONIDE
  - 80 mcg
  - 160 mcg

IPRAVENT

* IPRATROPIUM BROMIDE
* SALBUTAMOL
  - 20 / 100 mcg

IPRALEV

* IPRATROPIUM BROMIDE
* LEVALBUTEROL
  - 20 / 50 mcg

BRECUR

* SALBUTAMOL
  - 100 mcg

XENCORT

* FLUTICASONE PROPIONATE
  - 125 mcg
  - 250 mcg

FORPACK

* FORMOTEROL FUMARATE
* BUDESONIDE
  - 6 mcg / 100 mcg
  - 6 mcg / 200 mcg
  - 6 mcg / 400 mcg

AIRPUFF

* SALMETEROL XINAFOATE
* FLUTICASONE PROPIONATE
  - 25 mcg / 125 mcg
  - 25 mcg / 250 mcg

DRY POWDER INHALER
CAPSAIR®

SERAIR CAPSAIR

* SALMETEROL XINAFOATE
* FLUTICASONE PROPIONATE
  - 50 / 250 mcg
  - 50 / 500 mcg

TIODAY CAPSAIR

* TIOTROPIUM BROMIDE
  - 18 mcg

FORPACK CAPSAIR

* FORMOTEROL FUMARATE
* BUDESONIDE
  - 12 / 200 mcg
  - 12 / 400 mcg

BUDEFIX CAPSAIR

* BUDESONIDE
  - 200 mcg
  - 400 mcg

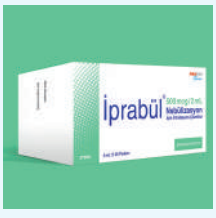
FORMOTEROL CAPSAIR

* FORMOTEROL FUMARATE
  - 12 mcg

FIXCORT CAPSAIR

* FORMOTEROL FUMARATE
* BUDESONIDE
  - 4.5 / 160 mcg
  - 9 / 320 mcg

NEBULES



IPRABUL

* IPRATROPIUM BROMIDE
  - 0.5 mg / 2 mL

BRECUR

* SALBUTAMOL
  - 2.5 mg / 2.5 mL

IPRAVENT

* IPRATROPIUM BROMIDE
* SALBUTAMOL
  - 0.5 mg 2.5 mL + 2.5 mg / 2.5 mL

BUDENOSIN

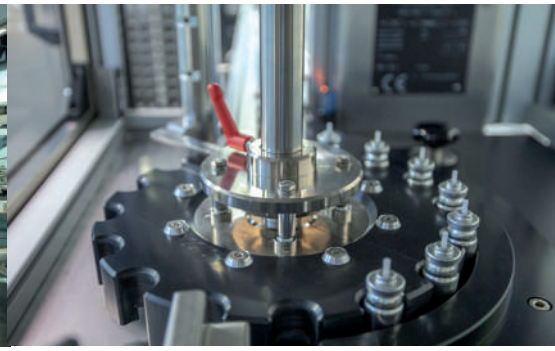
* BUDESONIDE
  - 0.5 mg / 2 mL
  - 1 mg / 2 mL

FLUXAIR (FLUXIT)

* FLUTICASONE PROPIONATE
  - 0.5 mg / 2 mL
  - 2 mg / 2 mL

FULLY AUTOMATED AND HIGH VOLUME INHALATION MANUFACTURING





STATE-OF-THE-ART TECHNOLOGY

Neutec manufacturing site equipped with world class manufacturing machines of inhalation technology.

Neutec invested in full automation and 100% on line quality control technologies.

INHALATION DEVICES

AIRMASTER & CAPSAIR

Neutec is competent on developing generic inhalation device platforms. Airmaster and capsair are substitutable generic inhalation devices.

FDA & EU STANDARDS

Neutec applies current best practices for combination product development and generates device development history files during device development activities.

PATENT PROTECTION

Neutec device platforms and products protected by intellectual property laws.

READY FOR THE FUTURE

Neutec is developing generic soft mist inhaler & dual blister inhalation devices.

neutec AR-GE Sanayi ve Ticaret A.Ş.

Yıldız Teknik Üniversitesi
Davutpaşa Kampüsü
Teknoloji Geliştirme Bölgesi D1 Blok
Esenler - İstanbul / TURKEY

neutec inhaler

Sakarya Organize Sanayi Bölgesi
2.Yol No.3
Adapazarı - Sakarya / TURKEY

Phone: +90 (850) 201 23 23
export@neutecrdc.com

AEROSOL

neutec Inhaler

* FORMOTEROL FUMARATE
* BECLOMETASONE DIPROPIONATE

- 6 / 100 mcg
- 6 / 200 mcg

* IPRATROPIUM BROMIDE
* SALBUTAMOL

- 20 / 100 mcg

* FLUTICASONE PROPIONATE

- 125 mcg
- 250 mcg

* SALMETEROL XINAFOATE
* FLUTICASONE PROPIONATE

- 25 mcg / 125 mcg
- 25 mcg / 250 mcg

AEROSOL

EU&US GMP

EU CTD DOSSIER

HIGH VOLUME PRODUCTION CAPACITY

HFA GENERIC PRODUCT

IPRAVENT is a HFA generic formulation of well-known and widely used Salbutamol and Ipratropium Bromide fixed dose combination product.

EU CTD DOSSIER

Product development has completed in line with CPMP/EWP/4151/00 EMEA guideline. Quality by Design (QbD) approach was applied throughout the development work.
High quality documentation secures the ease of registration.
Experienced Neutec regulatory team is capable of supporting worldwide registration.

BIOEQUIVALENCE ESTABLISHED

Clinical equivalence is established by demonstration of in-vitro bioequivalence required as in EMEA CPMP/EWP/ 4151/00.

US FDA & EU CGMP COMPLIANCE

Neutec Inhaler plant is dedicated to inhalation products manufacturing only. Neutec plant fully complies with US FDA and EU cGMP requirements.

CGMP APPROVED VIA PIC/S

Turkish Medicines and Medical Devices Agency (TMMDA) has been a PIC/S member since 01/01/2018. PIC/S will ease the burden of worldwide audit needs.

CONTINUOUS SUPPLY GUARANTEE

Ipravent product is fully commercialized in Turkish market. Fully automated and industrialized high volume manufacturing is securing continuous supply of the generic product in registered markets.

NEUTEC R&D CENTER

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Esenler - İstanbul / TURKEY

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DRY POWDER INHALER AIRMASTER®

neutec Inhaler

* SALMETEROL XINAFOATE * FLUTICASONE PROPIONATE

- 50 / 100 mcg
- 50 / 250 mcg
- 50 / 500 mcg

* FORMOTEROL FUMARATE * BUDESONIDE

- 12 / 200 mcg
- 12 / 400 mcg

* FORMOTEROL FUMARATE * BUDESONIDE

- 4.5 / 160 mcg
- 9 / 320 mcg

* TIOTROPIUM BROMIDE

- 18 mcg

* TIOTROPIUM BROMIDE * FORMOTEROL FUMARATE

- 18 / 12 mcg

* FLUTICASONE PROPIONATE

- 100 mcg
- 250 mcg
- 500 mcg

* BUDESONIDE

- 200 mcg
- 400 mcg

DRY POWDER INHALER AIRMASTER®

neutec Inhaler

* SALMETEROL XINAFOATE
* FLUTICASONE PROPIONATE

▸ 50 / 100 mcg

▸ 50 / 250 mcg

▸ 50 / 500 mcg

BRANDED GENERIC PLATFORM

AIRMASTER is a differentiated, easy to use, patient friendly generic device platform for Salmeterol & Fluticasone Propionate fixed dose formulation.

BIOEQUIVALENCE ESTABLISHED

Clinical equivalence is established by demonstration of in-vivo bioequivalence against reference product required as in EMEA CPMP/EWP/4151/00.

EU CTD DOSSIER

Product development has completed in line with CPMP/EWP/4151/00 EMEA guideline. Quality by Design (QbD) approach was applied throughout the development work.
EU CTD dossier was compiled and ready for submission.
High quality documentation secures the ease of registration.
Experienced Neutec regulatory team is capable of supporting worldwide registration.

US FDA & EU CGMP COMPLIANCE

Neutec Inhaler plant is dedicated to inhalation products manufacturing only. Neutec plant fully complies with US FDA and EU cGMP requirements.

CONTINUOUS SUPPLY GUARANTEE

Salmeterol & Fluticasone Propionate Neutec product is fully commercialized in Turkish market. Fully automated and industrialized high volume manufacturing is securing continuous supply of the generic product in registered markets.

DRY POWDER INHALER
CAPSAIR®

neutec Inhaler

* TIOTROPIUM BROMIDE

- 18 mcg

* FORMOTEROL FUMARATE
* BUDESONIDE

- 12 / 200 mcg
- 12 / 400 mcg

* SALMETEROL XINAFOATE
* FLUTICASONE PROPIONATE

- 50 / 250 mcg
- 50 / 500 mcg

* BUDESONIDE

- 200 mcg
- 400 mcg

* FORMOTEROL FUMARATE

- 12 mcg

* FORMOTEROL FUMARATE
* BUDESONIDE

- 4.5 / 160 mcg
- 9 / 320 mcg

CAPSAIR®

EU&US GMP

EU CTD DOSSIER

HIGH VOLUME PRODUCTION CAPACITY

BRANDED GENERIC PLATFORM

It has been confirmed by major regulatory agencies such as US-FDA and UK-MHRA that Neutec's CAPSAIR platform is acceptable as substitutable generic platform to reference product.

BIOEQUIVALENCE ESTABLISHED

Clinical equivalence is established by demonstration of in-vitro bioequivalence. In-vivo bioequivalence study against reference product required as in EMEA CPMP/EWP/4151/00 is scheduled for 2022.

CONTINUOUS SUPPLY GUARANTEE

For many years TIODAY product is fully commercialized in Turkish market. Fully automated and industrialized high volume manufacturing is securing continuous supply of the generic product in registered markets.

US FDA & EU CGMP COMPLIANCE

Neutec Inhaler plant is dedicated to inhalation products manufacturing only. Neutec plant fully complies with US FDA and EU cGMP requirements.

EU CTD DOSSIER

Product development has completed in line with CPMP/EWP/4151/00 EMEA guideline. Quality by Design (QbD) approach was applied throughout the development work.
High quality documentation secures the ease of registration.
Experienced Neutec regulatory team is capable of supporting worldwide registration.

CGMP APPROVED VIA PIC/S

Turkish Medicines and Medical Devices Agency (TMMDA) has been a PIC/S member since 01/01/2018. PIC/S will ease the burden of worldwide audit needs.

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NEBULES

neutec Inhaler

* IPRATROPIUM BROMIDE

- 0.5 mg / 2 mL

* IPRATROPIUM BROMIDE * SALBUTAMOL

- 0.5 mg / 2.5 mL + 2.5 mg / 2.5 mL

* SALBUTAMOL

- 2.5 mg / 2.5 mL

* BUDESONIDE

- 0.5 mg / 2 mL
- 1 mg / 2 mL

* FLUTICASONE PROPIONATE

- 0.5 mg / 2 mL
- 2 mg / 2 mL

NEBULES

EU&US GMP

EU CTD DOSSIER

HIGH VOLUME PRODUCTION CAPACITY

GENERIC INHALATION SOLUTION AND SUSPENSION NEBULES

Neutec has added inhalation solution and suspension products to its product range. By using blow-fill-seal Neutec nebule products developed and manufactured.

BIOEQUIVALENCE ESTABLISHED

Clinical equivalence is established by demonstration of in-vitro bioequivalence. In-vitro bioequivalence study against reference product required as in EMEA CPMP/EWP/4151/00.

CONTINUOUS SUPPLY GUARANTEE

Since two years nebule products are fully commercialized in Turkish market. Fully automated and industrialized high volume manufacturing is securing continuous supply of the generic product in registered markets.

US FDA & EU CGMP COMPLIANCE

Neutec Inhaler plant is dedicated to inhalation products manufacturing only. Neutec plant fully complies with US FDA and EU cGMP requirements.

EU CTD DOSSIER

Product development has completed in line with CPMP/EWP/4151/00 EMEA guideline. Quality by Design (QbD) approach was applied throughout the development work. EU CTD dossier is compiled and ready for submission. High quality documentation secures the ease of registration. Experienced Neutec regulatory team is capable of supporting worldwide registration.

CGMP APPROVED VIA PIC/S

Turkish Medicines and Medical Devices Agency (TMMDA) has been become a PIC/S member starting 01/01/2018. PIC/S will ease the burden of worldwide audit needs.

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