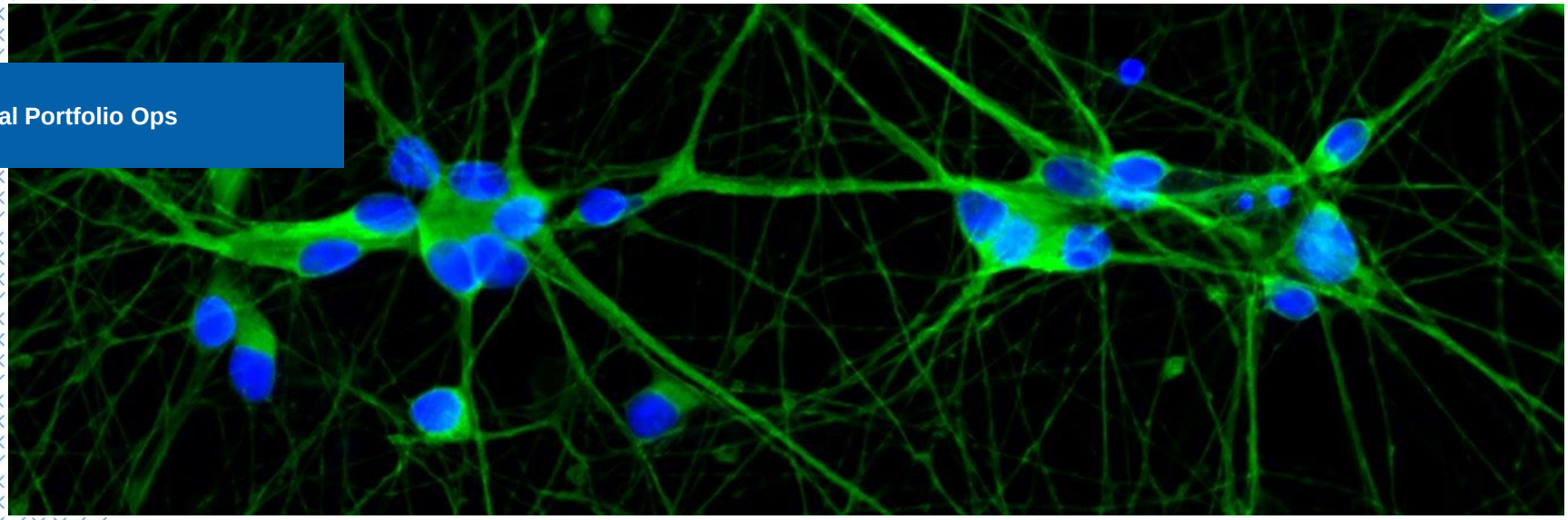
Global Portfolio Ops



Pack Size Definition

Global Portfolio Ops

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General Concept: Primary & Secondary Packaging

Primary Packaging

- Primary packaging contains the pharmaceutical product itself. Typical types of primary packaging are blisters, bottles, syringes, vials etc. The closure that seals the container or package is also considered part of the primary packaging.
- The formulation of a product defines the type of closure and packaging required to ensure the product is protected properly, therefore, primary packaging must be considered at the initial phase of product formulation.

Secondary Packaging

- Secondary packaging contains the primary package and is normally the form in which the pharmaceutical products are sold in the sales channels. It does not have direct contact with the product.
- Typical types of secondary packaging include boxes and cartons (incl. printing/labelling) that often contain several primary packaging units as well the leaflet.
- In exceptional cases, the secondary packaging contains multiple packs, which are not sold individually (e.g., 2 inhalers each packed in carton box are combined in an outer carton box).

General Concept: Primary & Secondary Pack Size

Primary Pack Size

- Primary pack size is defined by the filling volume/ quantity of the product (combining both API and adjuvant), not the potential capacity of the primary packaging

Secondary Pack Size

- Secondary pack size is defined by the number of primary packaging units available in one secondary packaging unit

Final Pack Size (extended/counting units)

- Final Pack Size = Primary Pack Size * Secondary Pack Size (when Primary Pack Unit = pcs)
- Final Pack Size = Secondary Pack Size (When Primary Pack Unit is not equal to pcs)

General Concept: Oral Solids

IR Oral Solids & XR Oral Solids[1]

- Unit for strength is g, mg, µg or IU
- Primary pack unit is pcs
- Secondary pack unit is pcs
- Primary pack type = BL - Blister, BO - Bottle, SA - Sachet, TU - Tube, UD - Unit dose blister
- Primary Pack Size = Number of tablets/ capsules in one Primary Packaging (e.g., blister or bottle)
- Secondary Pack size = Number of individual Primary Packaging inside one Secondary Packaging (e.g., box)
- Final Pack Size (extended/counting units) = Primary Pack Size * Secondary Pack Size (e.g., number of tablets in a box)

1 IR = immediate release, XR = extended release

Examples: Oral Solids

IR Oral Solids & XR Oral solids

TABLET (TAB) with strength 20 mg

- There are 50 tablets in one bottle and 2 bottles in one box
  - Primary Pack Size = 50 pcs
  - Secondary Pack Size = 2 pcs
  - Final Pack Size (extended/counting units) = 50 pcs * 2 pcs = 100 pcs

HARD GELATINE CAPSULE (HGC) with strength 50 mg

- There are 10 capsules in one blister and 5 blisters in one box
  - Primary Pack Size = 10 pcs
  - Secondary Pack Size = 5 pcs
  - Final Pack Size (extended/counting units) = 10 pcs * 5 pcs = 50 pcs

General Concept:
Liquids, IR Injectables & XR Injectables

Liquid, IR Injectables & XR Injectables[1] (except Lyos[2] and powders)

- Unit for strength is g / ml, mg / ml, µg / ml, µg / DOS, mg / DOS or %
- Primary pack unit is ml, DOS
- Secondary pack unit is pcs
- Primary pack type = AC - Aerosol cans, AM - Ampoule, BF - Blow fill seal, BG - Bag, BO - Bottle, CA - Carpoule (injection pen), CT - Cartridge, IB - Infusion bottle/bag, SY - Syringe, VI - Vial
- Primary Pack Size = amount of liquid in one Primary Packaging (e.g., vial)
- Secondary Pack size = Number of individual Primary Packaging inside one Secondary Packaging (e.g., box)
- Final Pack Size (extended/counting units) = Secondary Pack Size (e.g., number of vials in a box)

1 IR = immediate release, XR = extended release
2 Lyophilisates

Examples: Liquids, IR Injectables & XR Injectables

Liquid, IR Injectables & XR Injectables[1] (except Lyos[2] and powders)

LIQUID IN A VIAL (LIVI) with strength (5 mg) / 10 ml[3]

- There is 10 ml of liquid in a vial and 5 vials inside a box
  - Primary Pack Size = 10 ml
  - Secondary Pack Size = 5 pcs
  - Final Pack Size (extended/counting units) = 5 pcs

LIQUID IN AMPOULE (LIAM) with strength (1 mg) / 5 ml[3]

- There is 5 ml of liquid in an ampoule and 2 ampoules inside a box
  - Primary Pack Size = 5 ml
  - Secondary Pack Size = 2 pcs
  - Final Pack Size (extended/counting units) = 2 pcs

1 IR = immediate release, XR = extended release
2 Lyophilisates
3 Strength for liquids should be documented as total presentation size, check here for details

Examples: Liquids, IR Injectables & XR Injectables

Liquid, IR Injectables & XR Injectables[1] (except Lyos[2] and powders)

LIQUID AS SPRAY (LSP) with strength (27.5 µg) / 1 DOS[3]

- There are 120 spray doses in an aerosole can and 1 can inside a box
  - Primary Pack Size = 120 DOS
  - Secondary Pack Size = 1 pcs
  - Final Pack Size (extended/counting units) = 1 pcs

1 IR = immediate release, XR = extended release
2 Lyophilisates
3 Strength for liquids should be documented as total presentation size, check here for details

General Concept: Lyos and Powders

IR Injectables & XR Injectables[1] (Lyos[2] and powders)

- Unit for strength is g, mg, µg or IU
- Primary pack unit is g, mg, µg, IU or mIU
- Secondary pack unit is pcs
- Primary pack type = AM - Ampoule, BF - Blow fill seal[3], BG - Bag, BO - Bottle, IB - Infusion bottle/bag, VI - Vial
- Primary Pack Size = amount of lyophilized substance or powder in one Primary Packaging (e.g., vial)
- Secondary Pack size = Number of individual Primary Packaging inside one Secondary Packaging (e.g., box)
- Final Pack Size (extended/counting units) = Secondary Pack Size (e.g., number of vials in a box)

1 IR = immediate release, XR = extended release
2 Lyophilisates
3 Relevant for complimentary liquid for Lyos and powders

Examples: Lyos and Powders

IR Injectables & XR Injectables[1] (Lyos[2] and powders)

LYOPHILISATE IN A VIAL (LYVI) with strength 5 mg

- There is 5 mg lyophilized substance in a vial and 5 vials inside a box
  - Primary Pack Size = 5 mg
  - Secondary Pack Size = 5 pcs
  - Final Pack Size (extended/counting units) = 5 pcs

POWDER FOR SOLUTION FOR INFUSION (PSOIF) with strength 10 mg

- There is 10 mg powdered substance in a vial and 2 vials inside a box
  - Primary Pack Size = 10 mg
  - Secondary Pack Size = 2 pcs
  - Final Pack Size (extended/counting units) = 2 pcs

1 IR = immediate release, XR = extended release
2 Lyophilisates

General Concept: Semi-Solids

Semi-Solids

- Unit for strength is mg / g, g / g, mg / ml, g / ml or %
- Primary pack unit is g or ml
- Secondary pack unit is pcs
- Primary pack type = BO - Bottle, JA - Jar, TU - Tube, VI - Vial
- Primary Pack Size = quantity of semi-solid in one Primary Packaging (e.g., tube)
- Secondary Pack size = Number of individual Primary Packaging inside one Secondary Packaging (e.g., box)
- Final Pack Size (extended/counting units) = Secondary Pack Size (e.g., number of tubes in a box)

Examples: Semi-Solids

Semi-Solid

CREAM (CRM) with strength (100 mg) / 10 g[1]

- There is 10 g of cream in a tube and 2 tubes inside a box
  - Primary Pack Size = 10 g
  - Secondary Pack Size = 2 pcs
  - Final Pack Size (extended/counting units) = 2 pcs

GEL (GEL) with strength 5%

- There is 30 g of gel in a tube and 1 tubes inside a box
  - Primary Pack Size = 30 g
  - Secondary Pack Size = 1 pcs
  - Final Pack Size (extended/counting units) = 1 pcs

1 Strength for semi-solids should be documented as total presentation size, check here for details

General Concept: Inhalation

Inhalation

- Unit for strength is mg / DOS, µg / DOS, mg / ml, µg / ml, g / ml, % or g, mg, µg, IU
- Primary pack unit is DOS, ml or pcs
- Secondary pack unit is pcs
- Primary pack type = AC - Aerosol Can, BL - Blister, BO - Bottle, PC - Powder Can, PI - Powder Inhaler
- Primary Pack Size = amount of substance, doses or capsules in one Primary Packaging (e.g., powder inhaler)
- Secondary Pack size = Number of individual Primary Packaging inside one Secondary Packaging (e.g., box)
- Final Pack Size (extended/counting units) =
  - In case, primary pack unit is pcs: Primary Pack Size * Secondary Pack Size (e.g., number of capsules in a box)
  - In case, primary pack unit is **not** pcs: Secondary Pack Size (e.g., number of inhalers in a box)

Examples: Inhalation

Inhalation

POWDER FOR DRY INHALATION (PWDI) with strength (12 µg (MCG)) / 1 DOS

- There are 60 doses (DOS) in a powder inhaler (PI) and 2 inhalers inside a box
  - Primary Pack Size = 60 DOS
  - Secondary Pack Size = 2 pcs
  - Final Pack Size (extended/counting units) = 2 pcs

CAPSULES, FOR INHALATION (INHC) with strength 40 mg

- There are 10 capsules in a blister and 3 blisters inside a box
  - Primary Pack Size = 10 pcs
  - Secondary Pack Size = 3 pcs
  - Final Pack Size (extended/counting units) = 10 pcs * 3 pcs = 30 pcs

General Concept: Transdermal Therapeutic System

Transdermal Therapeutic System

- Unit for strength is mg or µg (Total API Quantity)
- Required complementary information is the concentration (delivery rate) – unit: mg / h, µg / h, mg / d or µg / d
- Primary pack unit is pcs
- Secondary pack unit is pcs
- Primary pack type = PO - Pouch, SA - Sachet, ST - Strip
- Primary Pack Size = Number of patches inside one Primary Packaging (e.g., pouch)
- Secondary Pack size = Number of individual Primary Packaging inside one Secondary Packaging (e.g., box)
- Final Pack Size (extended/counting units) = Primary Pack Size * Secondary Pack Size

Examples: Transdermal Therapeutic System

Transdermal Therapeutic System

MATRIX PATCH (TTSM) with strength 20 mg
(delivery rate: 20 µg / h)

- There is 20 mg of substance in 1 patch in 1 pouch (PO) and 2 pouches inside a box
  - Primary Pack Size = 1 pcs
  - Secondary Pack Size = 2 pcs
  - Final Pack Size (extended/counting units) = 1 pcs * 2 pcs = 2 pcs

General Concept: Oral Granulate / Powder

Oral Granulate / Powder

- Unit for strength is g, mg, µg or IU
- Primary pack unit is g, mg, µg , IU or mIU
- Secondary pack unit is pcs
- Primary pack type = BO - Bottle, PO – Pouch, SA - Sachet
- Primary Pack Size = amount of substance in one Primary Packaging (e.g., sachet)
- Secondary Pack size = Number of individual Primary Packaging inside one Secondary Packaging (e.g., box)
- Final Pack Size (extended/counting units) = Secondary Pack Size (e.g., number of sachets in a box)

Examples: Oral Granulate / Powder

Oral Granulate / Powder

POWDER FOR ORAL SUSPENSION (POS) with strength 10 g

- There is 10 g of substance in a sachet (SA) and 3 sachets inside a box
  - Primary Pack Size = 10 g
  - Secondary Pack Size = 3 pcs
  - Final Pack Size (extended/counting units) = 3 pcs

Strength by Presentation vs. Strength by Concentration (1/2)

Depending on the clinical relevance and/or the type, the strength of medicinal products is defined (labelled) by the presentation or its concentration. For most products, one or the other is the defined standard, but for some, both methodologies are possible or even mandated.

Beyond these primarily regulatory requirements, SANITY needs to contain further information to properly define the products and packs, e.g.,

- a (relative) presentation strength for a Dry Powder Inhaler in µg / DOS (delivered) requires complementary the total amount of DOS per inhaler. Further, the total API quantity (metered) needs to be documented.
- a concentration strength for a Cream in % requires complementary the total amount of cream

This allows, e.g., for calculation of total required API amount.

Strength by Presentation vs. Strength by Concentration (2/2)

Dosage type	Product type	Example	Strength by Presentation	Strength by Concentration	Complementary info required
Oral solids	Countable solids	Tablet, Capsule	Mandatory	-	-
Injectables	Total amount per presentation is clinically relevant	Ampoule or syringe as unit dose solutions	Mandatory	*System calculated*	-
	Concentration is clinically relevant rather than the total amount in the presentation	Multidose vial, partial dose syringe		Mandatory	Total quantity
Liquids, Semi-solids	Continuous presentation with individual dosing, total volume in the container is of less importance for dosing purposes	Eye drops, cream		Mandatory	Total quantity
Inhalation	Metered dose delivered by a metered actuation - dose cannot be adjusted	Dry-powder inhalers (DPI), nasal sprays	Mandatory	-	Number of doses, total API quantity
Patches	The dose of the product has a delivery rate	Transdermal patch		Mandatory (delivery over time)	Delivery duration, total API quantity
Lyos and powders for injection Oral Granulate / Powder	The whole content is delivered to the patient		Mandatory	-	

Summary (1/2)

DF Broad	Dosage form	Primary Pack type	Primary Pack Unit	Secondary Pack Unit
IR Oral Solid, XR Oral Solid	BCF - BUCCAL FILM; BCT - TABLET , BUCCAL; CHT - TABLET, CHEWABLE; CHY - CHEWY, FOR ORAL ADMINISTRATION; DRC - CAPSULE,DELAYED RELEASE; DRT - DELAYED-RELEASE TABLET; DT - TABLET, DISPERSIBLE; EFT - TABLET, EFFERVESCENT; FCT - TABLET, FILM-COATED; FRK - FORTIFIED RICE KERNELS; GRC - CAPSULES, GASTRO-RESISTANT; GRT - TABLET, GASTRO-RESISTANT; HGC - HARD GELATINE CAPSULE; HNGC - HARD NON-GELATINE CAPSULE; LOZ - LOZENGES; MRCH - CAPSULE, HARD GELATIN, MODIFIED RELEASE; MRT - TABLET, MODIFIED RELEASE; MUT - TABLETS, MULTI UNIT SYSTEM; ODF - ORODISPERSIBLE FILM; ODT - TABLET, ORAL DISINTEGRATING; OLY - ORAL LYOPHILISATE; ORF - ORAL FILM; PARV - PARVULET; PLSIP - PELLET SIPPING; PRCH - CAPSULE, HARD, PROLONGED RELEASE; PRCHTR - CAPSULE, HARD, PROLONGED RELEASE, TAMPER-RESISTANT; PRT - TABLET, PROLONGED RELEASE; PRTTR - TABLET, PROLONGED RELEASE, TAMPER-RESISTANT; PTAB - TABLET, PALATABLE; SCT - TABLET, SUGAR-COATED; SGC - CAPSULE, SOFT; SLT - TABLET, SUBLINGUAL; TAB - TABLET	BL - Blister, BO - Bottle, SA - Sachet, TU - Tube, UD - Unit dose blister	pcs	pcs
Liquid	LDP - LIQUID AS DROPS; LITP - LIQUID FOR TOPICAL APPLICATION; LQSIP - LIQUID SIPPING; SOL - SOLUTION; SPRSL - SPRAY, SUBLINGUAL SOLUTION; SSP - SUSPENSION; SYR - SYRUP	AC - Aerosol cans, AM - Ampoule, BF - Blow fill seal, BG - Bag, BO - Bottle, CA - Carpoule (injection pen), CT - Cartridge, IB - Infusion bottle/bag, SY - Syringe, VI - Vial	ml	pcs
Liquid, Inhalation	LSP - LIQUID AS SPRAY	AC - Aerosol cans, BO - Bottle, PC - Powder can, PI - Powder inhaler	DOS, ml	pcs
IR Injectable	LIAM - LIQUID IN AMPOULE	AM - Ampoule	ml	pcs
	LICA - LIQUID IN CARPULE	CA - Carpoule (injection pen)	ml	pcs
	LIIF - LIQUID FOR INFUSION	BG - Bag, BO - Bottle, IB - Infusion bottle/bag	ml	pcs
	CSPE - CELL SUSPENSION IN PERFUSION BAG OR BOTTLE	BG - Bag, BO - Bottle, IB - Infusion bottle/bag	ml	pcs
	LIPE - LIQUID IN PERFUSION BOTTLE	BF - Blow fill seal, BG - Bag, BO - Bottle, IB - Infusion bottle/bag	ml	pcs
	LIVILI - LIQUID IN VIAL, LIPOSOMAL	VI - Vial	ml	pcs
	INJ - INJECTION	AM - Ampoule, BF - Blow fill seal, BG - Bag, BO - Bottle, CA - Carpoule (injection pen), CT - Cartridge, IB - Infusion bottle/bag, SY - Syringe, VI - Vial	ml	pcs
	LISY - LIQUID IN SYRINGE	SY - Syringe	ml	pcs
IR Injectable, XR Injectable	LIBA - LIQUID IN BAG	BG - Bag, IB - Infusion bottle/bag	ml	pcs
	LIVI - LIQUID IN VIAL; GLVI - GEL IN VIAL	VI - Vial	ml	pcs
XR Injectable	IMSY - IMPLANT IN SYRINGE; MPSY - MICROCAPSULES IN SYRINGE +(VEHICLE)	SY - Syringe	ml	pcs
	MPVI - MICROCAPSULES IN VIAL	VI - Vial	ml	pcs

NOTE - Final Pack Size (extended/counting units) =
- Primary Pack Size * Secondary Pack Size (In case, primary pack unit is pcs)
- Secondary Pack Size (In case, primary pack unit is not pcs)

Summary (2/2)

DF Broad	Dosage form	Primary Pack type	Primary Pack Unit	Secondary Pack Unit
IR Injectable	LYAM - LYOPHILISATE IN AMPOULE	AM - Ampoule	g, mg, µg, IU, mIU	pcs
	LYVI - LYOPHILISATE IN VIAL	VI - Vial	g, mg, µg, IU, mIU	pcs
	PSOIF - POWDER FOR SOLUTION FOR INFUSION	BG - Bag, BO - Bottle, IB - Infusion bottle/bag	g, mg, µg, IU, mIU	pcs
	PSOIJ - POWDER FOR SOLUTION FOR INJECTION/INFUSION; PSSIJ - POWDER FOR SUSPENSION FOR INJECTION	AM - Ampoule, BF - Blow fill seal, BG - Bag, BO - Bottle, IB - Infusion bottle/bag, VI - Vial	g, mg, µg, IU, mIU	pcs
IR Injectable, XR Injectable	LYSY - LYOPHILISATE IN SYRINGE +(VEHICLE)	SY - Syringe	g, mg, µg, IU, mIU	pcs
IR Injectable, XR Injectable	LYPE - LYOPHILISATE IN PERFUSION BOTTLE	BF - Blow fill seal, BG - Bag, BO - Bottle, IB - Infusion bottle/bag	g, mg, µg, IU, mIU	pcs
Semi-Solid	CRM - CREAM; CRV - CREAM, VAGINAL; EGEL - GEL, EYE; EMU - EMULSION; EOIN - OINTMENT, EYE; FOAM - FOAM; GEL - GEL; GLV - GEL, VAGINAL; LOT - LOTION; OIN - OINTMENT; PAS - PASTE; SELQ - SELF EMULSIFYING LIQUID; SUP - SUPPOSITORY; VSUP - Vaginal Suppository	BO - Bottle, JA - Jar, TU - Tube, VI - Vial	g, ml	pcs
Inhalation	INHC - CAPSULES, FOR INHALATION	BL - Blister, BO - Bottle, PI - Powder inhaler	pcs	pcs
	ALP - AEROSOL, LIQUID + PROPELLANT; APW - AEROSOL, WITH POWDER CONTENT; ASP - AEROSOL, SUSPENSION + PROPELLANT; LIIN - LIQUID FOR INHALATION; PSOIH - POWDER FOR SOLUTION FOR INHALATION; PWDI - POWDER FOR DRY INHALATION	AC - Aerosol Can, BO - Bottle, PC - Powder can, PI - Powder inhaler	DOS, ml	pcs
Transdermal Therapeutic System	TTS - TRANSDERMAL THERAPEUTIC SYSTEM; TTSM - TRANSDERMAL THERAPEUTIC SYSTEM, MATRIX PATCH; TTSR - TRANSDERMAL THERAPEUTIC SYSTEM, RESERVOIR PATCH; TTSS - TRANSDERMAL THERAPEUTIC SYSTEM, MATRIX-S PATCH	PO - Pouch, SA - Sachet, ST - Strip	pcs	pcs
Oral Granulate / Powder	GOS - GRANULES FOR ORAL SUSPENSION; GOSO - GRANULES FOR ORAL SOLUTION; GRPO - GRANULES FOR LIQUID PAINT-ON APPLICATION; GTA - GRANULES FOR TABLETS; OGR - ORAL GRANULES; OPWD - ORAL POWDER; ORPESI - ORAL PELLET SIPPING; PDR - POWDER FOR DROPS; POS - POWDER FOR ORAL SUSPENSION; POSO - POWDER FOR ORAL SOLUTION; PWD - POWDER; PWU - POWDER, UNIT DOSE IN CONTAINER	BO - Bottle, PO – Pouch, SA - Sachet	g, mg, µg, IU, mIU	pcs
Other	API - API BULK SALES; BND - BAND-AID; DEV - DEVICE; DIA - DIAGNOSTIC; DIG - DIGITAL APPLICATION; ENE - ENEMA; IUD - INTRAUTERINE DEVICE; KIT - KIT (PRODUCTS FROM DIFFERENT DRUGS); NAL - NAIL LACQUER; PAD - TINCTURED PAD; PLA - PLASTER; PVTAB - TABLET, VAGINAL, PROLONGED RELEASE; SHAMP - SHAMPOO; SPO - SPONGE; STI - STICK; VHGC - CAPSULE, HARD, VAGINAL; VIR - VAGINAL RING; VTAB - TABLET, VAGINAL; WIPE - SATURATED WIPE	NO Limitation	NO Limitation	pcs

NOTE - Final Pack Size (extended/counting units) =
- Primary Pack Size * Secondary Pack Size (In case, primary pack unit is pcs)
- Secondary Pack Size (In case, primary pack unit is not pcs)

Abbreviations

Abbreviation	Denotation
%	Percent (1/100)
µg	Microgram
g	Gram
IR	Immediate Release
IU	International Unit
Lyos	Lyophilisates
mg	Milligram
MIU	MIU is Million IU, a Million times of an international unit
ml	Milliliter
pcs	Piece
XR	EXtended Release